DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 422, 423, 438, and 498

[CMS–4185–F]

RIN 0938–AT59

Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Programs of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule will revise the Medicare Advantage (MA) program (Part C) regulations and Prescription Drug Benefit program (Part D) regulations to implement certain provisions of the Bipartisan Budget Act of 2018; improve quality and accessibility; clarify certain program integrity policies for MA, Part D, and cost plans and PACE organizations; reduce burden on providers, MA plans, and Part D sponsors through providing additional policy clarification; and implement other technical changes regarding quality improvement. This final rule will also revise the appeals and grievances requirements for certain Medicaid managed care and MA special needs plans for dual eligible individuals to implement certain provisions of the Bipartisan Budget Act of 2018.

DATES: *Effective Dates:* These regulations are effective on January 1, 2020, except for the amendments to §§ 422.107(c)(9), (d), (e)(2), 422.560(a)(4) and (b)(5), 422.566(a), 422.629 through 422.634, 422.752(d), 438.210, 438.400, and 438.402, which are effective January 1, 2021, and for the amendments to §§ 422.222(a)(2), 423.120(c)(6)(iv), and 498.5(n)(1), which are effective June 17, 2019.

FOR FURTHER INFORMATION CONTACT: Theresa Wachter, (410) 786–1157, or Cali Diehl, (410) 786–4053, MA/Part C Issues. Elizabeth Goldstein, (410) 786–6665, Parts C and D Quality Ratings Issues. Kari Gaare, (410) 786–8612, Prescription Drug Plan Access to Parts A and B Data Issues. Vanessa Duran, (410) 786–8697, D–SNP Issues. Frank Whelan, (410) 786–1302, Preclusion List Issues.

SUPPLEMENTARY INFORMATION:

I. Executive Summary and Background

A. Executive Summary

1. Purpose

The primary purpose of this final rule is to revise the Medicare Advantage (MA) program (Part C) and Prescription Drug Benefit Program (Part D) regulations based on our continued experience in the administration of the Part C and Part D programs and to implement certain provisions of the Bipartisan Budget Act of 2018. The changes are necessary to—

- Implement the Bipartisan Budget Act of 2018 provisions;
- Improve program quality and accessibility;
- Clarify program integrity policies; and
- Implement other changes.

This final rule will meet the Administration's priorities to reduce burden across the Medicare program by reducing unnecessary regulatory complexity, and improve the regulatory framework to facilitate development of Part C and Part D products that better meet the individual beneficiary's healthcare needs. Because the Bipartisan Budget Act of 2018 requires the Secretary to establish procedures, to the extent feasible, for integration and unification of the appeals and grievance processes for dual eligible individuals who are enrolled in Medicaid and in MA special needs plans for dual eligible individuals (D–SNPs), this final rule also includes provisions to revise the appeals and grievances requirements for Medicaid managed care and MA D–SNPs. While the Part C and Part D programs have high satisfaction among beneficiaries, we continually evaluate program policies and regulations to remain responsive to current trends and newer technologies, and provide increased flexibility to serve patients. Specifically, this final rule meets the Secretary's priorities to: (1) Reform health insurance by increasing access to personalized health care, (2) transform our healthcare system to be value-based and innovative by promoting health information technology, and (3) support boosting transparency around price and quality. These changes being finalized will promote more convenient, cost-effective access to care within Part C and D plans, improve accountability and bolster program integrity, allow plans to innovate in response to patients' needs, and promote coordination within MA D–SNPs.

2. Summary of the Major Provisions

a. Requirements for Medicare Advantage Plans Offering Additional Telehealth Benefits (§§ 422.100, 422.135, 422.252, 422.254, and 422.264)

Section 50323 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123) created a new section 1852(m) of the Social Security Act (the Act), which allows MA plans the ability to provide ''additional telehealth benefits'' (referred to as ''MA additional telehealth benefits'' in this rule) to enrollees starting in plan year 2020 and treat them as basic benefits. The statute limits these authorized MA additional telehealth benefits to services for which benefits are available under Medicare Part B, but that are not payable under section 1834(m) of the Act and have been identified for the applicable year as clinically appropriate to furnish through electronic information and telecommunications technology (referred to as ''electronic exchange'' in this rule). Under this final rule, MA plans will be permitted to offer—as part of the basic benefit package—MA additional telehealth benefits beyond what is currently allowable under the original Medicare telehealth benefit (referred to as ''Medicare telehealth services'' in this rule). In addition, MA plans will continue to be able to offer MA supplemental benefits (that is, benefits not covered by original Medicare) via remote access technologies and/or telemonitoring (referred to as ''MA supplemental telehealth benefits'' in this rule) for those services that do not meet the requirements for coverage under original Medicare or the requirements for MA additional telehealth benefits.

Section 1852(m)(4) of the Act mandates that enrollee choice is a priority. If an MA plan covers a Part B service as an MA additional telehealth benefit, then the MA plan must also provide access to such service through an in-person visit and not only through electronic exchange. The enrollee must have the option whether to receive such service through an in-person visit or, if offered by the MA plan, through electronic exchange. In addition, section 1852(m)(2)(A)(ii) of the Act excludes from MA additional telehealth benefits capital and infrastructure costs and investments relating to such benefits. These statutory provisions have guided our rule.

In this final rule, we establish regulatory requirements that will allow MA plans to cover Part B benefits furnished through electronic exchange but not payable under section 1834(m) of the Act as MA additional telehealth

benefits—and as part of the basic benefits defined in § 422.101 instead of separate MA supplemental benefits. We believe MA additional telehealth benefits will increase access to patient-centered care by giving enrollees more control to determine when, where, and how they access benefits. We solicited comments from stakeholders on various aspects of our proposal, which informed how we are implementing the MA additional telehealth benefits in this final rule.

b. Dual Eligible Special Needs Plans Provisions (§§ 422.2, 422.60, 422.102, 422.107, 422.111, 422.560 Through 422.562, 422.566, 422.629 Through 422.634, 422.752, 438.210, 438.400, and 438.402)

Section 50311(b) of the Bipartisan Budget Act of 2018 amends section 1859 of the Act to require integration of the Medicare and Medicaid benefits provided to enrollees in Dual Eligible Special Needs Plans (D–SNPs). In particular, the statute requires: (1) Development of unified grievance and appeals processes for D–SNPs; and (2) establishment of new standards for integration of Medicare and Medicaid benefits for D–SNPs.

The statute specifies a number of key elements for unified D–SNP grievance and appeals processes and grants the Secretary discretion to determine the extent to which unification of these processes is feasible. In particular, the unified processes must adopt the provisions from section 1852(f) and (g) of the Act (MA grievances and appeals) and sections 1902(a)(3) and (5), and 1932(b)(4) of the Act (Medicaid grievances and appeals, including managed care) that are most protective to the enrollee, take into account differences in state Medicaid plans to the extent necessary, easily navigable by an enrollee, include a single written notification of all applicable grievance and appeal rights, provide a single pathway for resolution of a grievance or appeal, provide clear notices, employ unified timeframes for grievances and appeals, establish requirements for how the plan must process, track, and resolve grievances and appeals, and with respect to benefits covered under Medicare Parts A and B and Medicaid, incorporate existing law that provides continuation of benefits pending appeal for items and services covered under Medicare and Medicaid. The statute requires the Secretary to establish unified grievance and appeals procedures by April 1, 2020 and requires D–SNP contracts with state Medicaid agencies to use the unified procedures for 2021 and subsequent years.

Regarding the establishment of new standards for integration of Medicare and Medicaid benefits, the statute requires that all D–SNPs meet certain new minimum criteria for such integration for 2021 and subsequent years, either by covering Medicaid benefits through a capitated payment from a state Medicaid agency or meeting a minimum set of requirements as determined by the Secretary. The law also stipulates that for the years 2021 through 2025, if the Secretary determines that a D–SNP failed to meet one of these integration standards, the Secretary may impose an enrollment sanction, which would prevent the D–SNP from enrolling new members. In describing the ''additional minimum set of requirements'' established by the Secretary, the statute directs the Federally Coordinated Health Care Office in CMS to base such standards on input from stakeholders. We implement these new statutory provisions and clarify definitions and operating requirements for D–SNPs in this final rule.

c. Medicare Advantage and Part D Prescription Drug Plan Quality Rating System (§§ 422.162(a) and 423.182(a), §§ 422.166(a) and 423.186(a), §§ 422.164 and 423.184, and §§ 422.166(i) and 423.186(i))

In the Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program Final Rule (hereafter referred to as the April 2018 final rule), CMS codified at §§ 422.160, 422.162, 422.164, and 422.166 (83 FR 16725 through 16731) and §§ 423.180, 423.182, 423.184, and 423.186 (83 FR 16743 through 16749) the methodology for the Star Ratings system for the MA and Part D programs, respectively. This was part of the Administration's effort to increase transparency and advance notice regarding enhancements to the Part C and D Star Ratings program.

At this time, we are finalizing enhancements to the cut point methodology for non-Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures. We are also making substantive updates to the specifications for a few measures for the 2022 and 2023 Star Ratings, and finalizing rules for calculating Star Ratings in the case of extreme and uncontrollable circumstances. Data would be collected and performance measured using these final rules and regulations for the 2020 measurement period and the 2022 Star Ratings, except for the Plan All-Cause Readmission measure where the applicability date is the 2021 measurement period as described in section II.B.1.d.(1).(c) of this final rule.

d. Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in MA, Cost Plans, and PACE (§§ 422.222 and 423.120(c)(6))

In the April 2018 final rule, CMS removed several requirements pertaining to MA and Part D provider and prescriber enrollment that were to become effective on January 1, 2019. We stated in that final rule our belief that the best means of reducing the burden of the MA and Part D provider and prescriber enrollment requirements without compromising our payment safeguard objectives would be to focus on providers and prescribers that pose an elevated risk to Medicare beneficiaries and the Trust Funds. That is, rather than require the enrollment of MA providers and Part D prescribers regardless of the level of risk they might pose, we would prevent payment for MA items or services and Part D drugs that are, as applicable, furnished or prescribed by demonstrably problematic providers and prescribers. We therefore established in the April 2018 final rule a policy under which: (1) Such problematic parties would be placed on a ''preclusion list''; and (2) payment for MA services and items and Part D drugs furnished or prescribed by these individuals and entities would be rejected or denied, as applicable. The MA and Part D enrollment requirements, in short, were replaced with the payment-oriented approach of the preclusion list.

This final rule will make several revisions and additions to the preclusion list provisions we finalized in the April 2018 final rule. We believe these changes will help clarify for stakeholders CMS' expectations regarding the preclusion list.

3. Summary of Costs and Benefits

Provision	Description	Impact
Requirements for Medicare Advantage Plans Offering Additional Telehealth Benefits (§§ 422.100, 422.135, 422.252, 422.254, and 422.264).	Consistent with section 50323 of the Bipartisan Budget Act of 2018, MA plans have the ability to provide ''additional telehealth benefits'' to enrollees starting in plan year 2020 and treat them as basic benefits.	MA additional telehealth benefits are expected to produce $557 million in savings for enrollees over 10 years from reduced travel time to and from providers. The impact of paying for MA additional telehealth benefits out of the Medicare Trust Fund (as basic benefits) versus out of the rebates (as supplemental benefits) results in a transfer of $80 million from the Medicare Trust Fund to enrollees over 10 years.
Integration Requirements for Dual Eligible Special Needs Plans (§§ 422.2, 422.60, 422.102, 422.107, 422.111, and 422.752).	Consistent with section 50311(b) of the Bipartisan Budget Act of 2018, we are establishing, effective 2021, Medicare and Medicaid integration standards D–SNPs. Effective 2021 through 2025, we will require the imposition of an intermediate sanction of prohibiting new enrollment into a D–SNP if CMS determines that the D–SNP is failing to comply with these integration standards. Finally, we are creating new and modifying existing regulatory definitions that relate to D–SNPs.	For the initial year of implementation, we estimate a $3.4 million cost to MA plans and a $0.5 million cost to state Medicaid agencies, half of which is transferred to the federal government, in order to transition to the new requirements. After that, we estimate that impact will be negligible.
Unified Grievances and Appeals Procedures for Dual Eligible Special Needs Plans and Medicaid Managed Care Plans at the Plan Level (§§ 422.560–562, 422.566, 422.629–422.634, 438.210, 438.400, and 438.402).	Consistent with section 50311(b) of the Bipartisan Budget Act of 2018, we are unifying Medicare and Medicaid grievance and appeals procedures for certain D–SNPs that enroll individuals who receive Medicare and Medicaid benefits from the D–SNP and a Medicaid managed care organization offered by the D–SNP's MA organization, the parent organization, or subsidiary owned by the parent organization. Medicare and Medicaid grievance and appeals processes differ in several key ways, which in effect creates unnecessary administrative complexity for health issuers participating across product lines. This will allow enrollees to follow one resolution pathway at the plan level when filing a complaint or contesting an adverse coverage determination with their plan regardless of whether the matter involves a Medicare or Medicaid covered service.	The provision gives rise to both savings, from the increased efficiency of a unified process, and costs from the requirement to provide benefits while appeals are pending. Over 10 years there are three anticipated effects: (1) Plans will save $0.7 million from the increased efficiency of unified appeals and grievance processes; this savings is passed to the Medicare Trust Fund; (2) the Medicare Trust Fund will incur a $4.2 million expense for providing benefits while appeals are pending; and (3) enrollees will incur an extra $0.7 million in cost sharing for benefits while appeals are pending.
MA and Part D Prescription Drug Plan Quality Rating System (§§ 422.162(a) and 423.182(a), 422.166(a) and 423.186(a), 422.164 and 423.184, and 422.166(i)(1) and 423.186(i)(1)).	We are finalizing several measure specification updates, adjustments due to extreme and uncontrollable circumstances, and an enhanced cut point methodology. The measure changes are routine and do not have a significant impact on the ratings of contracts. The policy for disasters will hold contracts harmless from decreases in ratings from the prior year when there are extreme and uncontrollable circumstances affecting them. The methodology to set Star Ratings cut points will help increase the stability and predictability of cut points from year to year.	Negligible impact.
Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in MA, Cost Plans, and PACE (§§ 422.222 and 423.120(c)(6)).	We are making several revisions to the MA and Part D preclusion list policies that we finalized in the April 2018 final rule.	Negligible impact.

B. Background

We received approximately 180 timely pieces of correspondence containing multiple comments on the proposed rule titled ''Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021'' which published November 1, 2018, in the **Federal Register** (83 FR 54982). While we intend to address the Risk Adjustment Data Validation (RADV) proposals in subsequent rulemaking (due to an extended comment period for these proposals until April 30, 2019, per 83 FR 66661), we are finalizing all other provisions with changes varying from minor clarifications to more significant modifications based on comments received. We also note that some of the public comments received were outside of the scope of the proposed rule. These

out-of-scope public comments are not addressed in this final rule. Summaries of the public comments that are within the scope of the proposed rule and our responses to those public comments are set forth in the various sections of this final rule under the appropriate headings. However, we note that in this final rule we are not addressing comments received with respect to the RADV provision of the proposed rule that we are not finalizing at this time. Rather, we will address these comments in subsequent rulemaking, as appropriate.

II. Provisions of the Proposed Rule and Analysis of and Responses to Public Comments

A. Implementing the Bipartisan Budget Act of 2018 Provisions

1. Requirements for Medicare Advantage Plans Offering Additional Telehealth Benefits (§§ 422.100, 422.135, 422.252, 422.254, and 422.264)

Technologies that enable healthcare providers to deliver care to patients in locations remote from the providers (hereinafter referred to as ''telehealth'') are increasingly being used to complement face-to-face patient-provider encounters. Telehealth visits among rural Medicare beneficiaries participating in original Medicare have increased more than 25 percent a year from 2004 to 2013.[1] In Medicare Advantage (MA), about 81 percent of MA plans offered supplemental telehealth benefits in the form of remote access technologies in 2018, an increase from 77 percent in 2017.[2] This shows that the healthcare industry has made significant advances in technology that enable secure, reliable, real-time, interactive communication and data transfer that were not possible in the past. Moreover, the use of telehealth as a care delivery option for MA enrollees may improve access to and timeliness of needed care, increase convenience for patients, increase communication between providers and patients, enhance care coordination, improve quality, and reduce costs related to in-person care.[3]

MA basic benefits are structured and financed based on what is covered under Medicare Parts A and B (paid through the capitation rate by the government) with coverage of additional items and services and more generous cost sharing provisions financed as MA supplemental benefits (paid using rebate dollars or supplemental premiums paid by enrollees). Traditionally, MA plans have been limited in how they may deliver telehealth services outside of the original Medicare telehealth benefit under section 1834(m) of the Act (hereinafter referred to as ''Medicare telehealth services'') because of this financing structure; only services covered by original Medicare under Parts A and B, with actuarially equivalent cost sharing, are in the basic benefit bid paid by the capitation rate. Section 1834(m) of the Act and § 410.78 generally limit payment for Medicare telehealth services by authorizing payment only for specified services provided using an interactive audio and video telecommunications system that permits real-time communication between a Medicare beneficiary and either a physician or specified other type of practitioner, and by specifying where the beneficiary may receive telehealth services (eligible originating sites). Eligible originating sites are limited as to the type of geographic location (generally rural) and the type of care setting. The statute grants the Secretary the authority to add to the list of Medicare telehealth services based on an established annual process but does not allow for exceptions to the restrictions on types of practitioners that can furnish those services or on the eligible originating sites. Because sections 1852(a), 1853, and 1854 of the Act limit the basic benefits covered by the government's capitation payment to only Parts A and B services covered under original Medicare with actuarially equivalent cost sharing, telehealth benefits offered by MA plans in addition to those covered by original Medicare are currently offered as MA supplemental benefits and funded through the use of rebate dollars or supplemental premiums paid by enrollees.

On February 9, 2018, President Trump signed the Bipartisan Budget Act of 2018 (Pub. L. 115–123) into law. Section 50323 of the Bipartisan Budget Act of 2018 created a new section 1852(m) of the Act, which allows MA plans the ability to provide ''additional telehealth benefits'' (hereinafter referred to as ''MA additional telehealth benefits'') to enrollees starting in plan year 2020 and treat them as basic benefits (also known as ''original Medicare benefits'' or ''benefits under the original Medicare fee-for-service program option''). The statute limits these authorized MA additional telehealth benefits to services for which benefits are available under Medicare Part B but that are not payable under section 1834(m) of the Act and have been identified for the applicable year as clinically appropriate to furnish through electronic information and telecommunications technology (hereinafter referred to as ''electronic exchange''). While MA plans have always been able to offer more telehealth services than are currently payable under original Medicare through MA supplemental benefits, this change in how such MA additional telehealth benefits are financed (that is, accounted for in the capitated payment) makes it more likely that MA plans would offer them and that more enrollees would use the benefit.

We are adding a new regulation at § 422.135 to implement the new section 1852(m) of the Act and amending existing regulations at §§ 422.100, 422.252, 422.254, and 422.264. Specifically, we are codifying a new regulation at § 422.135 to allow MA plans to offer MA additional telehealth benefits, to establish definitions applicable to this new classification of benefits, and to enact requirements and limitations on them. Further, we are amending § 422.100(a) and (c)(1) to include MA additional telehealth benefits in the definition of basic benefits and adding a cross-reference to new § 422.135 to reflect how these benefits may be provided as part of basic benefits. Finally, we are amending the bidding regulations at §§ 422.252, 422.254, and 422.264 to account for MA additional telehealth benefits in the basic benefit bid.

We proposed that, beginning in contract year 2020, MA plans will be permitted to offer—as part of the basic benefit package—MA additional telehealth benefits beyond what is currently allowable under Medicare telehealth services. Pursuant to section 1852 of the Act and the regulation at § 422.100(a), MA plans are able to offer Medicare telehealth services including those described in existing authority at section 1834(m) of the Act and §§ 410.78 and 414.65 of the regulations. We proposed that in addition to Medicare telehealth services, MA plans will be able (but not required) to offer MA additional telehealth benefits described in this final rule and at section 1852(m) of the Act. In addition, we proposed to continue authority for MA plans to offer MA supplemental benefits (that is, benefits not covered by original Medicare) via remote access technologies and telemonitoring (as

[1] Mehrotra, A., Jena, A., Busch, A., Souza, J., Uscher-Pines, L., Landon, B. (2016). ''Utilization of Telemedicine Among Rural Medicare Beneficiaries.'' *JAMA,* 315(18): 2015–2016.

[2] *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/index.html*

[3] Medicare Payment Advisory Commission (MedPAC), *Report to the Congress: Medicare Payment Policy,* March 2018.

currently named in the plan benefit package (PBP) software; hereinafter referred to as ''MA supplemental telehealth benefits'') for those services that do not meet the requirements for coverage under original Medicare (for example, for Medicare telehealth services under section 1834(m)) or the requirements for MA additional telehealth benefits, such as the requirement of being covered by Part B when provided in-person. For instance, an MA plan may offer, as an MA supplemental telehealth benefit, a videoconference dental visit to assess dental needs because services primarily provided for the care, treatment, removal, or replacement of teeth or structures directly supporting teeth are not currently covered Part B benefits and thus would not be allowable as MA additional telehealth benefits.

We proposed to establish regulatory requirements that will allow MA plans to cover Part B benefits furnished through electronic exchange but not payable under section 1834(m) of the Act as MA additional telehealth benefits—and as part of the basic benefits defined in § 422.101 instead of separate MA supplemental benefits. We believe MA additional telehealth benefits will increase access to patient-centered care by giving enrollees more control to determine when, where, and how they access benefits.

Section 1852(m)(2)(A)(i) of the Act, as added by the Bipartisan Budget Act of 2018, defines ''additional telehealth benefits'' as services—(1) for which benefits are available under Part B, including services for which payment is not made under section 1834(m) of the Act due to the conditions for payment under such section; and (2) that are identified for the applicable year as clinically appropriate to furnish using electronic information and telecommunications technology (which we refer to as ''through electronic exchange'') when a physician (as defined in section 1861(r) of the Act) or practitioner (described in section 1842(b)(18)(C) of the Act) providing the service is not at the same location as the plan enrollee. In addition, section 1852(m)(2)(A)(ii) of the Act excludes from ''additional telehealth benefits'' capital and infrastructure costs and investments relating to such benefits. This statutory definition of ''additional telehealth benefits'' guided our proposal.

We proposed a new regulation at § 422.135 to authorize and govern the provision of MA additional telehealth benefits by MA plans, consistent with our interpretation of the new statutory provision. First, we proposed definitions for the terms ''additional telehealth benefits'' and ''electronic exchange'' in § 422.135(a). We proposed to define ''additional telehealth benefits'' as services that meet the following: (1) Are furnished by an MA plan for which benefits are available under Medicare Part B but which are not payable under section 1834(m) of the Act; and (2) have been identified by the MA plan for the applicable year as clinically appropriate to furnish through electronic exchange. For purposes of this specific regulation and addressing the requirements and limitations on MA additional telehealth benefits, we proposed to define ''electronic exchange'' as ''electronic information and telecommunications technology'' as this is a concise term for the statutory description of the means used to provide the MA additional telehealth benefits. We did not propose specific regulation text that defines or provides examples of electronic information and telecommunications technology because the technology needed and used to provide MA additional telehealth benefits would vary based on the service being offered. Examples of electronic information and telecommunications technology (or ''electronic exchange'') may include, but are not limited to, the following: Secure messaging, store and forward technologies, telephone, videoconferencing, other internet-enabled technologies, and other evolving technologies as appropriate for non-face-to-face communication. We believe this broad and encompassing approach will allow for technological advances that may develop in the future and avoid tying the authority in the regulation to specific information formats or technologies that permit non-face-to-face interactions for furnishing clinically appropriate services.

We did not propose specific regulation text defining ''clinically appropriate;'' rather, we proposed to implement the statutory requirement for MA additional telehealth benefits to be provided only when ''clinically appropriate'' to align with our existing regulations for contract provisions at § 422.504(a)(3)(iii), which requires each MA organization to agree to provide all benefits covered by Medicare ''in a manner consistent with professionally recognized standards of health care.'' We proposed to apply the same principle to MA additional telehealth benefits, as MA additional telehealth benefits must be treated as if they were benefits under original Medicare per section 1852(m)(5) of the Act.

The statute limits MA additional telehealth benefits to those services that are identified for the applicable year as clinically appropriate to furnish through electronic exchange. The statute does not specify who or what entity identifies the services for the year. Therefore, we proposed to interpret this provision broadly by not specifying the Part B services that an MA plan may offer as MA additional telehealth benefits for the applicable year, but instead allowing MA plans to independently determine each year which services are clinically appropriate to furnish in this manner. Thus, our definition of MA additional telehealth benefits at § 422.135(a) provides that it is the MA plan (not CMS) that identifies the appropriate services for the applicable year. We believe that MA plans are in the best position to identify each year whether MA additional telehealth benefits are clinically appropriate to furnish through electronic exchange. MA plans have a vested interest in and responsibility for staying abreast of the current professionally recognized standards of health care, as these standards are continuously developing with new advancements in modern medicine. As professionally recognized standards of health care change over time and differ from practice area to practice area, our approach is flexible enough to take those changes and differences into account.

Furthermore, § 422.111(b)(2) requires the MA plan to annually disclose the benefits offered under a plan, including applicable conditions and limitations, premiums and cost sharing (such as copayments, deductibles, and coinsurance) and any other conditions associated with receipt or use of benefits. MA plans satisfy this requirement through the Evidence of Coverage, or EOC, document provided to all enrollees. This disclosure requirement would have to include applicable MA additional telehealth benefit limitations. That is, any MA plan offering MA additional telehealth benefits must identify the services that can be covered as MA additional telehealth benefits when provided through electronic exchange. We believe that it is through this mechanism (the EOC) that the MA plan would identify each year which services are clinically appropriate to furnish through electronic exchange as MA additional telehealth benefits.

We solicited comment on this proposed implementation of the statute and our reasoning. We noted in the proposed rule how we had considered whether CMS should use the list of Medicare telehealth services payable by original Medicare under section 1834(m) of the Act as the list of services that are clinically appropriate to be

provided through electronic exchange for MA additional telehealth benefits. In that circumstance, services on the list could be considered as clinically appropriate to be provided through electronic exchange for MA additional telehealth benefits without application of the location limitations of section 1834(m) of the Act. However, we do not believe that is the best means to take full advantage of the flexibility that Congress has authorized for the MA program. The list of Medicare telehealth services for which payment can be made under section 1834(m) of the Act under the original Medicare program includes services specifically identified by section 1834(m) of the Act as well as other services added to the Medicare telehealth list using criteria and an annual process established by CMS. We stated in the proposed rule that we believe these limitations and criteria should not apply to MA additional telehealth benefits under new section 1852(m) of the Act for MA plans.

The statute requires the Secretary to solicit comment on what types of items and services should be considered to be MA additional telehealth benefits. Therefore, we also solicited comments on whether we should place any limitations on what types of Part B items and services (for example, primary care visits, routine and/or specialty consultations, dermatological examinations, behavior health counseling, etc.) can be MA additional telehealth benefits provided under this authority.

An enrollee has the right to request MA additional telehealth benefits through the organization determination process. If an enrollee is dissatisfied with the organization determination, then the enrollee has the right to appeal the decision. We believe these rights help ensure access to medically necessary services, including MA additional telehealth benefits offered by an MA plan as described in this rule. In addition, CMS audits plan performance with respect to timeliness and clinical appropriateness of organization determinations and appeals.

While the MA plan would make the ''clinically appropriate'' decision in terms of coverage of an MA additional telehealth benefit, we note that each healthcare provider must also provide services that are clinically appropriate. We acknowledge that not all Part B items and services would be suitable for MA additional telehealth benefits because a provider must be physically present in order to properly deliver care in some cases (for example, hands-on examination, administering certain medications). As stated earlier, we proposed that MA plans would independently determine each year which services are clinically appropriate to furnish in this manner. Behavioral health, in particular, is a prime example of a service that could be provided remotely through MA plans' offering of MA additional telehealth benefits under this rule. The President's Commission on Combating Drug Addiction and the Opioid Crisis recommends telehealth as useful in the effort to combat the opioid crisis when clinically appropriate, especially in geographically isolated regions and underserved areas where people with opioid use disorders and other substance use disorders may benefit from remote access to needed treatment.[4]

We proposed in paragraph (b) the general rule to govern how an MA plan may offer MA additional telehealth benefits. Specifically, we proposed that if an MA plan chooses to furnish MA additional telehealth benefits, the MA plan may treat these benefits as basic benefits covered under the original Medicare fee-for-service program as long as the requirements of proposed § 422.135 are met. We also proposed in § 422.135(b) that if the MA plan fails to comply with the requirements of § 422.135, then the MA plan may not treat the benefits provided through electronic exchange as MA additional telehealth benefits, but may treat them as MA supplemental telehealth benefits, subject to CMS approval of the MA supplemental telehealth benefits. For example, a non-Medicare covered service provided through electronic exchange cannot be offered as an MA additional telehealth benefit because it does not comply with § 422.135, which is limited to furnishing through electronic exchange otherwise covered Part B covered services, but it may be offered it as an MA supplemental telehealth benefit.

Section 1852(m)(4) of the Act mandates that enrollee choice is a priority. If an MA plan covers a Part B service as an MA additional telehealth benefit, then the MA plan must also provide access to such service through an in-person visit and not only through electronic exchange. We proposed to codify this statutory mandate preserving enrollee choice in regulation text at § 422.135(c)(1), which requires that the enrollee must have the option to receive a service that the MA plan covers as an MA additional telehealth benefit either through an in-person visit or through electronic exchange. Section 1852(m)(5) of the Act mandates that MA additional telehealth benefits shall be treated as if they were benefits under the original Medicare fee-for-service program option. In proposed regulation text at § 422.135(f), we proposed to allow MA plans to maintain different cost sharing for the specified Part B service(s) furnished through an in-person visit and the specified Part B service(s) furnished through electronic exchange.

We proposed § 422.135(c)(2) to require MA plans to use their EOC (at a minimum) to advise enrollees that they may receive the specified Part B service(s) either through an in-person visit or through electronic exchange. We proposed, at § 422.135(c)(3), that MA plans would have to use their provider directory to identify any providers offering services for MA additional telehealth benefits and in-person visits or offering services exclusively for MA additional telehealth benefits. We stated in the proposed rule that these notifications in the EOC and the provider directory are important to ensure choice, transparency, and clarity for enrollees who might be interested in taking advantage of MA additional telehealth benefits. We requested comments on what impact, if any, MA additional telehealth benefits should have on MA network adequacy policies. Specifically, we were looking for the degree to which MA additional telehealth benefit providers should be considered in the assessment of network adequacy (including for certain provider types and/or services in areas with access concerns) and any potential impact on rural MA plans, providers, and/or enrollees.

Section 1852(m)(3) of the Act requires the Secretary to specify limitations or additional requirements for the provision or furnishing of MA additional telehealth benefits, including requirements with respect to physician or practitioner qualifications, factors necessary for the coordination of MA additional telehealth benefits with other items and services (including those furnished in-person), and other areas identified by the Secretary. We recognize the potential for MA additional telehealth benefits to support coordinated health care and increase access to care in both rural and urban areas. We stated in the proposed rule how we expect MA plans would use these types of benefits to support an effective, ongoing doctor-patient relationship and the efficient delivery of needed care.

We proposed in regulation text at § 422.135(c)(4) to require an MA plan

[4] Retrieved at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Meeting%20Draft%20of%20Final%20Report%20-%20November%201%2C%202017.pdf.*

offering MA additional telehealth benefits to comply with the provider selection and credentialing requirements provided in § 422.204. An MA plan must have written policies and procedures for the selection and evaluation of providers and must follow a documented process with respect to providers and suppliers, as described in § 422.204. Further, we proposed that the MA plan, when providing MA additional telehealth benefits, must ensure through its contract with the provider that the provider meet and comply with applicable state licensing requirements and other applicable laws for the state in which the enrollee is located and receiving the service. We recognize, however, that it is possible for a state to have specific provisions regarding the practice of medicine using electronic exchange; our proposal reflected our intent to ensure that MA network providers comply with these laws and that MA plans ensure compliance with such laws and only cover MA additional telehealth benefits provided in compliance with such laws. We solicited comment on whether to impose additional requirements for qualifications of providers of MA additional telehealth benefits, and if so, what those requirements should be.

In order to monitor the impact of the MA additional telehealth benefits on MA plans, providers, enrollees, and the MA program as a whole, we also proposed to require MA plans to make information about coverage of MA additional telehealth benefits available to CMS upon request, per proposed § 422.135(c)(5). We proposed that this information may include, but is not limited to, statistics on use or cost of MA additional telehealth benefits, manner(s) or method(s) of electronic exchange, evaluations of effectiveness, and demonstration of compliance with the requirements in § 422.135. We explained in our proposed rule that the purpose of requiring MA plans to make such information available to CMS upon request would be to determine whether CMS should make improvements to the regulation and/or guidance regarding MA additional telehealth benefits.

In § 422.135(d), we proposed to require that MA plans furnishing MA additional telehealth benefits may only do so using contracted (that is, network) providers. We believe limiting service delivery of MA additional telehealth benefits to contracted providers offers MA enrollees access to these covered services in a manner more consistent with the statute because plans would have more control over how and when such services are furnished. The regulation at § 422.204 requires MA plans to have written policies and procedures for the selection and evaluation of providers and that such policies conform with MA specific credentialing requirements outlined in § 422.204. We explained in the proposed rule that these policies would also be a means to ensure additional oversight of providers' performance, thereby increasing plans' ability to provide covered services such as MA additional telehealth benefits. We also proposed to specify that if an MA plan covers benefits furnished by a non-contracted provider through electronic exchange, then those benefits may only be covered as MA supplemental telehealth benefits. These benefits are not MA additional telehealth or basic benefits if furnished by a non-contracted provider through electronic exchange. We requested comment on whether the contracted providers' restriction should be placed on all MA plan types or limited only to certain plan types, such as local/regional preferred provider organization (PPO) plans, medical savings account (MSA) plans, and/or private fee-for-service (PFFS) plans. Currently, pursuant to § 422.4(a)(1)(v), PPO plans must provide reimbursement for all plan-covered medically necessary services received from non-contracted providers without prior authorization requirements. We explained in the proposed rule our view that without an opportunity to review the qualifications of the non-contracted provider and to impose limits on how only clinically appropriate services are provided as MA additional telehealth benefits, PPO plans would not be able to meet the proposed requirements. Therefore, we solicited comment on whether to require just PPOs (or MSA plans, PFFS plans, etc.), instead of all MA plan types, to use only contracted providers for MA additional telehealth benefits.

Per section 1852(m)(2)(A)(ii) of the Act, the term ''additional telehealth benefits'' does not include capital and infrastructure costs and investments relating to such benefits. We proposed to codify this requirement in § 422.254(b)(3)(i) as a restriction on how MA plans include MA additional telehealth benefits in their bid submission. We stated that we believe that the statutory limit is tied only to the cost to the government, which is tied to how MA additional telehealth benefits may be included in the bid as basic benefits. Therefore, our proposal was to eliminate from the basic benefit bid those capital and infrastructure costs and investments that are required or used to enable the provision of MA additional telehealth benefits. We did not propose specific definitions of capital and infrastructure costs or investments related to such benefits because the costs and investments needed and used to provide MA additional telehealth benefits would vary based on the individual MA plan's approach to furnishing the benefits. In the proposed rule, we provided some examples of capital and infrastructure costs, including, but not limited to, high-speed internet installation and service, communication platforms and software, and video conferencing equipment. We also solicited comment on what other types of capital and infrastructure costs and investments should be excluded from the bid and how CMS should operationalize this statutory requirement in the annual bid process. We proposed to provide a more detailed list of examples in this final rule, based on feedback received from stakeholders.

We explained in the proposed rule that our proposal at § 422.254(b)(3)(i) meant that MA plans must exclude any capital and infrastructure costs and investments specifically relating to MA additional telehealth benefits from their bid submission for MA additional telehealth services offered directly by the plan sponsor and by a third party provider. Accordingly, we explained our proposal meant that the projected expenditures in the MA bid for services provided via MA additional telehealth benefits must not include the corresponding capital and infrastructure costs and that any items provided to the enrollee in the administration of MA additional telehealth benefits must be directly related to the care and treatment of the enrollee for the Part B benefit. In the proposed rule, we provided an example of this provision, noting that MA plans would not be able to provide enrollees with internet service or permanently install telecommunication systems in an enrollee's home as part of administration of MA additional telehealth benefits.

In addition to our proposal at § 422.135, we also proposed to amend paragraphs (a) and (c)(1) of § 422.100 to explicitly address how MA additional telehealth benefits may be offered by an MA plan. Section 1852(a)(1)(A) of the Act requires that each MA plan shall provide enrollees benefits under the original Medicare fee-for-service program option. As amended by the Bipartisan Budget Act of 2018, section 1852(a)(1)(B) of the Act defines ''benefits under the original Medicare fee-for-service program option'' to mean—subject to subsection (m) (regarding provision of MA additional

telehealth benefits)—those items and services (other than hospice care or coverage for organ acquisitions for kidney transplants) for which benefits are available under Parts A and B to individuals entitled to benefits under Part A and enrolled under Part B. Since this definition is subject to the statutory provision for MA additional telehealth benefits, this means that all of the same coverage and access requirements that apply with respect to basic benefits also apply to any MA additional telehealth benefits an MA plan may choose to offer. Therefore, we proposed to amend § 422.100(c)(1) to include MA additional telehealth benefits in the definition of basic benefits and to cross-reference § 422.135, which provides the rules governing MA additional telehealth benefits. We proposed to further clarify the regulation text in § 422.100(c)(1) to track the statutory language described earlier more closely in addressing both kidney acquisition and hospice in the definition of basic benefits. Finally, we proposed to make corresponding technical revisions to § 422.100(a) to reference the new paragraph (c)(1) for basic benefits (clarifying that MA additional telehealth benefits are voluntary benefits for MA plans to offer but are not required) and paragraph (c)(2) for MA supplemental benefits (instead of § 422.102 because MA supplemental benefits are listed as a benefit type in (c)(2)). We also proposed a small technical correction in the last sentence of § 422.100(a) to replace the reference to § 422.100(g) with ''this section'' because there are a number of provisions in § 422.100—not just paragraph (g)—that are applicable to the benefits CMS reviews.

Additionally, we proposed amendments to the bidding regulations at §§ 422.252, 422.254, and 422.264 to account for MA additional telehealth benefits and to correct the inconsistent phrasing of references to basic benefits (for example, these regulations variously use the terms ''original Medicare benefits,'' ''benefits under the original Medicare program,'' ''benefits under the original Medicare FFS program option,'' etc.). In order to make the MA additional telehealth benefits part of the basic benefit bid and included in the ''monthly aggregate bid amount'' as part of the original Medicare benefits that are the scope of the basic benefit bid, we proposed to update these various phrases to consistently use the phrase ''basic benefits as defined in § 422.100(c)(1).'' We also proposed a few minor technical corrections to the bidding regulations. Finally, we proposed a paragraph (e) in new § 422.135 to state that an MA plan that fully complies with § 422.135 may include MA additional telehealth benefits in its bid for basic benefits in accordance with § 422.254. This provision means that inclusion in the bid is subject to the bidding regulations we proposed to amend.

In offering MA additional telehealth benefits, MA plans must comply with existing MA rules, including, but not limited to: Access to services at § 422.112; recordkeeping requirements at § 422.118 (for example, confidentiality, accuracy, timeliness); standards for communications and marketing at § 422.2268 (for example, inducement prohibition); and non-discrimination at §§ 422.100(f)(2) and 422.110(a). Further, in addition to §§ 422.112, 422.118, 422.2268, 422.100(f)(2), and 422.110(a), MA plans must also ensure compliance with other federal non-discrimination laws, such as Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973, and section 1557 of the Affordable Care Act. We did not propose specific reference to these existing requirements in new § 422.135 because we do not believe that to be necessary. Compliance with these existing laws is already required; we merely note, as an aid to MA plans, how provision of MA additional telehealth benefits must be consistent with these regulations. We solicited comment on this policy choice, specifically whether there were other existing regulations that CMS should revise to address their application in the context of MA additional telehealth benefits.

Finally, section 1852(m)(2)(B) of the Act instructed the Secretary to solicit comments on the implementation of these MA additional telehealth benefits by November 30, 2018; in addition to the proposed regulations to implement section 1852(m) of the Act, we used the proposed rule and the associated comment period to satisfy this statutory requirement. We thank commenters for their input to help inform CMS's next steps related to implementing the MA additional telehealth benefits. We received the following comments on this proposal, and our response follows:

Comment: Many commenters suggested that CMS's approach to MA additional telehealth benefits align with CMS's existing approaches to what is currently available via telehealth under original Medicare. These commenters referenced the ''Medicare telehealth services'' definition in section 1834(m) of the Act, payment for remote patient monitoring (RPM) services outside of section 1834(m) of the Act, as well as the new communication technology-based services not subject to section 1834(m) restrictions, described in the Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019 (83 FR 59452, Nov. 23, 2018; hereinafter referred to as the Calendar Year 2019 Physician Fee Schedule final rule). Commenters also requested that CMS clarify the distinction between MA additional telehealth benefits and the various services in original Medicare that use communications technology (including Medicare telehealth services under section 1834(m) of the Act). Specifically, some commenters recommended that CMS state in the final rule that MA additional telehealth benefits are subject to the technological specifications for Medicare telehealth services furnished under section 1834(m) of the Act, that is, two-way audio and visual real-time and interactive services. Further, commenters requested that CMS explicitly state that under current original Medicare rules, MA plans may already include other clinically appropriate virtual services that are not subject to the location limitations of section 1834(m) of the Act—such as RPM technology—as part of basic benefits because such services are payable under Part B for original Medicare.

Response: We understand commenters' concerns that differences between telehealth services under original Medicare and MA additional telehealth benefits be clearly distinguished and explained. We appreciate the input offered by commenters and provide a thorough and clear discussion here.

First, we must emphasize that the term ''additional telehealth benefits'' is a term of art with a specific meaning in the MA program; it is defined in section 1852(m)(A) of the Act and in the regulation we finalize here at § 422.135(a). We are finalizing the regulatory definition with changes from the proposed rule to delete ''are furnished by an MA plan'' and to include the statutory provisions that MA additional telehealth benefits are services for which benefits are available under Part B and are provided when specific healthcare providers and enrollees are in different locations. As finalized, the definition reads that additional telehealth benefits means services:

(1) For which benefits are available under Medicare Part B but which are not payable under section 1834(m) of the Act; and

(2) That have been identified by the MA plan for the applicable year as clinically appropriate to furnish through electronic exchange when the physician (as defined in section 1861(r) of the Act) or practitioner (described in section 1842(b)(18)(C) of the Act) providing the service is not in the same location as the enrollee. We are focused here on the first part of this definition.

Second, determining whether a service may be offered by an MA plan as part of basic benefits requires addressing two questions: (1) Is the service covered and payable under Part A or Part B?; and (2) if not, is the reason it is not payable under Part B solely because of the limits in section 1834(m) of the Act? If the answer to the first question is yes, then the service is already a benefit under the original Medicare fee-for-service program option and, unless it is hospice care or coverage for organ acquisitions for kidney transplants, must be provided under current law at section 1852(a) of the Act and the MA regulations in 42 CFR part 422. If the answer to the second question is yes, then provision of the service through electronic exchange may be covered as an MA basic benefit under section 1852(m) of the Act, as added by the Bipartisan Budget Act of 2018, and the regulations (at §§ 422.100, 422.135, 422.252, 422.254, and 422.264) we are finalizing in this rule. We note that these regulations include other conditions that must also be satisfied in order for the service to be MA additional telehealth benefits that may be included as basic benefits, but our focus for this specific discussion is on the relationship to Part B coverage. We turn now to Part B coverage of telehealth services.

Under original Medicare, Part B provides for coverage and payment of services (and items, which are not relevant for purposes of this discussion), including services furnished in an in-person encounter between a physician or other practitioner, services furnished as Medicare telehealth services as specified under section 1834(m) of the Act, and certain other services that can be furnished in full without the patient being present. ''Medicare telehealth services,'' as defined in section 1834(m) of the Act and the implementing regulations at §§ 410.78 and 414.65 include professional consultations, office visits, office psychiatry services, and other similar services that must ordinarily be furnished in-person but instead may be furnished using interactive, real-time telecommunication technology subject to the restrictions on Medicare telehealth services specified under section 1834(m) of the Act. Also under section 1834 of the Act, synchronous ''store and forward'' telehealth services may be furnished as part of federal telemedicine demonstration projects in Alaska and Hawaii. Medicare telehealth services under section 1834(m) of the Act are limited in that they must only be furnished by physicians and other specified types of practitioners, and can be furnished and paid only when the beneficiary is located at an eligible originating site.

As we explained in the Calendar Year 2019 Physician Fee Schedule final rule, we have generally regarded the Medicare telehealth services for which payment can be made under section 1834(m) of the Act as being limited to services that must ordinarily be furnished in-person during an encounter between a clinician and the patient, but are instead furnished using telecommunication technology as a substitute for that in-person encounter (83 FR 59482–59483). There are other services under original Medicare that use telecommunication technology, but are not considered Medicare telehealth services as defined under section 1834(m) of the Act, for example, RPM and remote interpretation of diagnostic tests, chronic care management services, transitional care management services (other than the included evaluation and management service), and behavioral health integration services.

Additionally, as established in the Calendar Year 2019 Physician Fee Schedule final rule, effective January 1, 2019, original Medicare now makes separate payment for new ''communication technology-based services.'' These services are not subject to the limitations of section 1834(m) of the Act because they are not a substitute for an in-person, face-to-face encounter between a clinician and a patient. As such, these services are inherently non-face-to-face, are paid under the Physician Fee Schedule like other physicians' services, and are not subject to the restrictions on Medicare telehealth services specified under section 1834(m) of the Act. The communication technology-based services include brief communication technology-based service (virtual check-in), remote evaluation of pre-recorded patient information, and interprofessional internet consultation. These three services and their corresponding Healthcare Common Procedure Coding System (HCPCS) codes are described in detail in the Calendar Year 2019 Physician Fee Schedule final rule at 83 FR 59482 through 59491. That rule also finalized separate payment under the Physician Fee Schedule for chronic care remote physiologic monitoring services.

In the Calendar Year 2019 Physician Fee Schedule final rule, CMS also implemented sections 50302 and 50325 of the Bipartisan Budget Act of 2018 to remove certain section 1834(m) limitations on geography and originating site (patient setting) for certain services. Specifically, the policies under section 50302 of the Bipartisan Budget Act of 2018 added renal dialysis facilities and the homes of beneficiaries as allowable originating sites and removed the geographic restrictions for hospital-based or critical access hospital-based renal dialysis centers, renal dialysis facilities, and beneficiary homes, for purposes of monthly ESRD-related clinical assessments for patients receiving home dialysis. The policies under section 50325 of the Bipartisan Budget Act of 2018 added mobile stroke units as allowable originating sites and removed the originating site type and geographic restrictions, for acute stroke-related telehealth services. Both are effective January 1, 2019.

Additionally, CMS revised the Medicare telehealth regulations to reflect the amendments made to section 1834(m) of the Act by section 2001(a) of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) (Pub. L. 115–271) to remove the originating site geographic requirements for all originating sites described in section 1834(m)(4)(C)(ii) of the Act, except for renal dialysis facilities that are only permissible originating sites for purposes of monthly ESRD-related clinical assessments for patients receiving home dialysis, and to add the home of an individual as a permissible originating site, with respect to telehealth services furnished for purposes of the treatment of an individual with a substance use disorder diagnosis or co-occurring mental health disorder, effective July 1, 2019 (83 FR 59494 through 59496).

All of the telehealth services and other non-face-to-face services furnished via communication technology described earlier are covered and paid under original Medicare. Therefore, MA plans must cover these services because they are required basic benefits. Any services falling outside the scope of these services that an MA plan wishes to offer may potentially be covered as MA additional telehealth benefits, effective January 1, 2020, assuming they meet the requirements under section 1852(m) of the Act. In other words, MA additional telehealth benefits can

include an even broader range of telehealth services for enrollees in an MA plan offering MA additional telehealth benefits, beyond original Medicare benefits. An examination conducted using videoconferencing and/or other telecommunications systems to relay information (such as images and vital signs) may be covered as a primary care visit when the physician (as defined in section 1861(r) of the Act) or practitioner (described in section 1842(b)(18)(C) of the Act) and enrollee are in different locations that do not meet the requirements under section 1834(m) of the Act. As a practical matter, we do not expect MA plans to find implementation and compliance difficult because, if a service provided by the physician or practitioner is a Part B covered service for which payment could be made, but for the limitations in section 1834(m) of the Act, it may be an MA additional telehealth benefit if the MA plan complies with § 422.135 as finalized. If a service or item provided by a physician or practitioner is covered under Part B by the original Medicare program and payment is not prohibited based on the limitations in section 1834(m) of the Act, then the service or item is a basic benefit without consideration of whether § 422.135 could apply. Finally, if a service is not covered under Part B, even if the limitations in section 1834(m) of the Act are taken into account, then the service may only be covered by an MA plan as an MA supplemental telehealth benefit, and not offered as an MA additional telehealth benefit. In addition, we clarify in this final rule that if a service is covered under Part B and provided through electronic exchange but otherwise does not comply with § 422.135 (for example, if it is provided by an out-of-network healthcare provider), then the service may be covered only as an MA supplemental telehealth benefit per § 422.135(b). For example, a nursing hotline staffed by nurses, that are not practitioners specified in section 1842(b)(18)(C)[5] of the Act, that provides assistance in identifying when to seek additional medical help would not be covered under Part B even if the assistance were provided in person. We discuss these issues in more detail in our responses to comments below.

We thank commenters for their feedback on how to reconcile the telehealth differences between MA and original Medicare, and we hope our response provides adequate clarification and removes any misinterpretation. Please note, CMS intends to release more detailed sub-regulatory guidance relating to telehealth for both the original Medicare and MA programs.

Comment: Several commenters supported CMS's explicit recognition that MA plans may continue to offer other telehealth services through MA supplemental telehealth benefits. A commenter questioned whether non-contracted providers will be allowed to provide MA additional telehealth benefits as supplemental benefits.

Response: We thank commenters for their support for continuing to allow MA plans to offer MA supplemental telehealth benefits for those services that do not meet the requirements for coverage under original Medicare or as MA additional telehealth benefits. We are finalizing our proposal, at § 422.135(d), to require that MA additional telehealth benefits only be furnished using contracted providers. As discussed in the preamble of the proposed rule, an MA plan may still cover out-of-network services that would be considered MA additional telehealth benefits (and thus offered as MA basic benefits) when provided by a contracted provider, but these out-of-network services may only be covered as MA supplemental telehealth benefits because the MA plan has not complied with § 422.135(d). These services are not MA additional telehealth benefits if furnished by a non-contracted provider through electronic exchange.

Comment: Many commenters supported CMS's proposed definition for the term ''electronic exchange'' in proposed regulation text at § 422.135(a). The commenters stated that CMS's broad definition, which defines electronic exchange as ''electronic information and telecommunications technology,'' is reasonable as it allows MA plans to use evolving technology to provide MA additional telehealth benefits. Further, some commenters strongly urged CMS to rescind the electronic exchange examples listed in the proposed rule preamble, but finalize as proposed the definition of ''electronic exchange'' in the regulation text at § 422.135(a). Commenters stated CMS could not provide a list of electronic exchange examples that adequately takes in to account future technological innovation. Commenters also explained that a limited list of electronic exchange examples would cause confusion in the marketplace because plans and providers would be uncertain about permissible forms of electronic exchange technology.

Response: We appreciate all of the comments received on the proposed definition for the term ''electronic exchange.'' Our definition is based on how section 1852(m)(2) of the Act uses the phrase ''electronic information and telecommunications technology'' to describe how the services are provided when the physician or practitioner and the patient are not in the same location. In § 422.135(a) as finalized, we define ''electronic exchange'' as ''electronic information and telecommunications technology.'' We agree that this definition of ''electronic exchange'' allows MA plans the use of various forms of technology to provide MA additional telehealth benefits to enrollees. Our purpose in defining ''electronic exchange'' in this manner is to allow modernization in the MA program and the provision of evidence-based, effective health care. As noted in the proposed rule, we did not propose specific regulation text that defines or provides examples of electronic information and telecommunications technology. We stated that we believe this broad and encompassing approach will allow for technological advances that may develop in the future.

While our list of electronic exchange examples in the proposed rule preamble was not intended to be a comprehensive list for purposes of the final rule, we acknowledge that the list of electronic exchange examples does not take into account future technological innovation, and we seek to allow plans the flexibility to develop forms of electronic exchange without unnecessary burden. We are finalizing as proposed the definition of ''electronic exchange'' in the regulation text at § 422.135(a). We believe this more general approach allows for MA plan flexibility and innovation, does not inadvertently restrict MA plans to certain forms of electronic exchange, and avoids the possibility of overlap with original Medicare telehealth coverage. We explicitly clarify here that future technology that is within the scope of the phrase ''electronic information and telecommunications technology'' as used in the statute may be used for purposes of providing MA additional telehealth benefits.

Comment: Many commenters supported CMS's decision not to propose specific regulation text that defines or provides examples of electronic information and telecommunications technology because

[5] Such practitioners include: (i) A physician assistant, nurse practitioner, or clinical nurse specialist (as defined in section 1861(aa)(5)) of the Act; (ii) A certified registered nurse anesthetist (as defined in section 1861(bb)(2)); (iii) A certified nurse-midwife (as defined in section 1861(gg)(2)); (iv) A clinical social worker (as defined in section 1861(hh)(1)); (v) A clinical psychologist (as defined by the Secretary for purposes of section 1861(ii)) and (vi) A registered dietitian or nutrition professional.

the technology needed and used to provide MA additional telehealth benefits will vary based on the service being offered. A commenter suggested there be a governing body to review and certify the telehealth technology used and to ensure proper telehealth provider training.

Response: We agree with commenters' position that specific regulation text that defines or provides examples of electronic information and telecommunications technology should not be included in the final rule. We do not include this specific regulation text in the final rule because technology will vary based on user and over time. As discussed earlier, we believe this broad and encompassing approach will allow for technological advances that may develop in the future and avoid tying the authority in the new regulation to specific information formats or technologies.

We appreciate the commenter's suggestion that there be a governing body to review and certify the telehealth technology used and to ensure proper telehealth provider training. We are not requiring a governing body to conduct oversight of telehealth technology and providers at this time, but we will use authority codified in this final rule at § 422.135(c)(4) to review information about coverage of MA additional telehealth benefits, which may include, but is not limited to, statistics on use or cost, manner(s) or method of electronic exchange, evaluations of effectiveness, and demonstration of compliance with the requirements of this final rule.

Comment: Many commenters supported CMS allowing MA plans to independently determine each year which services are clinically appropriate to furnish through electronic exchange as MA additional telehealth benefits. These commenters stated that MA plans should have authority to make these determinations because plans and healthcare providers work directly with enrollees and are more aware of evolving methods of delivering care. A few commenters recommended that CMS authorize healthcare providers, rather than or in addition to MA plans, to make the annual determination of which services are clinically appropriate to furnish through MA additional telehealth benefits.

Response: We are finalizing our proposal that MA plans have the discretion to determine which Part B services are clinically appropriate to provide through electronic exchange and to make that determination for each applicable plan year. Such services, when the other requirements in § 422.135 are met, would be permissible MA additional telehealth benefits. As professionally recognized standards of health care change over time, we believe MA plans have an interest in working with providers to develop and use the methods of modern medicine necessary to provide MA additional telehealth benefits to enrollees who choose to have their health benefits delivered in this manner. MA plans are required, per § 422.202(b), to consult with their contracted network providers regarding the MA plan's medical policy; this would include any applicable MA additional telehealth benefits policy, and we believe that is sufficient for establishing the required involvement of healthcare providers. We encourage MA plans to involve their contracted providers when making determinations about which services are clinically appropriate to furnish through MA additional telehealth benefits beyond the consultation required under that regulation, but we are not adopting such a requirement in this final rule.

Furthermore, we note that in accordance with § 422.112(b)(3), all MA coordinated care plans are required to coordinate MA benefits with community and social services generally available in the plan service area. Therefore, we expect MA coordinated care plans offering MA additional telehealth benefits to coordinate care for enrollees receiving the specified Part B service(s) through electronic exchange in the same manner as for enrollees receiving the service in-person.

Comment: Many commenters opposed CMS placing limitations on the types of Part B items and services that can be MA additional telehealth benefits. Specifically, commenters urged CMS to use only the MA plan annual determination and medical review to define the types of items and services to be included as MA additional telehealth benefits. They explained that any definition of items or services will lock CMS into an approach supported by today's evidence, which will hinder CMS's ability to update its policies for future evidence-based innovation.

Response: We agree with the commenters that adopting a specific list of services that could be MA additional telehealth benefits when provided through electronic exchange creates a risk of not being sufficiently flexible in the future. We proposed and are finalizing regulation text that allows MA plans flexibility to determine which services are clinically appropriate to furnish through MA additional telehealth benefits on an annual basis consistent with the limits in the statute and § 422.135.

Comment: Some commenters supported CMS's proposal to allow MA plans offering MA additional telehealth benefits to maintain different cost sharing for in-person visits and visits through electronic exchange, while several commenters opposed differential cost sharing. Commenters expressed concerns that low-income enrollees living in rural, underserved areas without internet access may be disadvantaged because they would have to choose the in-person option, which may have higher cost sharing as compared to the alternative visit through electronic exchange. A few commenters, including the Medicare Payment Advisory Commission, recommended CMS ensure access to in-person services is not made prohibitively expensive by differential cost sharing as it could be discriminatory if undue financial burden is imposed on enrollees who choose in-person services instead of accessing services through electronic exchange. Further, commenters requested that CMS actively monitor differential cost sharing amounts to ensure they fairly reflect actual cost differentials and are not used to steer enrollees away from preferred methods of care. Commenters stated that enrollees lacking internet access should be able to get in-person services without facing an increase in out-of-pocket costs. Some commenters also requested that CMS clarify that a Qualified Medicare Beneficiary (QMB) would be protected from billing for cost sharing for all Part A/B services delivered via telehealth.

Response: As discussed in the proposed rule, section 1852(m)(5) of the Act mandates that MA additional telehealth benefits shall be treated as if they were benefits under the original Medicare fee-for-service program option. We acknowledged in the proposed rule that CMS has traditionally interpreted section 1852(a)(1)(B)(i) and (iii)–(v) of the Act to mean that, subject to certain exceptions, MA plans must cover basic benefits using cost sharing that is actuarially equivalent to the Part A and B cost sharing from a plan-level (not enrollee-level) perspective. MA plans are not required, in most cases, to have the exact same cost sharing as in original Medicare. Subject to certain beneficiary protections and limits on cost sharing for certain specific services,[6] MA plans have great flexibility in setting the cost sharing for specific benefits. Further, for in-network services, CMS has limited authority to set the payment structure, including the payment amount, an MA

[6] See 42 CFR 422.100(f), (j) and (k).

plan uses to pay its contracted providers; to some extent, the amount the MA plan has negotiated to pay its contracted providers may influence the cost sharing amount that the MA plan sets for the associated services. In addition, MA plans must have uniform cost sharing per § 422.100(d)(2). CMS has taken a broad and flexible approach to the uniformity requirement, including permitting MA plans to set up ''preferred'' networks that carry lower cost sharing for specific services.[7] In response to comments on this topic, we are clarifying the rationale for § 422.135(f).

In the context of original Medicare Part B, services furnished in an in-person encounter between a clinician and a patient are subject to different rules than those delivered through electronic exchange; in effect, the statutory provisions governing payment for original Medicare telehealth services treat services furnished through electronic exchange as different services than the in-person services, rather than as the same services delivered through different modalities. Section 1834(m) of the Act limits Part B payment for services furnished through electronic exchange to only certain healthcare services delivered through certain technology by specified types of clinicians to beneficiaries located in originating sites that meet specific conditions. Under the statutory scheme of section 1834(m) of the Act, services furnished through electronic exchange, where the physician or practitioner is not in the same location as the patient, are distinct and different services from those furnished in-person and in the same location.

We interpret the current law regulating the cost sharing in the MA context to mean that MA plans must charge enrollees the same cost sharing for the same item or service delivered by the same provider, and we view a service delivered in-person versus a service delivered via electronic exchange as different services because they are delivered differently. In order words, delivering a Part B service via electronic exchange is inherently different (for example, in modality and required infrastructure) than delivering the Part B service in-person under Medicare coverage rules; therefore, we consider these to be sufficiently different services for purposes of the MA requirement that cost sharing be uniform, and thus the services can be treated differently from a cost sharing perspective. Further, the cost of providing the service via electronic exchange might be lower, so having lower cost sharing is acceptable. For example, an MA plan may offer a dermatology exam using store-and-forward technology as an MA additional telehealth benefit, and the cost of this electronic exchange would likely be lower than the cost of an in-person dermatology exam. Thus, differential cost sharing for the electronic exchange versus the in-person visit would be appropriate in this scenario. This overall reasoning is consistent with our traditional interpretation of the Medicare statute and the applicable provisions in Part C, therefore we are finalizing the regulation text at § 422.135(f) as proposed.

We understand commenters' apprehensions about enrollee discrimination and enrollee access to MA additional telehealth benefits. The anti-discrimination requirements in current CMS regulations at § 422.100(f)(2) and § 422.110(a) are traditionally related to discrimination based on health status. Other federal non-discrimination laws, such as Title VI of the Civil Rights Act of 1964, focus on specific protected classes (such as race and age). Economic status or geographic location (rural/urban) are not protected classes under those laws, nor under current CMS regulations. Consequently, we do not have clear authority to enforce anti-discrimination rules based solely on an enrollee's economic status or geographic location.

However, the statutory requirement (section 1852(m)(4) of the Act) and our corresponding regulatory requirement in this final rule (§ 422.135(c)(1)) protecting the enrollee's choice to receive covered services in-person control how an MA plan offers MA additional telehealth benefits. An MA plan offering MA additional telehealth benefits must preserve the enrollee's right to choose whether to access the service in-person or, if offered by the MA plan, through electronic exchange. MA plans may not circumvent or limit enrollee choice by using differential cost sharing to steer beneficiaries or inhibit access to services. We view such steering and inhibiting access as violations of § 422.100(f)(2) because of how those activities would inhibit an enrollee from exercising his or her rights under section 1852(m)(4) of the Act and § 422.135(c). If an MA plan chooses to maintain differential cost sharing for MA additional telehealth benefits, we expect the primary purpose would be to parallel the actual cost of administering the service and not to steer beneficiaries or inhibit access. We will actively monitor complaints regarding differential cost sharing for MA additional telehealth benefits. If we identify a problem with enrollee access or steering, we may take compliance or enforcement actions, as necessary, and we may modify our policy to address the issue.

As discussed previously, MA plans have great flexibility in setting cost sharing for specific benefits. We believe that restricting this flexibility for certain plans that offer MA additional telehealth benefits, for example in cases where an MA plan operates in a rural or underserved area, could result in MA plans choosing not to offer MA additional telehealth benefits in rural service areas. Given this, and given the existing beneficiary cost sharing protections described previously, we do not believe it is appropriate to limit MA plans' existing flexibility to set cost sharing for MA additional telehealth benefits. However, we encourage MA plans to take issues like this into consideration in establishing cost sharing for MA additional telehealth benefits.

Finally, we appreciate the comments regarding QMB cost sharing protections. However, we believe that the current requirements at § 422.504(g)(1)(iii) requiring MA plans to take steps to ensure that QMBs are protected from providers billing cost sharing are adequate. This regulation prohibits MA plans from imposing cost sharing on dual eligible individuals when the state is responsible for paying for the cost sharing and from imposing cost sharing on such enrollees that is higher than the cost sharing permitted by the state Medicaid plan. For more information on cost sharing protections provided under the Act for QMBs and other dual eligible individuals, we refer readers to the CMS website for the QMB program at: *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/QMB.html.*

Comment: In accordance with section 1852(m)(4) of the Act, if an MA plan covers a Part B service as an MA additional telehealth benefit, then the MA plan must also provide access to such service through an in-person visit and not only through electronic exchange. We proposed § 422.135(c)(2) to require MA plans to use their EOC (at a minimum) to advise enrollees that they may receive the specified Part B service(s) either through an in-person visit or through electronic exchange. We also proposed, at § 422.135(c)(3), that MA plans would have to use their provider directory to identify any

[7] See Announcement of Calendar Year 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter.

providers offering services for MA additional telehealth benefits and in-person visits or offering services exclusively for MA additional telehealth benefits. While we received some support for our proposed disclosure (that is, EOC and provider directory) requirements for MA additional telehealth benefits, other commenters believed that these requirements would be overly restrictive, burdensome, and/or time consuming.

Several commenters recommended that CMS provide more flexibility in how MA plans can disclose information about MA additional telehealth benefits to enrollees. For example, commenters suggested that CMS allow plans to use more general terminology instead of explicitly listing each service in the EOC, and allow plans to describe in the EOC how enrollees can obtain information on telehealth services. In terms of the provider directory, a commenter believed CMS should let plans make the determination regarding inclusion of telehealth providers in a way the plan believes optimizes clarity for enrollees, especially since the common industry approach is for telehealth vendors to contract with licensed providers, and the list of providers is not static. Another commenter requested that CMS require only an indication of which providers are exclusively available via telehealth in directories, and allow sufficient lead-time for plans to implement any new directory requirements. A commenter suggested CMS work with plans on alternative ways to responsibly share information on MA additional telehealth benefits with enrollees. A few commenters requested clear guidance (for example, model language) on the proposed disclosure requirements and clarification, such as whether provider directory updates would need to be made for all providers or only a specific subset.

Response: We appreciate commenters' concerns about the proposed disclosure requirements being too restrictive and onerous on plans, and we thank those who offered alternative solutions and ideas for more flexibility. As discussed in the proposed rule, we believe that choice, transparency, and clarity are vital when it comes to disclosing MA additional telehealth benefits to enrollees. However, we also recognize that there are various ways to effectively communicate with enrollees consistent with the mandatory disclosure and information requirements in § 422.111. CMS has traditionally discussed specific required elements for mandatory disclosures (for example, the provider directory and EOC) and marketing materials in sub-regulatory guidance to explain and interpret the applicable regulations as well as describe best practices for MA plans and Part D sponsors.

We agree with commenters that more flexibility may be needed, and sub-regulatory guidance provides an opportunity for flexibility in applying the applicable regulations where possible and for regular updates as necessary to account for changes in technology or evolving methods of compliance. Therefore, we are not finalizing our proposed regulation text for the provider directory requirement at proposed § 422.135(c)(3). Instead, we will address any provider directory elements pertaining to plans offering MA additional telehealth benefits in future sub-regulatory guidance. We note that the provider directory requirements in § 422.111 are not being amended and continue to apply. Therefore, provider directories must be complete, accurate, and updated timely to identify the healthcare providers currently under contract with the MA plan to furnish covered services to enrollees. In response to comments claiming that the common industry approach is for telehealth vendors to contract with licensed providers and that the list of providers is not static, we remind MA plans of the requirement to issue provider directories and notify enrollees of network changes per § 422.111. As the providers of MA additional telehealth services must be contracted providers, we expect that they will be identified as contracted providers in provider directories.

We intend to be as clear as possible in our sub-regulatory guidance to assist plans with their enrollee communications and to address how the existing provider directory requirements apply in the context of MA plan obligations in connection with furnishing MA additional telehealth benefits. We note that, as discussed in more detail below, we are finalizing our proposal that only contracted (that is, in-network) providers may be used by an MA plan to furnish MA additional telehealth benefits.

For similar reasons, we are also not finalizing our reference to the EOC at proposed regulation text § 422.135(c)(2). The regulation at § 422.111 establishing what information must be provided to enrollees (and when) regarding benefits covered by the MA plan is sufficient. We have historically used sub-regulatory guidance to address the specific level of detail required by that regulation and will issue guidance specific to how MA additional telehealth benefits must be addressed in mandatory communication materials such as the EOC and the Annual Notice of Change. None of our other regulations about specific benefits require specific content in the EOC. We believe that it is appropriate to follow that practice for addressing how information about MA additional telehealth benefits must be disclosed and provided to enrollees.

However, we are finalizing the remaining text at (c)(2), which requires an MA plan furnishing MA additional telehealth benefits to advise enrollees that they may receive the specified Part B service(s) either through an in-person visit or through electronic exchange. We have decided to maintain this general enrollee disclosure requirement (without reference to the EOC) because of the statutory requirement at section 1852(m)(4)(B) of the Act that the enrollee must have that choice. We believe the MA plan must disclose this right of choice to enrollees in a transparent manner in order to ensure that the right is meaningfully provided. We plan to issue sub-regulatory guidance specifically for § 422.135(c)(2) regarding the requirement that an MA plan advise enrollees that they may receive the specified Part B service(s) through an in-person visit or through electronic exchange; we will also issue guidance on disclosure requirements of MA plans, including model language for both the EOC and the provider directory, in the context of MA additional telehealth benefits.

Comment: In the proposed rule, we sought comment on what impact, if any, MA additional telehealth benefits should have on MA network adequacy policies, and the comments we received were mixed. Commenters who were supportive of a change to network adequacy policies for MA additional telehealth benefits stated that CMS should allow telehealth providers to be considered in the network adequacy assessment, either in the network criteria itself or through the exceptions process. Some suggested CMS update the network criteria to account for how MA plans may offer MA additional telehealth benefits (for example, allow telehealth providers to count in the network review or comprise a certain percentage of a plan's providers per specialty) or eliminate the time and distance standard and maintain just the minimum number per enrollee standard for telehealth providers. Others believed the current exceptions process was sufficient, that is, commenters expressed that through the current exceptions process, CMS could potentially allow plans to substitute telehealth providers for in-person providers only where there is a shortage

of specialty providers. A commenter suggested CMS consider telehealth exceptions for network adequacy when a plan can demonstrate that access to certain specialties would otherwise be problematic without permitting the MA plan to use telehealth providers to meet the network adequacy requirements; the commenter believed such policy would allow for more competition and more attractive MA plan options. Some commenters indicated that incorporating telehealth into network adequacy would improve enrollee choice and access in MA, particularly in rural/underserved areas, for certain specialties like behavioral health, and through an increase in after-hours and weekend care. A few commenters further encouraged CMS to provide flexibility regarding time and distance standards and allow telehealth to fill in network gaps, which might in turn streamline the network review process.

Other commenters asserted that a telehealth provider should not carry the same weight as an in-person provider and should only be used as a supplement, not a replacement, for in-person services. A few commenters suggested CMS continue basing network adequacy only on in-person services given the disparity in internet access.

Still others suggested CMS do a complete study to assess data in light of increased telehealth utilization, which could inform future changes to network adequacy policies and measurement options. A commenter recommended that, minimally, CMS should wait to reevaluate network criteria until there is a higher market saturation of telehealth providers for Part B services. Another commenter believed CMS should collect specific feedback on current plan-provider telehealth arrangements and current enrollee experience and satisfaction with telehealth providers, both within and outside MA.

Response: We thank the commenters for their feedback on MA additional telehealth benefits' potential impact on network adequacy. We will consider these comments as we perform further research on the issue and update sub-regulatory guidance to reflect any applicable changes in policy. We are not using this final rule to announce or adopt changes in current policies for evaluating MA network adequacy under § 422.112 because CMS interprets the requirements at § 422.112 through the MA network adequacy criteria, which have traditionally been addressed in sub-regulatory guidance.

Comment: Many commenters supported CMS's proposal to require MA plans to ensure through their provider contracts that providers meet and comply with applicable state licensing requirements and other applicable laws for the state in which the enrollee is located and receiving the service. Specifically, the commenters suggested CMS allow plan providers to utilize state-based credentialing standards for telehealth services as opposed to federal standards for MA provider participants authorized in § 422.204(b). A commenter believed that plans should be allowed to apply additional provider requirements.

Response: We support requiring the MA plan to ensure through its contract with the provider that the provider meet and comply with applicable state licensing requirements and other applicable laws for the state in which the enrollee is located and receiving the service. This standard is codified in the final rule at § 422.135(c)(3). We believe creating additional provider licensing requirements is unnecessary, but we acknowledge that states may have specific provisions regarding the practice of medicine using electronic exchange. We remind readers and MA plans that existing provider credentialing and network participation requirements, specifically in §§ 422.200 through 422.224, continue to apply. As this final rule requires MA plans to use only contracted (that is, in-network) physicians and practitioners to furnish MA additional telehealth benefits, those existing regulations will apply.

Comment: Several commenters expressed an openness to CMS occasionally collecting data on MA additional telehealth benefits, per the proposal to require MA plans to make information about coverage of MA additional telehealth benefits available to CMS upon request. However, these commenters were leery of the potential for administrative burden on MA plans. Some voiced concern about CMS collecting confidential or sensitive information and specifically requested that CMS exclude information that could be held under contractual consideration. For example, a commenter stated that specific information on use or cost of MA additional telehealth benefits is proprietary and commercially sensitive, and revealing contract-specific details would be anti-competitive. Another commenter concurred with CMS collecting data on the costs and benefits of MA plans' MA additional telehealth benefits as long as it was not overly onerous on plans.

Response: We understand commenters' concerns about burden and confidentiality when it comes to CMS data collection. However, we note that the regulation text at proposed § 422.135(c)(5)—finalized at § 422.135(c)(4)—includes the language ''upon request,'' which implies that CMS does not intend to establish uniform data collection at this time, but instead reserves the right to ask for this information from MA plans. We encourage readers to refer to section III.B.1. of this final rule, which provides additional detail and explicitly states that the information collection provision at § 422.135(c)(4) is exempt from the requirements of the Paperwork Reduction Act (PRA) since we estimate fewer than 10 respondents. Thus, we do not anticipate a significant increase in plan burden due to § 422.135(c)(4). We also remind readers that any uniform request to more than nine MA plans would require further review and would be subject to public comment under the PRA requirements.

Comment: A few commenters questioned whether CMS will allow MA plans (including PPO plans) to use only contracted providers for MA additional telehealth benefits. Some commenters believed that the contracted providers' restriction should apply to all MA plan types. Some commenters rejected CMS's proposal that all plan types be required to use only contracted providers. A few commenters recommended CMS limit this requirement to HMOs, thus allowing PPOs to use both contracted and non-contracted providers for MA additional telehealth benefits. Other commenters recommended that CMS extend the allowable providers beyond just contracted, in-network providers, stating that the issue of no oversight of out-of-network providers exists whether or not telehealth is involved.

Response: We are finalizing the proposal at § 422.135(d) to require that all MA plan types, including PPO plans, use only contracted providers to provide MA additional telehealth benefits. We are clarifying that if a PPO plan furnishes MA additional telehealth benefits consistent with the requirements at § 422.135, then the PPO plan requirement at § 422.4(a)(1)(v) (that the PPO must furnish all services both in-network and out-of-network) will not apply to the MA additional telehealth benefits; all other benefits covered by the PPO must be covered on both an in-network and out-of-network basis. In other words, a PPO plan is not required to furnish its MA additional telehealth benefits out-of-network, as is the case for all other plan-covered services. However, if a PPO plan would like to cover a service delivered through electronic exchange on an out-of-network basis, then the PPO plan has that option but may only cover the service as an MA supplemental

telehealth benefit, consistent with the regulation text at § 422.135(d).

In response to comments that recommended CMS extend the allowable providers beyond contracted providers because the issue of no oversight for non-contracted providers exists whether or not telehealth is involved, we note that MA plans must be able to review and pre-certify the qualifications and compliance of contracted providers to ensure that telehealth services are furnished consistent with clinically appropriate standards of care for the MA additional telehealth benefits offered by the MA plan and that all state licensure and credentialing requirements are met. We are therefore finalizing the proposed regulation text at paragraph (d), that an MA plan must furnish MA additional telehealth benefits only using contracted providers. Therefore the regulation will require that all MA plans, including PPOs that cover benefits provided by non-contracted providers, use only contracted providers for MA additional telehealth benefits.

Comment: Commenters recommended that CMS remain flexible in the ultimate determination of what will be considered capital and infrastructure costs and investments to be excluded from their bid submissions relative to MA additional telehealth benefits. Some commenters offered ideas to operationalize the exclusions. One suggestion was for CMS to stipulate a percentage that represents the industry average of allowed fees as representative of the capital and infrastructure costs, which could be trended over time. Another commenter suggested that CMS align the definition of capital and infrastructure costs and investments with a traditional understanding, such that those items that would add permanent or depreciable value to the plan or enrollee would be excluded, thus allowing the cost of necessary support items or services for telehealth delivery. A few commenters mentioned the 15 percent used in the Regulatory Impact Analysis of the proposed rule as a proxy for these costs. A commenter stated that the percentage was too high while another stressed that it was too low.

Commenters also raised concerns about the difficulty of identifying with specificity (for bid purposes) the capital and infrastructure components of MA additional telehealth benefits for services offered directly by the plan or through downstream entities such as providers and third party vendors. Specifically, a few commenters were concerned with the difficulty in excluding these costs from their claims capture and data reporting and in obtaining this information from contracted providers and vendors absent an additional contractual provision. Commenters also stated that capital and infrastructure costs would vary significantly from provider to provider. These commenters pointed out that currently there is no incentive for providers or vendors to accurately identify these costs, and plans would not be able to verify if the costs were reasonably stated. Consequently, commenters expressed, this lack of standardization and reliability could lead to challenges of plans' actuarial attestations and potential inequitable reporting in the bid. Another commenter also opposed the exclusion of capital and infrastructure costs from MA plans' basic benefit bid.

Response: We appreciate the comments concerning the exclusion of capital and infrastructure costs relating to MA additional telehealth benefits from the basic benefit bid submission. Section 1852(m)(2)(A)(ii) of the Act excludes from MA additional telehealth benefits capital and infrastructure costs and investments related to MA additional telehealth benefits. We are codifying this requirement in § 422.254(b)(3)(i) as a restriction on how MA plans include MA additional telehealth benefits in their bid submission. We believe the statutory limit is tied only to the cost to the government, which is tied to how MA additional telehealth benefits may be included in the bid as basic benefits. Therefore, our proposal was to eliminate from the basic benefit bid those capital and infrastructure costs and investments that are required or used to enable the provision of MA additional telehealth benefits.

We appreciate the concerns raised by commenters about broad interpretations of the statutory exclusion of capital and infrastructure costs and investments. In recognition of these challenges, we are clarifying in regulation text that the exclusion from the bid of capital and infrastructure costs and investments relating to MA additional telehealth benefits, codified at § 422.254(b)(3)(i), applies to capital and infrastructure costs and investments ''directly incurred or paid by the MA plan.'' The bid for basic benefits submitted by an MA plan cannot include such capital and infrastructure costs or investments for MA additional telehealth benefits.

We do not propose a specific definition of capital and infrastructure costs or investments related to such benefits here because the costs and investments needed and used to provide MA additional telehealth benefits would vary based on the individual MA plan's approach to furnishing the benefits.

We also thank the commenters for providing lists of capital and infrastructure examples. Although we stated in the proposed rule that we would provide a more detailed list of examples in this final rule based on stakeholder feedback, after further consideration we have chosen not to do so. We made this decision in acknowledgment of the variety of potential capital and infrastructure models, for which a given MA plan could incur or pay costs, related to MA additional telehealth benefits.

Comment: Many commenters requested clarification on how the annual bid submission process will work for MA additional telehealth benefits. Specifically, commenters questioned how plans will be expected to file MA additional telehealth benefits in the PBP.

Response: We appreciate this request for greater clarity concerning how the annual bid submission process will be impacted by MA additional telehealth benefits. We will take these comments into consideration when developing the annual bid guidance, which we consider to be a more appropriate place to provide instruction for completing the bid.

Comment: Several commenters supported CMS's proposal to allow MA plans to provide MA additional telehealth benefits because the proposal does not include geographic and originating site limitations. A few commenters believed CMS should extend authority for MA additional telehealth benefits to original Medicare, specifically to eliminate geographic and originating site limitations applicable in original Medicare. Some commenters requested that CMS make efforts to ensure parity for original Medicare beneficiaries, claiming they would be disadvantaged since they cannot access MA additional telehealth benefits as MA enrollees can. Some commenters urged CMS to reference and ensure alignment with the Part B definition of telecommunications systems and note that the section 1834(m) originating site and geographic restrictions do not apply to MA additional telehealth benefits.

Response: This final rule will allow MA plans the ability to offer—as part of the basic benefit package—MA additional telehealth benefits beyond what is currently allowable under Medicare telehealth services; this is authorized by section 1852(m) of the Act, which was added by section 50323 of the Bipartisan Budget Act of 2018. Neither the statute nor this final rule includes geographic or originating site

limitations as part of defining or authorizing MA additional telehealth benefits. With regard to comments regarding coverage and payment under the original Medicare program, we note that we are constrained by the statutory requirements and that the original Medicare program is not within the scope of this final rule.

Comment: A commenter requested that CMS provide permissible MA additional telehealth benefit designs to ensure MA plan compliance with CMS's final rule.

Response: We appreciate the commenter's request for permissible MA additional telehealth benefit designs. However, we do not provide any specific MA additional telehealth benefit designs in the final rule in order to provide MA plans with the discretion to develop their plan benefit offerings.

Comment: A commenter requested information regarding whether MA additional telehealth benefits can be used to furnish the Medicare Diabetes Prevention Program (MDPP) services. A few commenters referenced CMS previously declining to test online MDPP diabetes self-management training.

Response: As discussed above, we are finalizing this rule to define ''additional telehealth benefits'' as services that: (1) Are furnished by an MA plan for which benefits are available under Medicare Part B but which are not payable under section 1834(m) of the Act; and (2) have been identified by the MA plan for the applicable year as clinically appropriate to furnish through electronic exchange when the physician (as defined in section 1861(r) of the Act) or practitioner (described in section 1842(b)(18)(C) of the Act) providing the service is not in the same location as the enrollee. Because this definition requires MA additional telehealth benefits to be services provided by a physician or practitioner, and MDPP services, pursuant to § 410.79, must be provided by an MDPP supplier, MDPP services cannot be offered as MA additional telehealth benefits. Existing guidance about how MDPP services may be provided on a virtual basis or through electronic exchange still applies and can be covered as a supplemental benefit.

Comment: Some commenters requested that CMS include in the definition of a telehealth provider specific specialty types such as pharmacists, audiologists, speech-language pathologists, home health care aides, and telerehabilitation providers.

Response: We appreciate comments requesting additional specificity in identifying permissible telehealth provider types. However, we did not define a telehealth provider in the proposed rule and will not finalize such a definition here. Section 1852(m)(2)(A)(i)(2) uses the term ''physician'' as defined in section 1861(r) of the Act and the term ''practitioner'' described in section 1842(b)(18)(C) of the Act. We have codified these statutory requirements in our final definition of ''additional telehealth benefits'' at § 422.135(a)(2), described previously. Both the statute and this final rule limit MA additional telehealth benefits to services furnished by physicians and practitioners as so defined. Further, the statute and regulation require that the service be clinically appropriate to furnish through electronic exchange, which in some cases may prohibit certain services from being covered as MA additional telehealth benefits. Finally, in § 422.135(d), we are codifying the requirement that MA plans furnishing MA additional telehealth benefits only do so using contracted providers.

Comment: A few commenters questioned how MA additional telehealth benefits will interact with encounter data and risk adjustment. For example, commenters recommended CMS establish rules or clarify the criteria under which diagnoses obtained through telehealth encounters can be considered and submitted for risk adjustment purposes. A commenter specifically requested that CMS allow telehealth encounters to be included for MA risk adjustment, while other requestors requested future guidance on telehealth encounter data submissions.

Response: We appreciate commenters raising this particular issue. This regulation does not change the existing obligation to submit encounters. Consistent with the requirements under § 422.310, MA plans must submit risk adjustment data that characterize the context and purpose of each item and service provided to an MA enrollee, and must also conform to CMS's requirements for submitting these data. We will be releasing guidance regarding MA additional telehealth benefits and encounter data and risk adjustment in the future.

Summary of Regulatory Changes

We received a range of comments pertaining to this proposal, the majority of which reflected support for the regulations. After careful consideration of all comments received, and for the reasons set forth in the proposed rule and in our responses to the related comments summarized earlier, we are finalizing the proposed changes to §§ 422.100, 422.252, 422.254, and 422.264 and new regulation at § 422.135, with the following modifications:

- In proposed regulation text § 422.135(a), we are removing the phrase ''that meet the following.'' Thus, we are revising § 422.135(a) to read as follows: ''*Definitions.* For purposes of this section, the following definitions apply: *Additional telehealth benefits* means services:''
- In proposed regulation text § 422.135(a)(1), we are removing the phrase ''are furnished by an MA plan'' but finalizing the remaining text in (a)(1). Thus, we are revising (a)(1) to read as follows: ''For which benefits are available under Medicare Part B but which are not payable under section 1834(m) of the Act; and''
- In proposed regulation text § 422.135(a)(2), we are adding the word ''That'' and adding the phrase ''when the physician (as defined in section 1861(r) of the Act) or practitioner (described in section 1842(b)(18)(C)) of the Act) providing the service is not in the same location as the enrollee.'' Thus, we are revising (a)(2) to read as follows: ''That have been identified by the MA plan for the applicable year as clinically appropriate to furnish through electronic exchange when the physician (as defined in section 1861(r) of the Act) or practitioner (described in section 1842(b)(18)(C)) of the Act) providing the service is not in the same location as the enrollee.''
- In proposed regulation text § 422.135(c)(2), we are removing the phrase ''at a minimum in the MA plan's Evidence of Coverage required at § 422.111(b)'' but finalizing the remaining text in (c)(2). Thus, we are revising (c)(2) to read as follows: ''Advise each enrollee that the enrollee may receive the specified Part B service(s) through an in-person visit or through electronic exchange.''
- We are not finalizing our proposed regulation text for the provider directory requirement at proposed § 422.135(c)(3). Thus, we are removing proposed (c)(3) in its entirety, redesignating proposed (c)(4) as (c)(3), and redesignating proposed (c)(5) as (c)(4).
- In proposed regulation text § 422.254(b)(3)(i), we are adding the phrases ''directly incurred or paid by the MA plan'' and ''for the unadjusted MA statutory non-drug monthly bid amount.'' Thus, we are revising (b)(3)(i) to read as follows: ''MA plans offering additional telehealth benefits as defined in § 422.135(a) must exclude any capital and infrastructure costs and investments directly incurred or paid by the MA plan relating to such benefits from their bid submission for the unadjusted MA

statutory non-drug monthly bid amount.''

2. Dual Eligible Special Needs Plans

Special needs plans (SNPs) are MA plans created by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173) that are specifically designed to provide targeted care and limit enrollment to special needs individuals. Under the law, SNPs are able to restrict enrollment to: (1) Institutionalized individuals, who are defined in § 422.2 as those residing or expecting to reside for 90 days or longer in a long term care facility; (2) individuals entitled to medical assistance under a state plan under Title XIX; or (3) other individuals with certain severe or disabling chronic conditions who would benefit from enrollment in a SNP. As of June 2018, the CMS website listed 297 SNP contracts with 641 SNP plans that have at least 11 members.[8] These figures included 190 Dual Eligible SNP contracts (D–SNPs) with 412 D–SNP plans with at least 11 members, 49 Institutional SNP contracts (I–SNPs) with 97 I–SNP plans with at least 11 members, and 58 Chronic or Disabling Condition SNP contracts (C–SNPs) with 132 C–SNP plans with at least 11 members. This final rule implements the provisions of the Bipartisan Budget Act of 2018 that establish new requirements for D–SNPs for the integration of Medicare and Medicaid benefits and unification of Medicare and Medicaid grievance and appeals procedures that are effective in 2021. This final rule also clarifies definitions and operating requirements for D–SNPs that will be applicable to D–SNPs starting January 1, 2020, as specified earlier in this final rule.

a. Integration Requirements for Dual Eligible Special Needs Plans (§§ 422.2, 422.60, 422.102, 422.107, 422.111, and 422.752)

Beneficiaries who are dually eligible for both Medicare and Medicaid can face significant challenges in navigating the two programs, which include separate or overlapping benefits and administrative processes. Fragmentation between the two programs can result in a lack of coordination for care delivery, potentially resulting in: (1) Missed opportunities to provide appropriate, high-quality care and improve health outcomes, and (2) ineffective care, such as avoidable hospitalizations and a poor beneficiary experience of care. Advancing policies and programs that integrate care for dual eligible individuals is one way in which we seek to address such fragmentation. Under plans that offer integrated care, dual eligible individuals can receive the full array of Medicaid and Medicare benefits through a single delivery system, thereby improving care coordination, quality of care, beneficiary satisfaction, and reducing administrative burden. Some studies have shown that highly integrated managed care programs perform well on quality of care indicators and enrollee satisfaction.[9]

D–SNPs are a type of MA plan that is intended to integrate or coordinate care for this population more effectively than standard MA plans or original Medicare by focusing enrollment and care management on dual eligible individuals. As of June 2018, approximately 2.3 million dual eligible individuals (1 out of every 6 dual eligible individuals) were enrolled in 412 D–SNPs. About 170,000 dual eligible individuals are enrolled in fully integrated dual eligible special needs plans, or FIDE SNPs (that is, where the same organization receives capitation to cover both Medicare and Medicaid services).[10] A number of states, including Arizona, Idaho, Hawaii, Massachusetts, Minnesota, New Jersey, New Mexico, New York, Pennsylvania, Tennessee, Texas, Virginia, and Wisconsin, operate Medicaid managed care programs for dual eligible individuals in which the state requires that the Medicaid managed care organizations serving dual eligible individuals offer a companion D–SNP product.

As summarized in our proposed rule, since the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) first authorized D–SNPs' creation, subsequent legislation has been enacted that has extended their authority to operate and set forth additional programmatic requirements, including sections 164 and 165 of the Medicare Improvements for Patients and Providers Act (MIPPA) (Pub. L. 110–275), which amended sections 1859(f) and 1852(a) of the Act, and section 3205 of the Patient Protection and Affordable Care Act (Pub. L. 111–148), which revised section 1853(a)(1)(B) of the Act. Regulations promulgated following the enactment of these laws implemented these statutory provisions.

Using the contract that D–SNPs are required to have with states under section 1859(f)(3)(D) of the Act, implemented in the regulation at § 422.107, state Medicaid agencies are able to establish requirements that surpass the minimum standards set in federal regulations for D–SNPs with regard to integration and coordination of Medicare and Medicaid benefits. To that end, we have seen states leverage their contracts with D–SNPs to limit D–SNP enrollment to individuals who also receive Medicaid benefits through the same organization, collect certain data from the D–SNP, and integrate beneficiary communication materials and care management processes to provide D–SNP enrollees a more seamless, coordinated experience of care.[11] CMS supports states that have an interest in pursuing integrated care models for dual eligible individuals, including through the use of their contracts with MA organizations offering D–SNPs, and provides technical assistance to states seeking to develop solutions tailored to their local market conditions, beneficiary characteristics, and policy environment.

Through this final rule, we are adopting new requirements in accordance with section 50311(b) of the Bipartisan Budget Act of 2018, which amended section 1859 of the Act to require that all D–SNPs meet certain new minimum criteria for Medicare and Medicaid integration for 2021 and subsequent years. Beyond the newly enacted amendments to the Act, we are

[8] Centers for Medicare & Medicaid Services (2018, June). SNP Comprehensive Report. Retrieved from *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Special-Needs-Plan-SNP-Data.html.*

[9] *See:* Kim, H., Charlesworth, C.J., McConnell, K.J., Valentine, J.B., and Grabowski, D.C. (2017, November 15). *Comparing Care for Dual-Eligibles Across Coverage Models: Empirical Evidence From Oregon.* Retrieved from *http://journals.sagepub.com/doi/abs/10.1177/1077558717740206;* Anderson, W.L., Feng, Z., & Long, S.K. (2016, March 31). *Minnesota Managed Care Longitudinal Data Analysis,* prepared for the U.S. Department of Health and Human Services Assistant Secretary for Planning and Evaluation (ASPE). Retrieved from *https://aspe.hhs.gov/report/minnesota-managed-care-longitudinal-data-analysis;* Health Management Associates (2015, July 21). *Value Assessment of the Senior Care Options (SCO) Program.* Retrieved from *http://www.mahp.com/wp-content/uploads/2017/04/SCO-White-Paper-HMA-2015_07_20-Final.pdf;* and Medicare Payment Advisory Committee (2012, June 16). ''*Care coordination programs for dual-eligible beneficiaries.*'' In *June 2012 Report to Congress: Medicare and Health Care Delivery System.* Retrieved from *http://www.medpac.gov/docs/default-source/reports/chapter-3-appendixes-care-coordination-programs-for-dual-eligible-beneficiaries-june-2012-report-.pdf?sfvrsn=0.*

[10] Centers for Medicare & Medicaid Services (2018, June). *SNP Comprehensive Report.* Retrieved from *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Special-Needs-Plan-SNP-Data.html.*

[11] Verdier, J, Kruse, A., Sweetland Lester, R., Philip, A.M., & Chelminsky, D. (2016, November). ''State Contracting with Medicare Advantage Dual Eligible Special Needs Plans: Issues and Options.'' Retrieved from *http://www.integratedcareresourcecenter.com/PDFs/ICRC_DSNP_Issues__Options.pdf.*

also using this final rule to add requirements and clarifications to existing regulations to codify guidance and policy since D–SNPs were established nearly 15 years ago and to update certain aspects of the regulations. Under the newly enacted section 1859(f)(8)(D)(i) of the Act, the statute calls for D–SNPs, for 2021 and subsequent years, to meet one or more of three specified requirements, to the extent permitted under state law, for integration of benefits:

- A D–SNP must, in addition to meeting the existing requirement of contracting with the state Medicaid agency under section 1859(f)(3)(D) of the Act, coordinate long-term services and supports (LTSS), behavioral health services, or both, by meeting an additional minimum set of requirements for integration established by the Secretary based on input from stakeholders. Such requirements for integration could include: (1) Notifying the state in a timely manner of hospitalizations, emergency room visits, and hospital or nursing home discharges of enrollees; (2) assigning one primary care provider for each enrollee; or (3) data sharing that benefits the coordination of items and services under Medicare and Medicaid.
- A D–SNP must either: (1) Meet the requirements of a fully integrated dual eligible special needs plan described in section 1853(a)(1)(B)(iv)(II) of the Act (other than the requirement that the plan have similar average levels of frailty as the PACE program); or (2) enter into a capitated contract with the state Medicaid agency to provide LTSS, behavioral health services, or both.
- The parent organization of a D–SNP that is also the parent organization of a Medicaid managed care organization providing LTSS or behavioral services must assume ''clinical and financial responsibility'' for benefits provided to beneficiaries enrolled in both the D–SNP and Medicaid managed care organization.

Section 50311(b) of the Bipartisan Budget Act of 2018 also authorizes the Secretary, in section 1859(f)(8)(D)(ii) of the Act, to impose an enrollment sanction on an MA organization offering a D–SNP that has failed to meet at least one of these integration standards in plan years 2021 through 2025. In the event that the Secretary imposes such a sanction, the MA organization must submit to the Secretary a plan describing how it will come into compliance with the integration standards.

We received a number of comments on our proposals to implement these new integration requirements, both in general and with regard to specific proposals. We summarize and respond to the comments below.

Comment: We received numerous comments in support of our integration proposal, with many commenters citing the proposal's fulfillment of statutory intent and expressing appreciation for the flexibility afforded to states to define what integrated care looks like in their state. For example, some of these commenters noted the diversity of state policies, which impact what the D–SNP market looks like in each state, and cautioned against any proposal that upon implementation would disrupt existing integrated care models and beneficiaries' coverage. A subset of commenters, while supportive of our proposal, also encouraged CMS to raise the bar of integration even further. One commenter encouraged CMS to help states move toward integration and not penalize plans and states that are not yet able to integrate further, advising that focus should also remain on minimizing administrative burden and reducing complexity for beneficiaries. The Medicare Payment Advisory Commission (MedPAC) stated its belief that the proposed rule will do little to promote greater integration, citing in particular the first of the proposed new standards for integration—requiring D–SNPs to share information on inpatient and SNF admissions—as having a very limited impact on improving care coordination, as discussed in more detail in the comments we received on proposed § 422.107(d). Another commenter objected to our integration proposal and recommended that CMS leave all decision-making to the states, including granting them the ability to opt out of any of the D–SNP integration requirements.

Response: We appreciate the widespread support we received for our proposal. We believe that the requirements we are finalizing in this rule strike an appropriate balance between increasing integrated care in D–SNPs for dual eligible individuals and preserving state flexibility, within the framework established by the amendments to section 1859(f)(8) of the Act made by section 50311(b) of the Bipartisan Budget Act of 2018. While our aim is to support states that are operating successful programs and assist those seeking to establish more integrated programs, we also recognize that our proposal must account for the current state of integrated care and the need to meet states where they are by setting reasonable and achievable integration benchmarks. As the D–SNP landscape evolves, we will continue to consider ways to advance integrated care, including further rulemaking. Finally, we note that the statute does not authorize CMS or states to disregard a D–SNP's obligation to meet one or more of the integration requirements, and imposes consequences for non-compliance, as discussed in response to comments on proposed § 422.752(d).

Comment: One commenter expressed concern about D–SNPs' ability to meet the integration requirements by 2021 due to the potential for delayed decision-making on the part of states. Another commenter requested a one-year delay in the effective date in consideration of the time required to negotiate and execute contracts between states and D–SNPs and to develop new processes, which will vary depending on each state's capabilities. Conversely, another commenter stated that 2021 is an achievable date for meeting one of the three integration requirements.

Response: The statute requires that D–SNPs comply with the integration requirements by 2021. As discussed throughout this preamble, the Medicare-Medicaid Coordination Office provides technical assistance to states on integration issues, and we expect to continue to engage states, plans, and other stakeholders as we implement the requirements in this final rule.

Comment: One commenter observed that CMS does not make any additional funding available for the coordination activities that D–SNPs perform today and that adding to these requirements could create burdens on plans and CMS or cause D–SNPs to exit the market. Another commenter urged CMS to establish nationwide standards to ensure plans can scale best practices and that beneficiaries receive the same high quality service no matter where they live.

Response: While we believe that states are well positioned to drive innovation in care delivery for dual eligible individuals, we also recognize that the Bipartisan Budget Act of 2018 set forth a minimum level of integration for all D–SNPs to meet. We believe that the proposal we set forth is a reasonable one that preserves state flexibility while fulfilling our statutory obligation. While we recognize the desirability of having national standards, particularly for MA organizations that operate D–SNPs in multiple markets across the country, we have to balance this desire with the differences that exist in states' capabilities, ranging from states where some or all dual eligible individuals may be precluded from enrolling in any capitated plan for their Medicaid services to states with highly integrated D–SNP models. Notwithstanding our reluctance to mandate the use of

national standards, we are committed to cataloguing and disseminating best practice information as part of the final rule's implementation and our ongoing administrative alignment efforts, discussed later in the preamble to this final rule.

Comment: Several commenters supported our D–SNP integration proposals but considered them only a starting point for ensuring better alignment and encouraged CMS to build upon these requirements in the future. Several commenters also recommended that CMS provide strong oversight to ensure that integration requirements are being met and that dual eligible individuals enrolled in D–SNPs are actually benefiting from increased integration. One commenter urged CMS to go further in recognizing states' authority and options to implement even more robustly integrated programs.

Response: We appreciate these commenters' perspectives on our proposal. We acknowledge the importance of working in close partnership with states to advance integration within each state-specific context. CMS will monitor the implementation of these provisions to determine market and beneficiary impacts and assess the need for additional rulemaking to modify or expand upon the integration standards we are finalizing in this rule.

Comment: One commenter recommended that CMS conduct a comprehensive review of basic operational processes to determine where Medicare and Medicaid could be further aligned to enhance care delivery and quality and to reduce burdens on plans, providers, and beneficiaries and to facilitate plans' moving along the integration continuum toward a FIDE SNP or HIDE SNP status. This commenter further suggested that CMS advance integration using all available statutory authorities, including seeking clarification from Congress regarding its intent in enacting provisions in the Bipartisan Budget Act of 2018 related to the Medicare-Medicaid Coordination Office.

Several commenters recommended that CMS extend to D–SNPs processes and flexibilities developed under the Financial Alignment Initiative for MMPs and under the Minnesota Demonstration to Align Administrative Functions for Improvements in Medicare-Medicaid Beneficiary Experience, including use of the contract management team structure for joint oversight of plans, integrated beneficiary communications materials, joint CMS-state marketing reviews, coordinated enrollment processes and timelines, integrated MOCs, dual eligible-specific network adequacy requirements, and streamlined and plan-level reporting processes. Several commenters suggested other areas in which CMS could create additional administrative and policy incentives to reward states for moving toward further Medicare-Medicaid alignment, including year-round marketing to dual eligible individuals; expansion of current passive enrollment and default enrollment authorities; establishment of a Special Election Period for enrollment in integrated plans; plan payment reforms, including changes to the frailty adjustment for FIDE SNPs; an increase of the enhanced Medicaid match for care coordination and IT activities; and alignment of state and federal contracting cycles. A commenter recommended that CMS improve its messaging about D–SNPs in its beneficiary-centered materials and tools.

Response: We thank commenters for their robust feedback about additional alignment opportunities for D–SNPs. Since 2013, the Financial Alignment Initiative and Minnesota demonstration have provided us with opportunities to test a number of programmatic and administrative flexibilities for MMPs and some D–SNPs, and many of these flexibilities have been positively received by beneficiaries, states, and health plans. We will continue to consider additional ways to promote better outcomes and experiences for dual eligible individuals.

As we have indicated in the CY 2016 Draft and Final Call Letters, the CY 2019 Draft and Final Call Letters, and the CY 2020 Draft Call Letter,[12] CMS remains committed to providing administrative flexibility that facilitates efforts by state Medicaid agencies and MA organizations to use D–SNPs to integrate coverage of Medicare and Medicaid benefits, including in the areas of integrated beneficiary communications, D–SNP models of care, and enrollment processes. That commitment is also evidenced by our recent CY 2019 final rule (CMS–4182–F, Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program) codifying our authority to permit default enrollment of newly Medicare-eligible individuals into integrated D–SNPs at § 422.66(c)(2) and, at § 422.60(g)(1)(iii), to allow passive enrollment to preserve continuity of care and integrated care related to D–SNP non-renewals or state Medicaid managed care organization procurements. We have also worked with states and integrated D–SNPs to develop integrated beneficiary communications materials, integrate model of care requirements and reviews with states, and provide state Medicaid agencies with technical assistance and information on plan performance and audit results of their contracted D–SNPs so that the quality of Medicare services delivered by those D–SNPs can inform state contracting strategies. We look forward to continuing our work in this area with additional states and plans.

Comment: A number of commenters recommended CMS consideration of additional regulatory and operational policies on a number of issues related to dual eligible individuals that were not related to the D–SNP integration requirements in the proposed rule. One commenter urged CMS to make funds available for ombudsman programs to serve dual eligible individuals in integrated D–SNPs. Several commenters recommended that CMS continue to work with plans on identifying a long-term solution impacting dual eligibility status and socioeconomic factors in Medicare Advantage Star Ratings. One commenter reiterated the need for CMS to develop a risk adjustment model that adequately accounts for the costs of serving beneficiaries with functional limitations. Another commenter urged CMS to consider how D–SNPs should be designed to minimize cost-sharing obligations that are ultimately unpaid and to consider a more holistic approach to coverage for dual eligible individuals that does not simply transfer cost-sharing liability to providers. Another commenter noted the critical importance of home and community-based service (HCBS) eligibility barriers when determining how the D–SNP-to-Medicaid transition should occur and recommended that the federal government ease this transition through reform of the Medicaid HCBS eligibility requirements. One commenter requested that CMS consider recognizing Part B premium buy-downs in Puerto Rico D–SNPs as part of plans' bids to provide Parts A and B benefits, rather than requiring plans to use rebate dollars to buy down the Part B premium as a supplemental benefit. Another commenter recommended cost-sharing integration processes for dual eligible individuals at the pharmacy counter or, in the shorter-term, implementation of real time beneficiary eligibility solutions for use within the NCPDP Telecommunication standard.

Response: These recommendations are not within the scope of our final rule

[12] *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2020Part2.pdf.*

provisions establishing integration criteria for D–SNPs effective in 2021, and some of them are beyond our programmatic authority. We do, however, appreciate the many comments and suggestions related to programmatic improvements for dual eligible individuals, including those enrolled in D–SNPs.

Comment: A range of commenters, including the Medicaid and CHIP Payment and Access Commission (MACPAC), expressed concern that the market entry of non-D–SNP MA plans designed and marketed exclusively to dual eligible individuals—so-called ''D–SNP look-alike plans''—threatens to undermine efforts by CMS, states, and D–SNPs to increase integration and coordination of Medicare and Medicaid services. Some of these commenters recommended that CMS address this issue including by requiring MA plans with a minimum percentage of dual eligible members to meet all D–SNP requirements, including the obligation to contract with the states in which the plans operate.

Response: Although the issue of D–SNP look-alike plans is beyond the scope of this rule, we share the commenters' concern with the impact of such plans on our efforts to increase Medicare-Medicaid integration. We call attention to the CY 2020 Draft Call Letter [13] in which we sought comment on the impact of D–SNP look-alike plans in order to inform future policy development.

Comment: A commenter recommended that CMS continue and expand efforts to help states adopt policies and incentives that assist D–SNPs in moving toward higher levels of integration (including FIDE SNP or HIDE SNP status with better aligned enrollments) for dual eligible individuals.

Response: States and CMS both play important roles in implementing more integrated care delivery systems for dual eligible individuals. The Medicare-Medicaid Coordination Office facilitates this technical assistance and dialogue with states, including through its Integrated Care Resource Center (see *https://www.integratedcareresourcecenter.com/*). We are committed to continuing our work with states based on their specific policy priorities following the implementation of this final rule.

Comment: One commenter reaffirmed their support for Medicare-Medicaid Plans (MMPs) offered under the Financial Alignment Initiative and urged CMS to make them permanent. The same commenter urged CMS to develop a common statutory and regulatory framework for all forms of integrated plans, including MMPs, PACE organizations, and FIDE SNPs, that would include uniform rules on marketing, enrollment processes, claims reporting, rate-setting, and risk adjustment.

Response: We appreciate the commenter's support for our work with states and MMPs in the Financial Alignment Initiative. CMS will continue to explore ways within our programmatic authority to improve the current regulatory framework for integrated care as we gain experience and gather data about the impacts of the FAI capitated model and other demonstrations, our administrative alignment efforts, streamlining of the PACE program, and the implementation of new D–SNP integration requirements finalized in this rule.

Comment: We received comments from one organization expressing concerns about CMS' sole reliance on the D–SNP delivery model and urging us to consider other plan types (including Institutional SNPs (I–SNPs) and fee-for-service Medicare) that can help achieve integrated care goals. This commenter expressed concern that sole reliance on D–SNPs would result in unnecessary disruptions to care.

Response: We support beneficiary choice in selecting the health care delivery system that best meets each individual's needs. The final rule focuses on the specific requirements added to section 1859(f) of the Act for D–SNPs by section 50311 of the Bipartisan Budget Act. Comments related to fee-for-service Medicare and I–SNPs are therefore outside the scope of this final rule.

Comment: A few commenters requested that CMS consider providing guidance on how the integration requirements will affect the operations of MMPs.

Response: We clarify that there is no direct impact on MMPs as a result of this final rule. The D–SNP requirements in this final rule are not applicable to MMPs, and MMP policy and operations will continue to be established in three-way contract agreements among CMS, health plans, and states.

(1) Definitions of a ''Dual Eligible Special Needs Plan'', ''Fully Integrated Dual Eligible Special Needs Plan'', ''Highly Integrated Dual Eligible Special Needs Plan'', and ''Aligned Enrollment'' (§ 422.2)

D–SNPs are described in various sections of 42 CFR part 422, including provisions governing the definition of specialized MA plans for special needs individuals in § 422.2, the supplemental benefit authority for D–SNPs that meet a high standard of integration and minimum performance and quality-based standards in § 422.102(e), state Medicaid agency contracting requirements in § 422.107, and specific benefit disclosure requirements in § 422.111(b)(2)(iii). In the proposed rule, we proposed to consolidate statutory and regulatory references to D–SNPs; we also proposed to establish a definition for such a plan in § 422.2. In addition to proposing a new definition for the term ''dual eligible special needs plan,'' we also proposed a revised definition of the term ''fully integrated dual eligible special needs plan,'' and new definitions of the terms ''highly integrated dual eligible special needs plan'' and ''aligned enrollment,'' for purposes of part 422 (that is, the rules applicable to the MA program) and the proposed rule.

In our proposed definition at § 422.2, we described a dual eligible special needs plan as a type of specialized MA plan for individuals who are eligible for Medicaid under Title XIX of the Act that provides, as applicable, and coordinates the delivery of Medicare and Medicaid services, including LTSS and behavioral health services, for individuals who are eligible for such services; has a contract with the state Medicaid agency consistent with § 422.107 that meets the minimum requirements in paragraph (c) of such section; and satisfies at least one of following integration requirements:

- It meets the additional state Medicaid agency contracting requirement we proposed at § 422.107(d) (described in section II.A.2.a.(2) of the proposed rule) that surpasses the minimum requirements in current regulations at § 422.107(c);
- It is a highly integrated dual eligible special needs plan (HIDE SNP), as described in further detail later in this section; or
- It is FIDE SNP.

In addition, we proposed additional performance requirements for D–SNPs that we did not incorporate into the definition; for example, a D–SNP would provide assistance to individuals filing a grievance or appeal for a Medicaid services in accordance with proposed

[13] *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2020Part2.pdf.*

§ 422.562(a)(5) (described in section II.A.2.b.(1) of the proposed rule). As discussed in the proposed rule, we believed this proposed definition identified the minimum requirements for an MA plan to be a D–SNP under section 1859 of the Act as amended by the Bipartisan Budget Act of 2018. We also explained that the proposed definition would clarify the applicability of the separate regulatory provisions that establish the minimum standards for D–SNPs. We solicited comment on whether our proposed definition met these goals or should be revised to include other regulatory provisions that establish requirements for D–SNPs.

We discussed in the proposed rule and reiterate here that it is important to clarify through this final rule the meaning of the requirement in section 1859(f)(3)(D) of the Act, which is currently codified at § 422.107(b), that the MA organization have responsibility under the contract for providing benefits or arranging for benefits to be provided for individuals entitled to Medicaid. Prior to our proposed rule, we had not adopted a specific interpretation of this statutory language, ''arranging for benefits,'' in previous rulemaking or in subregulatory guidance. We proposed to interpret ''arranging for benefits'' as requiring a D–SNP, at a minimum, to coordinate the delivery of Medicare and Medicaid benefits. We proposed to relocate this requirement to our proposed D–SNP definition. As stated in the proposed rule, while our interpretation is consistent with the new statutory integration standards, the proposed clarification was based on requirements for D–SNPs that existed prior to the enactment of the Bipartisan Budget Act of 2018 that we believe should be strengthened. We believe coordination would encompass a wide range of activities that a D–SNP may engage in for their dual eligible members and provided some examples of such coordination in the preamble to the proposed rule. If a D–SNP identifies through an enrollee's health risk assessment and/or individualized care plan, as required by § 422.101(f), functional limitations or mental health needs, the D–SNP could: (1) Verify the enrollee's eligibility for LTSS and/or behavioral health services under Medicaid; (2) determine how the enrollee receives such services (through FFS Medicaid or through another Medicaid managed care product); or (3) make arrangements with the applicable Medicaid program (state Medicaid agency or managed care plan) for the provision of such services by the appropriate payer or provider. We solicited comment on whether our proposed definition should be more prescriptive in identifying which plan activities constitute coordination or whether it should remain broadly defined as proposed.

We proposed revising the definition of fully integrated dual eligible special needs plan (FIDE SNP) at § 422.2 to align with the proposed definition of a D–SNP and to codify current policy. Specifically, we proposed the following:

- Striking the reference to a ''CMS approved MA–PD'' plan in the current FIDE SNP definition and paragraph (1), which refers to the individuals eligible for enrollment in a FIDE SNP, because those provisions duplicate elements of the new proposed definition of a D–SNP at § 422.2;
- Replacing the reference to ''dual eligible beneficiaries'' with ''dual eligible individuals'' in newly redesignated paragraph (1) to align with the terminology used in section 1935(c) of the Act;
- Adding to newly redesignated paragraph (2) that a FIDE SNP's capitated contract with a state Medicaid agency may include specified behavioral health services, as well as replacing the term ''long-term care'' benefits with ''long-term services and supports'' to better describe the range of such services FIDE SNPs cover in capitated contracts with states. We also proposed codifying in paragraph (2) the current policy that the FIDE SNP's capitated contract with the state provide coverage of nursing facility services for at least 180 days during the plan year; [14]
- Striking references to coordination of covered Medicare and Medicaid ''health and long-term care'' and referring more broadly to Medicare and Medicaid services in in newly redesignated paragraph (3); and
- Replacing the reference to ''member'' materials with ''beneficiary communication materials,'' consistent with the definition of ''communication materials'' at § 422.2260.

We proposed to codify a definition of highly integrated dual eligible special needs plan (HIDE SNP) at § 422.2. Under the proposed definition, a HIDE SNP would be a type of D–SNP offered by an MA organization that has—or whose parent organization or another entity that is owned and controlled by its parent organization has—a capitated contract with the Medicaid agency in the state in which the D–SNP operates that includes coverage of LTSS, behavioral health services, or both, consistent with state policy. We solicited comment on this proposed definition, including on whether additional requirements for HIDE SNPs should be addressed in the definition.

We also proposed to establish at § 422.2 a definition for the term aligned enrollment, as many of the other D–SNP proposals in the proposed rule were based on this concept. Under our proposal, aligned enrollment is when a full-benefit dual eligible individual is a member of a D–SNP and receives coverage of Medicaid benefits from the D–SNP or from a Medicaid managed care organization, as defined in section 1903(m) of the Act, that is: (1) The same organization as the MA organization offering the D–SNP; (2) its parent organization; or (3) another entity that is owned and controlled by the D–SNP's parent organization. Aligned enrollment, as we proposed to define it, would not arise where the MA organization or its parent organization solely has a contract with the applicable state to offer a prepaid inpatient health plan (PIHP) or prepaid ambulatory health plan (PAHP) in the state's Medicaid program. Unlike a Medicaid MCO, these other Medicaid managed care plans cover only a specific and non-comprehensive set of services. In the event that it is the policy of the state Medicaid agency to limit a D–SNP's membership to individuals with aligned enrollment, we proposed describing this practice as ''exclusively aligned enrollment,'' which was embedded in the proposed definition of ''aligned enrollment.'' As noted in the proposed rule, some states limit D–SNP enrollment to full-benefit dual eligible individuals who also choose to receive Medicaid benefits through the D–SNP or a Medicaid MCO operated by the same entity (that is, by the MA organization) or by the MA organization's parent organization. Such a limitation would be included in the state Medicaid agency contract with the D–SNP. Exclusively aligned enrollment is relevant to how we proposed to apply the integrated grievance and appeals requirements described in section II.A.2.b. of the proposed rule. We solicited comment on our proposed definition of aligned enrollment given its relevance to the category of D–SNPs to which the integrated grievance and appeals procedures apply. We also solicited comment on whether we should consider other types of Medicaid managed care arrangements beyond companion Medicaid MCOs, as defined

[14] Following the April 2, 2012 issuance of the ''Announcement of Calendar Year (CY) 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter,'' Chapter 16b of the Medicare Managed Care Manual was revised to include this policy.

in section 1903(m) of the Act and codified at § 438.2, operated by a HIDE SNP's parent organization.

Finally, we proposed in our definition of a D–SNP at § 422.2 to codify that an MA organization seeking to offer a D–SNP must satisfy any one (or more) of the three integration requirements in section 1859(f)(3)(D)(i) of the Act. We noted that the statutory language requires that plans meet one or more statutorily identified integration requirements to the extent permitted under state law. We explained in the proposed rule how we interpreted the integration standard in section 1859(f)(8)(D)(i)(II) of the Act (that the D–SNP be a FIDE SNP or have a capitated contract with the state Medicaid agency to provide LTSS or behavioral health services, or both) to mean that the D–SNP is a FIDE SNP or HIDE SNP; we also explained how we interpreted the integration standard in section 1859(f)(8)(D)(i)(III) of the Act (that clinical and financial responsibility for Medicare and Medicaid benefits for enrollees of the D–SNP be borne by an entity that is both the parent organization of the D–SNP and of the Medicaid managed care organization providing LTSS or behavioral health services under a contract under section 1903(m) of the Act) means that the D–SNP is a HIDE SNP or FIDE SNP with exclusively aligned enrollment. We interpreted the phrase ''to the extent permitted under state law'' as acknowledging and respecting the flexibility provided to states under the Medicaid program while imposing on D–SNPs integration requirements that Congress has deemed necessary. Given this flexibility, we proposed to interpret this statutory provision in a way that provides multiple avenues for a MA plan to qualify as a D–SNP. However, we considered other interpretations of this particular provision. For example, we considered whether ''to the extent permitted under state law'' should mean that in states that have Medicaid managed care programs for dual eligible individuals, all MA organizations seeking to offer a D–SNP could do so only if they were under contract with the state to offer a companion Medicaid managed care plan in that state, on the grounds that such an opportunity is permitted under state law. We solicited comments on our proposed interpretation as well as alternatives. We also requested comment on whether and how our proposed definition could or should be revised consistent with our statutory interpretation.

As discussed in the proposed rule, our intent was for the proposed definitions to describe different types of D–SNPs based on the degree to which they integrate Medicaid benefits at the plan level. Under section 1859(f)(8)(D)(i) of the Act, those D–SNPs that are neither FIDE SNPs nor HIDE SNPs must meet an additional state Medicaid contracting requirement beginning in 2021. Our proposed definition of a D–SNP addressed this in paragraph (1), cross-referencing the new requirement proposed to be codified in paragraph (d) of § 422.107. This proposed new requirement, which involves the provision of notice when an individual who belongs to a group of high-risk dual eligible individuals has a hospital and skilled nursing facility admission, is discussed in section II.A.2.a.(2) of this final rule in greater detail. We solicited comments on this proposal and, in particular, on alternative approaches to classifying D–SNPs consistent with requirements of section 1859(f)(8)(D)(i) of the Act.

We received the following comments on these proposed definitions and respond to them below:

Comment: Many commenters expressed support for CMS' proposed regulatory framework for defining D–SNPs, whereby a D–SNP could satisfy any one or more of three integration requirements: (1) As a D–SNP subject to the hospital and skilled nursing facility admission notification requirement in proposed § 422.107(d); (2) as a HIDE SNP; or (3) as a FIDE SNP. In justifying their support, several of these commenters cited one or more of the following:

- The benefits that accrue to beneficiaries and taxpayers when there is a market that permits an array of D–SNPs to compete with each other, rather than one that limits the types of D–SNPs that can compete in that market;
- The need for state flexibility in promoting integration in a manner that is incremental and minimizes market disruption;
- The importance of preserving a pathway for D–SNPs that do not hold a Medicaid managed care contract in the state or operate in states where no such Medicaid managed care market exists; or
- The opportunity for D–SNPs to make the transition on a gradual basis to greater, and eventually full, integration. Another commenter indicated that this proposal would create a spectrum of integration and give states and plans clear starting points from which to better define their goals and objectives.

Response: We appreciate the commenters' support of our proposal to create multiple pathways for an MA plan to qualify as a D–SNP, which—as discussed later in this preamble—we are finalizing in this final rule.

Comment: Several commenters raised objections to the alternative we discussed in the proposed rule to require, in states that have Medicaid managed care programs for dual eligible individuals, all MA organizations seeking to offer a D–SNP to be under contract as a Medicaid managed care plan. One commenter did not believe that the statute granted CMS authority to implement this restriction, while others noted that it would constrain state decision-making on integration, unnecessarily limit plan choice and reduce competition, lead D–SNPs to cease operating, or create a disincentive for D–SNPs to invest in care models and infrastructure. Another commenter advised that CMS should recognize that integration is contingent on state decision-making and incent the states to move state Medicaid policy toward more integrated models. Conversely, other commenters supported this alternative interpretation and encouraged CMS to reconsider its rejection of it. According to one commenter, without a policy that requires the parent organization of a D–SNP to contract with the state Medicaid agency, a beneficiary in a non-aligned D–SNP has no option other than enrolling in a Medicaid managed care plan operated by another sponsor (or, if permitted, receiving fee-for-service Medicaid services); where there is no alignment of Medicare and Medicaid coverage, the opportunity for effective care coordination is reduced. Commenters also noted the potential of such a policy to promote aligned enrollment and coordinate the full spectrum of needs for this population as well as the greater familiarity with Medicaid of organizations that operate in both Medicare and Medicaid markets in states, which is helpful in assisting beneficiaries.

Response: We appreciate the feedback on this alternative on which we requested comment and acknowledge that without such a policy there may be a missed opportunity to support the integration of Medicare and Medicaid services in states that adopt managed care delivery systems for their dual eligible population. We also recognize the concerns raised by commenters relative to the potential for adverse impacts on beneficiaries. We will take all of these comments into consideration should we decide to address this issue in future rulemaking. However, we are not moving forward with the alternative in this final rule.

Comment: We received significant comment on our proposed D–SNP, HIDE

SNP, and FIDE SNP definitions. Several commenters expressed appreciation for CMS' effort to create regulatory definitions for the different types of D–SNPs that exist in the marketplace today. A commenter supported our proposal under the HIDE SNP definition to permit arrangements in which the MA organization offering the D–SNP or its parent organization has a contract to offer a PIHP or PAHP in the state's Medicaid program. Many commenters expressed appreciation for the ability of D–SNPs to be defined as HIDE SNPs. One commenter noted that the proposed modifications provide far greater clarity for states and D–SNPs and offer the appropriate amount of detail to inform agreements between MAOs and state Medicaid agencies. Another commenter noted that the proposed D–SNP definition is a good first step but that it alone is insufficient, as truly meaningful integration for dual eligible individuals whose enrollment is not aligned requires a whole host of additional requirements and activities in key areas, including, but not limited to, integrated administrative, information technology, communications, reporting, and financial systems; integrated assessment and care coordination processes and data sharing; and integrated transition activities.

Response: We appreciate the support of our proposal, which, as we explained earlier in this preamble, reflects our desire to create a framework in which we are able to distinguish among the types of D–SNPs based on the way they integrate Medicaid services and, as applicable, align enrollment across Medicare and Medicaid, while also accounting for variation in how states cover these Medicaid services.

Comment: Several commenters supported our proposal to interpret the meaning of the statutory language in section 1859(f)(3)(D) of the Act, ''arranging for benefits,'' as requiring a D–SNP to coordinate the delivery of Medicare and Medicaid benefits and to relocate this requirement within our proposed D–SNP definition. One commenter commended CMS for the example of coordination included in the preamble to the proposed rule that interpreted such activities to include verifying dual eligible individuals' eligibility for LTSS or behavioral health services, determining how the individual receives such services, and making arrangements with the LTSS or behavioral health payer for the provision of services. A few commenters supported CMS' example of D–SNPs playing an active role in helping beneficiaries access Medicaid services as necessary.

Response: We thank the commenters for their support of our proposed interpretation and coordination examples.

Comment: One commenter opposed any requirement that D–SNPs extensively coordinate Medicaid benefits, citing the lack of additional compensation or clear expectations, and recommended that CMS instead work with states to address barriers to accessing Medicaid benefits. This commenter opposed any requirement that D–SNPs assist enrollees with such activities as completing paperwork or securing financial, medical, or other documentation needed to access Medicaid benefits or any other benefits not covered by the plan (housing, food stamps, utility assistance), instead recommending that plans undertake these activities at their discretion.

Response: While we agree that reducing barriers to access in Medicaid is important, we believe that for all enrollees who are eligible for Medicaid services, the D–SNP must fulfill its statutory responsibility to arrange for the provision of Medicaid benefits by facilitating a beneficiary's meaningful access to such benefits. As we discussed in the proposed rule, we believe it would be insufficient for a D–SNP to limit its coordination activity simply to telling a beneficiary to call or write their Medicaid managed care plan or state agency without giving specific contact information, giving specific coaching on the roles of the Medicaid program (that is, the state agency or Medicaid managed care plan versus the D–SNP), and offering additional support if needed. As discussed in section II.A.2.b.(1) of this final rule, we believe that an important aspect of D–SNPs' statutory responsibilities includes providing assistance to dual eligible individuals with Medicaid-related coverage issues and grievances. We also note that our proposed coordination requirement in the definition of a D–SNP is specific to Medicaid benefits and did not extend to some of the services and programs referenced by this commenter.

Comment: One commenter expressed overall support for our inclusion of a coordination requirement in the definition of a D–SNP, but noted that states, unaffiliated Medicaid managed care organizations, and non-contracted providers may present barriers to information-sharing that is necessary to make such coordination work. A few commenters endorsed the development of a system or process for collecting information about D–SNP enrollee Medicaid coverage and enrollment (when enrollment is not aligned) in order to meaningfully implement this provision. One of these commenters recommended that CMS establish a process by which states must provide individual-level data on the D–SNP's enrollees, including the enrollee's Medicaid coverage and plan name (if applicable) and specific contacts within each organization (names, phone numbers, emails, leadership contact information), in order to facilitate this coordination across Medicare and Medicaid.

Response: We appreciate the commenters' concern about access to information about their enrollees' Medicaid coverage. Establishing a standardized system or process such as the one suggested by these commenters is an option for states and CMS to consider. However, as discussed in section II.A.2.b.(1) of this final rule, there are other ways in which plans can endeavor to obtain information or connect enrollees with the appropriate resources to facilitate coordination of their Medicare and Medicaid benefits.

Comment: Several commenters supported the proposed rule's approach of broadly requiring D–SNPs to coordinate the delivery of Medicare and Medicaid benefits without specifying particular types of coordination activities in the regulatory definition of a D–SNP, citing the need for flexibility to accommodate differences in plans and state policies. One commenter appreciated the broad requirement as a way of ensuring that D–SNPs have ownership in coordinating the points where the D–SNP's services end and those provided under Medicaid begin and are not simply acting as an additional layer in the process. However, more commenters requested that CMS be more specific in identifying specific plan activities that constitute coordination, including several commenters who requested additional specificity within the regulation text. One commenter suggested that, without additional specificity in the definition about the types of activities that constitute coordination, plans might misinterpret or misunderstand the requirements. Another commenter anticipated that plans could face barriers in arranging Medicaid benefits for enrollees, especially if such benefits are managed by other health plans, and cited Tennessee's requirements that D–SNPs use the TennCare Online System to coordinate benefits for enrollees who are eligible for Medicaid.

A few commenters requested that CMS incorporate elements of person-centered care as part of the D–SNP care coordination requirements. One of these commenters stated that D–SNPs should

be held accountable for actively coordinating benefits and linking plan members to services (including those services that are not provided by the D–SNP). The other commenter encouraged CMS to emphasize that coordination for D–SNPs with aligned members that require LTSS or behavioral health services includes assessment and care planning processes that are: (1) At a minimum, compliant with the person-centered requirements of sections 1915(c), 1915(i), and 1915(k) of the Act, which were added in two January 16, 2014 final rules (CMS–2249–F and CMS–2296–F),[15] and (2) incorporate the provision of needed LTSS and/or behavioral health either directly or in close coordination with the entity owned or controlled by the D–SNP's parent organization that has contractual responsibility for LTSS and behavioral health benefits. Another commenter stated that in order for coordination to be effective, D–SNP personnel must have sufficient training related to the suite of services available under Medicaid and through the D–SNP and a thorough understanding of how to assist a beneficiary in navigating the delivery system to access services. One commenter recommended that CMS include in the D–SNP definition the following activities: Staffing plans with care coordinators who meet specific criteria; providing comprehensive information about Medicare, Medicaid, and plan benefits through plan materials, customer service, and care coordinators; ensuring that members have a primary care physician and that their providers are actively communicating through models such as interdisciplinary care teams; sharing information about claims, service authorizations, and care plans with the state, providers, beneficiaries, and beneficiaries' appointed representatives; and providing assistance with filing grievances and appeals and comprehensive explanations of the appeals process. Another commenter suggested that further clarification would be helpful around the role of the D–SNP related to transitions of care, the responsibilities of the D–SNP regarding arrangements for follow up care, and coordination with the discharging entity. Another commenter encouraged CMS to work with plans and states to ensure that provisions related to improved care transitions are effective and consequential for individuals with dementia.

Response: We appreciate the comments about additional activities CMS should consider to be essential for D–SNPs in coordinating their members' Medicare and Medicaid benefits. We do not agree at this time with the commenters who recommended including additional detail regarding those coordination activities in our regulatory definition of a D–SNP. Wide variation in the level of integration of Medicaid benefits across D–SNPs, local market conditions, and state initiatives to integrate care for dual eligible individuals leads us to believe that it is not prudent to add specific coordination responsibilities and requirements in this regulatory definition at this time. Further, some of the specific recommendations raise issues related to compliance with privacy rules protecting beneficiary information or other regulations governing D–SNPs (such as mandatory disclosure requirements), which are more appropriately addressed in other regulations. Our goal in this final rule is to establish an explicit requirement of coordination in regulation for the first time since D–SNPs were established in 2006 and to implement a flexible approach to coordination that allows plans to test approaches that best work for them and in their specific state context. We are therefore finalizing a coordination requirement in the definition of a D–SNP.

Comment: A number of commenters requested additional clarification of the role of D–SNPs in coordinating Medicare and Medicaid benefits, including in subregulatory guidance, guiding principles, and additional examples, to inform states and their contracted D–SNPs as they collaborate to identify specific plan activities that might differ by program or type of service. One commenter specifically requested that any list of coordination activities promulgated by CMS be considered a set of minimum requirements. Another commenter suggested that CMS provide a set of standardized approaches or acceptable frameworks that would assist states and plans in developing aligned approaches to this requirement, including best practices for data transfers and tips on overcoming administrative hurdles. Another commenter urged CMS to provide more clarity, citing concerns about burden on providers.

Response: We appreciate the commenters' request for clarification and anticipate issuing subregulatory guidance to further clarify the requirement that D–SNPs coordinate Medicare and Medicaid benefits for the dual eligible individuals enrolled in their plans.

Comment: A commenter suggested that CMS provide ongoing support to states in the implementation of our coordination requirements. Another commenter suggested that CMS consider whether further guidance regarding D–SNP coordination could serve as a means of persuading states to standardize their approaches to the alignment of their Medicaid programs with the MA program. This commenter suggested that CMS could, for example, issue further guidance on how states can work to establish viable health information exchanges as a means of facilitating communication and data exchange between plans and state Medicaid agencies, as such actions could qualify as ''coordinating the delivery of'' these services.

Response: CMS supports states that have an interest in pursuing integrated care models for dual eligible individuals, including through the use of their contracts with MA organizations offering D–SNPs, and provides technical assistance to states seeking to develop solutions tailored to their local market conditions, beneficiary characteristics, and policy environment. We are committed to continuing our work with states based on their specific policy priorities following the implementation of this final rule.

Comment: A few commenters stated that D–SNPs should be held accountable for actively coordinating benefits and linking plan members with services, both when those services are provided by the D–SNP or its affiliate and when they are provided by an unaffiliated third party. One of these commenters suggested that CMS look into the extent to which D–SNPs without Medicaid contracts may primarily serve partial-benefit dual eligible individuals [16] for whom there is no need or opportunity to coordinate Medicaid benefits.

[15] Medicaid Program; State Plan Home and Community-Based Services, 5-Year Period for Waivers, Provider Payment Reassignment, and Home and Community-Based Setting Requirements for Community First Choice and Home and Community-Based Services (HCBS) Waivers (79 FR 3029, January 16, 2014). Accessible at: *https://www.govinfo.gov/content/pkg/FR–2014–01–16/pdf/2014–00487.pdf.*

[16] Partial-benefit dual eligible programs are commonly referred to collectively as the ''Medicare Savings Program'' (MSP). The MSP includes 4 eligibility groups: Qualified Medicare Beneficiary Program without other Medicaid (QMB Only) for whom Medicaid pays their Medicare Part A premiums, if any, Medicare Part B premiums, and to the extent consistent with the Medicaid State plan, Medicare Part A and B deductibles, coinsurance and copays for Medicare services provided by Medicare providers; Specified Low-Income Medicare Beneficiary Program without other Medicaid (SLMB Only) and Qualifying Individual (QI) Program for whom Medicaid pays the Part B premiums; Qualified Disabled and Working Individual (QDWI) Program for whom Medicaid pays the Part A premiums.

Response: As we stated in the preamble to the proposed rule, we recognize that not all D–SNP membership will be eligible for the full complement of Medicaid services, particularly those who are partial-benefit dual eligible individuals whose Medicaid eligibility is limited to payment of their Medicare premiums, and, if applicable, deductibles and cost-sharing. Coordination approaches for partial-benefit dual eligible individuals will, of necessity, be different than those for members will full Medicaid benefits. However, for all enrollees who are eligible for Medicaid services, the D–SNP must fulfill its statutory responsibility to arrange for the provision of Medicaid benefits by facilitating a beneficiary's meaningful access to such benefits, regardless of their source or scope of Medicaid coverage. We discuss the issue of D–SNPs assisting their members with Medicaid benefit issues in more detail in section II.a.2.b.(1) of this final rule.

Comment: Several commenters emphasized the need for CMS to monitor D–SNPs' efforts at coordination and gauge their effectiveness.

Response: We agree that CMS oversight and monitoring of D–SNPs' coordination responsibilities are important. As we implement the provisions of this final rule, we will identify ways in which we can leverage current tools, including audits, model of care requirements, and reporting requirements, to ensure that D–SNPs assist dual eligible individuals in connecting with the Medicaid benefits to which they are entitled.

Comment: A few commenters expressed concern about the construction of the proposed D–SNP definition insofar that it could be misread or misinterpreted to require all D–SNPs to provide LTSS and behavioral health services.

Response: We did not intend our proposed definition to impose a new obligation on D–SNPs to provide coverage of Medicaid services. Therefore, we are finalizing the proposed definition of a D–SNP with modifications to the text to clarify this point and otherwise make grammatical and organizational changes to improve the regulation text. Specifically, a D–SNP is a plan offered by an MA organization for dual eligible individuals that, as provided in new paragraph (1), coordinates the delivery of Medicare and Medicaid services for individuals eligible for such Medicaid services; as provided in new paragraph (2), may provide coverage of Medicaid services, including LTSS and behavioral health services (for individuals eligible for such services); as provided in new paragraph (3), has a contract with the state Medicaid agency consistent with the requirements of § 422.107 that meets the minimum requirements detailed in § 422.107(c); and (4) beginning January 1, 2021, satisfies one of the three criteria for integration of Medicare and Medicaid benefits detailed in the proposed rule (and now designated as paragraphs (4)(i) through (iii)). We intend through these revisions to clarify that, regardless of whether a D–SNP provides coverage of Medicaid services under a capitated or other arrangement with the state Medicaid agency, it at minimum must coordinate the enrollee's Medicare and Medicaid services.

As discussed in section II.A.2.a.(2) of this final rule, to better align with our proposed definition of a D–SNP, we proposed a change to § 422.107(c)(1) to specify that the contract between a state Medicaid agency and a D–SNP must document the MA organization's responsibility to provide, as applicable, and coordinate the delivery of Medicaid benefits, including LTSS and behavioral health services, for individuals who are eligible for such services. In response to the concerns raised by these commenters, we are finalizing § 422.107(c)(1) with minor changes that express our intent more clearly and parallel the revisions we are finalizing in the D–SNP definition described earlier. Specifically, we are restructuring paragraph (c)(1) to avoid any misinterpretation that D–SNPs must cover LTSS and behavioral health services. We clarify in paragraph (c)(1)(i) that the D–SNP must document its responsibility to coordinate the delivery of Medicaid services for individuals who are eligible for such services, and in paragraph (c)(1)(ii) that, to the extent a D–SNP provides coverage of Medicaid benefits—including LTSS and behavioral health services (for individuals eligible for such services)—it must also document in the state Medicaid agency contract its responsibility to do so. We believe this revision clarifies that, in some cases, the D–SNP may cover (that is, provide directly or pay health care providers for providing) Medicaid benefits under a capitated contract with the state Medicaid agency; however in all cases it must coordinate the delivery of Medicaid benefits.

Comment: A few commenters were concerned about the introduction of a new term, HIDE SNP, which did not exist in regulations previously. Two of these commenters noted that it is already difficult for consumers and advocates to determine which plans are D–SNPs and what type of D–SNP they are. They noted that clear, consistent regulatory definitions can make important differences between the plan types and beneficiary options more understandable.

Response: While we sympathize with commenters' reluctance to create another regulatory definition, we believe that the definition of HIDE SNP is meaningful, as it correlates directly with our interpretation of the D–SNP integration standard that appears in section 1859(f)(8)(D)(i)(II) of the Act (D–SNPs that enter into a capitated contract with the state Medicaid agency to provide LTSS or behavioral health services, or both). We agree with the commenters that making these terms understandable to stakeholders, especially beneficiaries, is an important aim.

Comment: A commenter recommended that the proposed definition of HIDE SNP be redrafted to allow for risk-sharing arrangements other than capitation. This commenter noted that the state or D–SNP may wish to contract initially on a shared savings/shared risk or performance-based model as opposed to a full capitation model. Another commenter recommended that CMS consider creating another regulatory standard of integration other than a HIDE SNP that would describe D–SNPs that are at risk for a set of Medicaid services other than LTSS or behavioral health services, which can serve as stepping stones to further alignment.

Response: We appreciate that there are varying levels of integration, including, for example, arrangements in which a state Medicaid agency may capitate payment for Medicaid cost-sharing or a subset of services. However, the statute is clear that D–SNPs seeking to meet the integration standard at section 1859(f)(8)(D)(i)(II) of the Act must either be a FIDE SNP or enter into a capitated contract with the state Medicaid agency for the provision of LTSS, behavioral health services, or both. We proposed the definition of HIDE SNP to align with this statutory standard of integration, and therefore we are not making revisions to the HIDE SNP definition based on these specific recommendations. As discussed in the proposed rule (83 FR 54994), a D–SNP could satisfy the requirements of a HIDE SNP if its parent organization offered a companion Medicaid product that covered only LTSS, behavioral health services, or both, under a capitated contract. We believe that this definition is appropriate for purposes of addressing and aligning with the statutory integration standards and for

establishing which D–SNPs are eligible, pursuant to §§ 422.60(g)(2)(i) and 422.102(e), to receive passive enrollments or offer supplemental benefits, respectively.

We may consider for future rulemaking the merits of having a more detailed classification system that identifies variations of D–SNPs other than FIDE SNPs and HIDE SNPs relative to the extent to which they coordinate Medicare and Medicaid benefits. We note that technical assistance resources are available through the Integrated Care Resource Center that provide information about the varied approaches states have taken to coordinate with D–SNPs operating in their states.

Comment: A commenter suggested that CMS consider a HIDE SNP as a temporary model that could be utilized as part of a state's longer term strategy toward integration of Medicaid benefits in which all HIDE SNPs transition to a FIDE SNP model once full integration is achieved.

Response: We are supportive of states and plans that wish to pursue a FIDE SNP model; however, as stated earlier in this preamble, section 1859(f)(8)(D)(i) of the Act recognizes a level of integration that does not meet the requirements of a FIDE SNP with respect to the breadth of services provided under a Medicaid capitated contract with the state (that is, D–SNPs that cover LTSS, behavioral health services, or both, under a capitated contract) as meeting one of the three required integration standards. We therefore believe it is useful to codify a term that encompasses this statutory standard.

Comment: A commenter requested that CMS clarify that enrollment in a HIDE SNP be open to all dual eligible individuals, including those not yet eligible for LTSS and/or behavioral health services, on the grounds that their needs may change over the course a year such that they attain eligibility for these services. According to the commenter, a plan can play a role in helping the individual navigate their options.

Response: The proposed HIDE SNP definition stated that the MA organization offering the D–SNP, or the MA organization's parent organization or another entity that is owned or controlled by its parent organization, must have a capitated contract with the Medicaid agency that includes coverage of LTSS, behavioral health services, or both, consistent with state policy. The HIDE SNP definition, as proposed and finalized in this rule, does not itself require that the plan limit its MA enrollment to dual eligible individuals who qualify for LTSS, behavioral health services, or both. However, it is important to note that these plans are financially responsible under a capitated contract for covering these services for individuals who are eligible for them, and a state Medicaid agency may elect to impose enrollment restrictions on the D–SNP consistent with its contracting authority in § 422.107.

Comment: A commenter observed that the proposed definition of HIDE SNP appears to exclude a plan offered by an organization that subcontracts on a capitated basis with an organization or county agency to which the state Medicaid agency has ''delegated Medicaid financial and administrative responsibility.'' According to the commenter, this type of arrangement is common in California where counties use different Medicaid managed care models and recommended that CMS amend the HIDE SNP definition to encompass such an arrangement. The commenter further noted that while the organization that does not have a direct, capitated contract with the state, even though it is providing LTSS, behavioral health services, or both, under the Medicaid program, it can provide highly integrated benefits and should be considered a HIDE SNP. Relatedly, this commenter recommended that the definition of aligned enrollment be expanded to accommodate this arrangement, noting that aligned enrollment could occur for D–SNP enrollees who receive their Medicaid benefits from the D–SNP's parent organization via this subcontract.

Response: We believe that the commenter is referring to situations where the county or another entity has a contract with the state Medicaid agency to furnish Medicaid benefits to eligible individuals on a risk basis; we disagree that such a contract amounts to a delegation of financial or administrative responsibility for the Medicaid program. A county or entity with a managed care contract with the state Medicaid agency may subsequently subcontract certain aspects of the managed care contract to another entity under § 438.230. In such situations where that subcontractor also is a D–SNP, we recognize that there may be a level of integration for enrollees that is greater than that of a D–SNP that has no contract—directly or indirectly—with a state to provide LTSS, behavioral health services, or both. However, we do not believe that the subcontractor in that situation should be treated as a HIDE SNP. Our proposed definition of a HIDE SNP at § 422.2 requires a contract between the state and the D–SNP, its parent organization, or another subsidiary of its parent organization and is more consistent with the statutory language at section 1859(f)(8)(D)(i)(II) of the Act, which requires that a D–SNP enter into a capitated contract with a state to provide LTSS, behavioral health services, or both. The relationship between a D–SNP and its parent organization (or another plan owned and operated by the same parent organization) is one where we believe it is appropriate to attribute those other contract arrangements to the D–SNP itself for purposes of evaluating integration in the management, provision, and coordination of benefits for enrollees. That statutory provision is the basis for our codification of this definition. We therefore decline the commenter's recommendations that the definitions of a HIDE SNP and aligned enrollment be modified to accommodate this particular contracting arrangement.

Comment: A commenter requested more information about the eligibility for each type of D–SNP for passive enrollment, seamless conversion, and the frailty adjuster. Several commenters inquired about how CMS would designate each type of D–SNP.

Response: We intend to release guidance prior to the effective date of these provisions that explains how D–SNPs will be designated as FIDE SNPs and HIDE SNPs consistent with the terms of this final rule. As noted later in this final rule, we are amending § 422.60(g)(2)(i) to clarify that HIDE SNPs are eligible to receive passive enrollments; this is not a change in policy, per se, but a technical update to use the newly defined term where we previously used different language. Chapter 2 of the Medicare Managed Care Manual provides additional information for MA organizations about passive and default enrollment.[17] Eligibility for the frailty adjustment is governed by section 1853(a)(1)(B)(iv) of the Act and § 422.308(c)(4), which limit the payment adjustment to FIDE SNPs that have a similar average level of frailty, as determined by the Secretary, as the PACE program; the eligibility of plans for the frailty adjustment is not impacted by this rulemaking.

Comment: Commenters were generally supportive of our proposal to account for differences in how states cover Medicaid services, including states' decisions to carve out particular Medicaid services and deliver them through a separate arrangement. However, a number of these

[17] Chapter 2 of the Medicare Managed Care Manual can be accessed here: *https://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicareMangCareEligEnrol/index.html.*

commenters also urged us to clarify our use of the phrase ''consistent with State policy,'' which appears in the proposed definitions of HIDE SNP and FIDE SNP. In particular, they wanted to understand how this phrase impacts D–SNPs that are seeking to be defined as a HIDE SNP or FIDE SNP and how HIDE SNPs were different from FIDE SNPs in relation to carve-outs. A commenter questioned whether a state's carve-out of LTSS services from its Medicaid managed care program would that mean that no D–SNP in that state can qualify as a FIDE SNP, since FIDE SNPs must cover some element of LTSS. A commenter requested clarification about the obligation of FIDE SNPs to provide comprehensive Medicaid services and whether that same obligation applied to HIDE SNPs, while other commenters requested clarification about whether a D–SNP would still be considered a HIDE SNP if the state were to carve out behavioral health services or offered a limited scope of behavioral health services for dual eligible individuals, assuming all other HIDE SNP requirements were met. Yet another commenter cited its experience using Medicaid benefit carve-outs and the potential for the misalignment of incentives, which may result in inappropriate utilization or gaps in care.

Response: We proposed to interpret the phrase ''consistent with State policy'' as allowing CMS to permit certain carve-outs where consistent with or necessary to accommodate state policy, except for where specifically prohibited (such as the minimum of 180 days of coverage of nursing facility services during the plan year in the FIDE SNP definition). For A FIDE SNP, a carve-out by the state of a minimal scope of services is permissible so long as the applicable services, as described in the FIDE SNP definition, are covered under a Medicaid managed care organization contract under section 1903(m)(2) of the Act. This means that if a state opted to carve out LTSS entirely from capitation, in that state no D–SNP could qualify as a FIDE SNP. Similarly for a HIDE SNP, a carve-out by the state of a minimal scope of services is permissible so long as the applicable services, as described in the HIDE SNP definition, are covered under a capitated Medicaid contract with the D–SNP or the affiliated Medicaid managed care plan. For example, if a state were to carve out certain targeted case management services for full-benefit dual eligible individuals receiving behavioral health services, a D–SNP could still satisfy the FIDE SNP or HIDE SNP definition, provided that: (1) LTSS were covered under the capitated contract; or (2) behavioral health services, other than the carved-out case management, were covered under the capitated contract.

Our intent is to apply the phrase ''consistent with State policy,'' to HIDE SNPs as we have done historically for D–SNPs seeking FIDE SNP status. In the case of FIDE SNPs, our policy for determining whether a D–SNP meets the FIDE SNP definition at 42 CFR 422.2 was first addressed in the April 2, 2012, ''Announcement of Calendar Year (CY) 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter'' and later memorialized in section 20.2.5 of Chapter 16b of the Medicare Managed Care Manual.[18] Under this policy, CMS permits long-term care benefit carve-outs or exclusions only if the plan can demonstrate that it—

- Is At risk for substantially all of the services under the capitated rate;
- Is at risk for nursing facility services for at least six months (180 days) of the plan year;
- Does not disenroll an individual from the plan as a result of exhausting the service covered under the capitated rate; and
- Remains responsible for managing all benefits including any carved-out service benefits, notwithstanding the method of payment (for example, fee-for-service, separate capitated rate) received by the plan (we note that we interpret ''managing all benefits'' to be equivalent to coordinating the delivery of Medicare and Medicaid services, consistent with changes made elsewhere in this final rule, including in the definition of a D–SNP).

Also under this policy, FIDE SNPs are not required to cover behavioral health services in cases where the state decides to carve out or exclude behavioral health services from the capitated rate. We believe that the phrase ''consistent with State policy'' in the FIDE SNP and HIDE SNP definitions serves as an important acknowledgement of variation in how states elect to cover Medicaid services under their capitated contracts with D–SNPs and Medicaid managed care plans. As such, among the states that have capitated contracts with D–SNPs or the D–SNPs' parent organizations, CMS has the ability to determine that D–SNPs operating in such states meet the FIDE SNP or HIDE SNP definition notwithstanding this variation. However, in consideration of the request for clarification, we are making a minor modification to the HIDE SNP and FIDE SNP definitions in § 422.2 to change the placement of the phrase ''consistent with State policy,'' so that it appears prior to the categories of services to which it applies, as opposed to placement after them.

Comment: A commenter recommended that CMS clarify that HIDE SNPs are not required to cover under a capitated contract both LTSS and behavioral health services. Another commenter recommended that CMS remove the requirement that the contract with the state Medicaid agency include coverage of LTSS, behavioral health services, or both, and consider instead the existence of a contract with the Medicaid agency to cover an overlapping or potentially overlapping Medicaid population as the D–SNP, on the basis that such a plan already understands the Medicaid market in which it operates and is well situated to serve as a platform as states move to advance integrated care models for dual eligible individuals.

Response: HIDE SNPs are not required to cover *both* LTSS and behavioral health services but must cover at least one of those categories of services. We are finalizing the HIDE SNP definition at § 422.2 to require that a HIDE SNP cover LTSS, behavioral health services, or both, consistent with state policy. While we recognize that there is a variety of ways in which D–SNPs coordinate with Medicaid agencies, including coverage of Medicare cost-sharing and Medicaid services other than LTSS or behavioral health, we disagree with the comment that HIDE SNP status should be met without coverage of either LTSS or behavioral health services. Our intent in establishing a definition for HIDE SNPs is to describe one of the two types of D–SNPs that satisfies the integration requirement at section 1859(f)(8)(D)(i)(II) of the Act. Under this provision, the integration requirement is satisfied if the D–SNP meets the requirements of a FIDE SNP (other than the requirement that it has a similar level of frailty as the PACE program) or enters into a capitated contract with the state Medicaid agency to provide LTSS or behavioral health services, or both. We note that we are electing to make a non-material change to how we refer to the coverage of LTSS, behavioral health services, or both, in our HIDE SNP definition. We are finalizing the regulation with the phrase ''provides coverage'' instead of ''includes coverage.''

[18] See *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2020Part2.pdf* and *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c16b.pdf.*

Comment: A commenter urged CMS to work with states that have carve-outs to ensure that states are committed to coordinating carved-out services with D–SNPs. This commenter believed that state carve-outs, although conceptually a barrier to integration, are in some cases well-established and provide quality services. Though longer term integration is a goal, a hurried dismantling of those systems would be unwise and could cause beneficiary harm.

Response: We agree that it is an essential element of any D–SNP to coordinate the delivery of all Medicaid services, irrespective of how they are covered by the state Medicaid agency. Therefore, as discussed elsewhere in this final rule, we have made such coordination a requirement in § 422.2 for any plan that operates as a D–SNP.

Comment: A few commenters requested that CMS clarify the differences between HIDE SNPs and FIDE SNPs, and raised questions about any notable differences in types of contracting arrangements that are permitted (or not) and categories of services that the plan must cover, including the requirement that FIDE SNPs cover behavioral health services.

Response: Conceptually, we proposed to distinguish D–SNPs based on the degree to which they integrate Medicaid benefits at the plan level. FIDE SNPs that limit enrollment to full-benefit dual eligible individuals and require (or have) exclusively aligned enrollment across Medicare and Medicaid constitute the most extensive level of integration, with the greatest potential for holistic and person-centered care coordination, integrated appeals and grievances, comprehensive beneficiary communication materials, and quality improvement. HIDE SNPs with exclusively aligned enrollment are plans that share much of this potential but may integrate a narrower set of Medicaid benefits than FIDE SNPs. FIDE SNPs and HIDE SNPs where aligned enrollment is possible—but not required—under the state contract with the D–SNP and the state's administration of its Medicaid managed care program would constitute another form of integration, albeit to a lesser degree. The table below highlights some of the key differences between HIDE SNPs and FIDE SNPs. First, from a contracting perspective, a FIDE SNP's Medicare and Medicaid benefits are covered under a single legal entity that contracts (1) with CMS to operate as an MA plan; and (2) with the state to operate as a Medicaid MCO. This latter requirement means that the FIDE SNP has a contract under section 1903(m) of the Act to provide a comprehensive set of services. In the case of a HIDE SNP, however, there is no stipulation that a single legal entity must hold the Medicare and Medicaid contracts, only that the parties to the capitated contract are the state Medicaid agency (or state Medicaid agency's contractor) and one of the following: (1) The MA organization itself; (2) the MA organization's parent organization; or (3) another entity that is owned and controlled by the MA organization's parent organization. Additionally, with respect to a HIDE SNP, the entity or entities holding the MA contract and the Medicaid contract may provide coverage of Medicaid services as a PIHP, PAHP, or Medicaid MCO. Second, as noted in an earlier response to a comment, the breadth of coverage provided by FIDE SNPs and HIDE SNPs is different. For example, FIDE SNPs must provide at least 180 days of nursing facility coverage; as reflected in the definitions of the terms in § 438.2, PIHPs and PAHPs cover less comprehensive sets of services than MCOs and are distinguished from each other based on whether inpatient or ambulatory services are covered.

TABLE 1—ATTRIBUTES OF FIDE SNPS AND HIDE SNPS

	FIDE SNP	HIDE SNP
Must have a contract with the state Medicaid agency that meets the requirements of a managed care organization as defined in section 1903(m) of the Social Security Act.	Yes	No.
May provide coverage of Medicaid services via a PIHP or a PAHP.	No	Yes.
Must provide coverage of applicable Medicaid benefits through the same entity that contracts with CMS to operate as an MA plan.	Yes	No. The state Medicaid contract may be with: (1) The MA organization offering the D–SNP; (2) the MA organization's parent organization; or (3) another entity owned and controlled by the MA organization's parent organization.
Must have a capitated contract with the state Medicaid agency to provide coverage of long-term services and supports (LTSS), consistent with state policy.	Yes	No, if it otherwise covers behavioral health services.
Must have a capitated contract with the state Medicaid agency to provide coverage of behavioral health services, consistent with state policy.	No. Complete carve-out of behavioral health coverage by the state Medicaid agency is permitted.	No, if it otherwise covers LTSS.
Must have a capitated contract with the state Medicaid agency to provide coverage of a minimum of 180 days of nursing facility services during the plan year.	Yes	No.

In consideration of these comments, we are electing to make one additional change to our FIDE SNP definition to mirror language that appears in the HIDE SNP definition. Specifically, in paragraph (2) of the FIDE SNP definition, we are finalizing the regulation with the phrase ''provides coverage'' instead of ''includes coverage,'' which will make references to the provision of coverage consistent between the HIDE SNP and FIDE SNP definition.

Comment: A commenter recommended that CMS replace in its definition of FIDE SNP ''aligned'' care management processes with ''fully integrated'' care management processes, with the expectation that either a single person is responsible for coordination of the full continuum of Medicare and Medicaid benefits, or the health plan uses an integrated team approach, with clear lines of communication and

accountability, and with integrated care management data systems that facilitate timely access to information needed to facilitate integrated care management processes.

Response: While we support the approaches to care identified by this commenter, we do not believe that such a change to the FIDE SNP definition is necessary. Our use of the phrase ''aligned care management processes'' in paragraph (3) of the FIDE SNP definition at § 422.2 is intended to encompass the variety of ways in which FIDE SNPs seek to coordinate care for full-benefit dual eligible individuals.

Comment: We received several comments concerning the requirement that FIDE SNPs cover nursing facility services for at least 180 days during the plan year and whether this signified a change in existing FIDE SNP coverage policy or an expansion of the Medicare skilled nursing facility benefit.

Response: As noted in a prior response to a comment, it has been longstanding CMS policy for a FIDE SNP to be at risk for providing coverage of at least 180 days of nursing facility services, and this rulemaking codifies rather than revises or reinterprets this policy. If a state were to carve out institutionally-based LTSS from its capitated contract, it would not be possible for an MA plan to operate as a FIDE SNP in that state, although it may be possible to qualify as a HIDE SNP, assuming all applicable requirements were met. Similarly, if a state were to carve out community-based LTSS from its contract because the state opted to provide coverage of these services under a separate arrangement, it would not be possible for such a plan to qualify as a FIDE SNP because section 1853(a)(1)(B)(iv) of the Act establishes that FIDE SNPs must cover long-term care under a capitated contract with the state for Medicaid benefits. Community-based LTSS are long-term care services and essential to the coverage model offered by a FIDE SNP.

Comment: A few commenters supported our proposed definition of aligned enrollment and its applicability to particular types of plans. MedPAC and another commenter agreed with our proposal to limit the definition of aligned enrollment to Medicaid coverage provided by a comprehensive Medicaid MCO instead of including plans that provide more limited Medicaid services as PIHPs or PAHPs. A few commenters agreed with our proposal to account for not only D–SNPs whose Medicaid benefits are covered by the plan directly but also by a Medicaid MCO operated by the same organization, its parent organization, or another entity that is owned and controlled by its parent organization. One commenter recommended that we explicitly incorporate in the definition the concept from the statute that such plans have clinical and financial responsibility for any individual enrolled in both programs and expressed concern that a parent company could sponsor Medicaid plans and D–SNP products that might be operated quite separately with little or no coordination while still accepting ''clinical and financial responsibility with respect to any individual enrollee.''

Response: We thank commenters for their support of how we defined aligned enrollment. We disagree, however, with the commenter about the necessity of including the phrase ''clinical and financial responsibility for any individual enrolled in both programs'' in the definition of aligned enrollment.

Under our proposed definition, we stated that aligned enrollment refers to full-benefit dual eligible D–SNP enrollees whose Medicaid benefits are covered by that D–SNP or by a Medicaid MCO that is the same organization, its parent organization, or another entity that is owned and controlled by its parent organization. When a full-benefit dual eligible individual is enrolled in aligned plans, one entity (or entities that share a parent organization) provides coverage of Medicare benefits and Medicaid benefits such as LTSS, behavioral health services, or both. By virtue of the provision of coverage under these types of contractual relationships, the relevant entity intrinsically has clinical and financial responsibility for the covered Medicare and Medicaid services provided to enrollees. We believe that explicitly using the phrase ''clinical and financial responsibility for benefits'' in the definition of aligned enrollment might imply otherwise and suggest that a contractual obligation to cover benefits does not mean financial and clinical responsibility for those benefits.

We are finalizing the proposed definition of the term ''aligned enrollment'' with some modifications to clarify this relationship. Rather than referring to the enrollee's Medicaid benefits as being covered by the D–SNP or by a Medicaid MCO, the final regulation text refers to the enrollee's Medicaid benefits as being covered by the D–SNP under a Medicaid MCO contract between the state and: (1) The MA organization offering the D–SNP; (2) the D–SNP's parent organization; or (3) another entity that is owned and controlled by the D–SNP's parent organization. We believe this regulation text change clarifies the meaning and adequately addresses that financial and clinical responsibility for the enrollees is held by the MA organization or its parent organization.

Comment: One commenter, while supportive of how we intended to incorporate exclusively aligned enrollment relative to unifying Medicare and Medicaid grievance and appeal procedures, encouraged us to consider developing additional incentives and tools for states and plans to move toward increased alignment. This commenter expressed interest in the creation of a combination of rewards, incentives, new tools, and pathways to facilitate improvement in enrollment alignment, which is not a pervasive practice among states.

Response: The commenter's point is well taken. We intend to exercise the administrative authority we have under current law to support states that wish to pursue this particular integrated care strategy and will consider the necessity of future rulemaking consistent with our programmatic authority. We will also continue to make technical assistance resources available to states through the Integrated Care Resource Center.

Comment: A commenter expressed concern that the definition of exclusively aligned enrollment may limit state flexibility insofar that it would be difficult for one-hundred percent of a D–SNP's membership to be aligned. According to the commenter, a D–SNP that failed to meet this threshold wouldn't be able to benefit from unified appeals and grievance processes. This commenter would be opposed to a policy of having to disenroll members anytime misalignment occurred. Another commenter requested that CMS confirm that HIDE SNPs and exclusively aligned HIDE SNPs are different types of plans.

Response: We clarify that through this rulemaking, the concept of exclusively aligned enrollment is only relevant to how we define an applicable integrated plan, which must unify its Medicare and Medicaid grievance and appeals procedures consistent with rules described in §§ 422.629 through 422.634. Unifying grievance and appeals procedures is most feasible when everyone in the plan is receiving Medicare and Medicaid services from the same organization (or through a companion product offered by the parent organization or through a common ownership relationship with the parent organization). In the absence of aligned enrollment, D–SNP enrollees may be enrolled in and receiving coverage from two or more plans simultaneously, complicating

coordination of care and the beneficiary experience. For FIDE SNPs and HIDE SNPs, this situation of receiving coverage from two or more plans may be true for only some enrollees. Even if this lack of alignment exists for some and not all of the D–SNP's enrollees, there would be at least two (if not more) sets of grievance and appeals rules applying to the D–SNP's members. State Medicaid agencies have the ability to take other steps to integrate grievance and appeals procedures through their contracts with D–SNPs. We welcome the opportunity to partner with states in developing and implementing these strategies.

Comment: MedPAC advised that aligned enrollment should be a requirement for D–SNPs that provide significant Medicaid services and meet both the second and third integration standards at sections 1859(f)(8)(D)(i)(II) and (III) of the Act, respectively, where our proposal only contemplated applying a requirement of exclusively aligned enrollment to the third integration standard (where the parent organization of the enrollee's D–SNP is also the parent organization of the enrollee's Medicaid MCO). MedPAC further stated that the second integration standard in the statute should apply to plans where states have capitated Medicaid contracts directly with D–SNPs and the D–SNPs provide Medicaid services, and the third standard should apply to situations where states have capitated Medicaid contracts with another legal entity (a Medicaid managed care plan) that is part of the same parent organization as the D–SNP.

Response: We agree with MedPAC insofar that alignment of Medicare and Medicaid coverage, which occurs when a full-benefit dual eligible individual is receiving Medicare and all or substantially all Medicaid services from one organization, constitutes the most extensive level of integration. As we noted in the preamble of the proposed rule, this arrangement offers the greatest potential for holistic and person-centered care coordination, integrated appeals and grievances, comprehensive beneficiary communication materials, and quality improvement. However, we remain concerned about imposing such a requirement at this time, as states that have contracts with Medicaid MCOs and D–SNPs currently have the authority to require aligned enrollment but for policy or other reasons, do not impose one. Finally, we believe that the most salient differentiator between the second and third integration standards at sections 1859(f)(8)(D)(i)(II) and (III) of the Act is exclusively enrolled alignment, rather than whether the state contract is with the D–SNP directly or a related entity. We are therefore not adopting this recommendation.

Comment: A commenter recommended that CMS codify the third integration requirement, which appears in section 1859(f)(8)(D)(i)(III) of the Act, and stipulates that a D–SNP's parent organization assumes clinical and financial responsibility for the provision of Medicare and Medicaid benefits. While this commenter was supportive of our interpretation that such clinical and financial responsibility was only possible in FIDE SNPs and HIDE SNPs where there was exclusively aligned enrollment, the commenter was concerned that our interpretation only existed in preamble and not the regulation text itself.

Response: As noted by the commenter, in the proposed rule, we did not explicitly cite or summarize the integration requirement at section 1859(f)(8)(D)(i)(III) of the Act in our definition of a D–SNP. Instead, we interpreted the statutory language on assuming clinical and financial responsibility for benefits to mean that an entity can only truly hold ''clinical and financial responsibility'' for the provision of Medicare and Medicaid benefits, as described at section 1859(f)(8)(D)(i)(III) of the Act, in the scenarios of exclusively aligned enrollment. Therefore, the D–SNPs that meet this integration standard would be FIDE SNPs and HIDE SNPs that have exclusively aligned enrollment. As implemented in our definitions, section 1859(f)(8)(D)(i)(II) of the Act also establishes being a FIDE SNP or a HIDE SNP as a means to satisfy the new, minimum integration requirements for D–SNPs. We believe that our proposed definitions and requirements are clearer without adding the statutory terminology from section 1859(f)(8)(D)(i)(III) of the Act. As we interpreted the statute and proposed the new rules, any plan that meets the requirement for clinical and financial responsibility for the provision of Medicare and Medicaid benefits would already meet the second integration requirement because it would be a FIDE SNP or HIDE SNP. As discussed in section II.A.2.b.(2) of this final rule, the combination of terms that we proposed is relevant to how we define an applicable integrated plan that must unify grievance and appeals procedures for Medicare and Medicaid services. Therefore, we believe that adding the statutory terminology would complicate the definitions and requirements relative to any benefits.

After considering the comments we received, we are finalizing the provisions related to D–SNP definitions as proposed with the following modifications:

- In the definition of aligned enrollment at § 422.2, we are finalizing the regulatory text with some modifications to clarify our intended meaning regarding financial and clinical responsibility for enrollees. The final regulation text refers to the enrollee's Medicaid benefits as being covered by the D–SNP under a Medicaid MCO contract between the state and: (1) The MA organization offering the D–SNP; (2) the D–SNP's parent organization or (3) another entity that is owned and controlled by the D–SNP's parent organization.
- In the definition of a D–SNP at § 422.2, we are finalizing the substance of our proposed definition with modifications that are primarily organizational. In the final regulation text, we are inserting ''title'' prior to ''XIX of the Act,'' which was inadvertently excluded in the proposed rule. We are also using a new paragraph (1) to clarify that a D–SNP coordinates the delivery of Medicare and Medicaid services for individuals eligible for such Medicaid services, and a new paragraph (2) to clarify that a D–SNP may provide coverage of Medicaid services, including LTSS and behavioral health services. The requirement that a D–SNP have a contract with the state Medicaid agency consistent with the requirements of § 422.107 and that meets the minimum requirements detailed in § 422.107(c) is now contained in new paragraph (3), and the requirement that the D–SNP satisfy, beginning January 1, 2021, one of the three criteria for integration of Medicare and Medicaid benefits detailed in the proposed rule is now contained in new paragraph (4), with the specific integration requirements redesignated as paragraphs (4)(i) through (iii)).
- In paragraph (2) of the definition of a FIDE SNP at § 422.2, we are finalizing the definition with a change in the placement of the phrase ''consistent with State policy'' so that it modifies the verb phrase ''provides coverage'' and appears prior to the categories of services to which it applies. Also in paragraph (2), we are using ''provides'' in place of ''includes'' prior to the phrase ''coverage, consistent with State policy.''
- In the definition of a HIDE SNP at § 422.2, we are finalizing the proposal with non-substantive modifications. First, we are changing the placement of the phrase ''consistent with State policy'' so that it modifies the verb

phrase ''provides coverage'' and appears prior to the categories of services to which it applies. Second, we are reorganizing the text to use new paragraphs (1) and (2) to identify the options for the capitated contract to provide Medicaid services. A HIDE SNP's capitated contract to cover LTSS, behavioral services, or both, must be between: (1) The MA organization and the Medicaid agency; or (2) the MA organization's parent organization (or another entity that is owned and controlled by its parent organization) and the Medicaid agency. Third, we are using ''provides'' in place of ''includes'' prior to the phrase, ''consistent with State policy, of long-term services and supports, behavioral health services, or both. . .''

(2) Dual Eligible Special Needs Plans and Contracts With States (§ 422.107)

We proposed changes in § 422.107 to more clearly articulate the requirements of the contract between the D–SNP and the state Medicaid agency, while also incorporating the changes required by the Bipartisan Budget Act of 2018. In summary, we proposed to make the following specific changes:

- Delete language in paragraph (b) that is extraneous and duplicative of the proposed definition of a D–SNP in § 422.2;
- Make clarifying edits in paragraphs (c)(1) through (c)(3), which govern the minimum requirements of the contract between the D–SNP and the state Medicaid agency;
- Redesignate paragraph (d) as paragraph (e), which relates to compliance dates; and
- Establish a revised paragraph (d) that describes the new minimum contracting requirement under the Bipartisan Budget Act of 2018 that the newly designated paragraph (e)(2) would make effective January 1, 2021.

Section 50311(b) of the Bipartisan Budget Act of 2018 amended section 1859(f) of the Act by creating a new paragraph (8)(D)(i)(I) to require that the Secretary establish additional requirements for D–SNPs' contracts with state Medicaid agencies. In the proposed rule preamble, we discussed how this provision requires a D–SNP to have a state Medicaid agency contract that includes additional coordination requirements (subsection (f)(8)(D)(i)(I) of the Act); be a FIDE SNP or HIDE SNP (subsection (f)(8)(D)(i)(II) of the Act); or have exclusively aligned enrollment and have its parent organization accept full clinical and financial responsibility for all Medicare and Medicaid covered services (subsection (f)(8)(D)(i)(III) of the Act), depending on the state's election.

We proposed to implement subsection (f)(8)(D)(i)(I) of the Act by establishing at § 422.107(d) that any D–SNP that is not a FIDE SNP or HIDE SNP is subject to an additional contracting requirement. Under this proposed new contract requirement, the D–SNP would be required to notify the state Medicaid agency, or individuals or entities designated by the state Medicaid agency, of hospital and skilled nursing facility (SNF) admissions for at least one group of high-risk full-benefit dual eligible individuals, as determined by the state Medicaid agency. We clarified in the proposed rule that this proposal would also permit the D–SNP to authorize another entity or entities (such as a D–SNP's network providers) to notify the state Medicaid agency and/or individuals or entities designated by the state Medicaid agency on its behalf, with the understanding that the D–SNP ultimately would retain responsibility for complying with this requirement. We direct readers to the proposed rule, 83 FR 54996, for a more detailed explanation of our intent and rationale for this approach.

As discussed in the proposed rule, we believe that our proposal to establish a notification requirement for D–SNPs for high-risk individuals' hospital and SNF admissions is consistent with the criteria we used to evaluate various options for the minimum contracting requirements. We considered whether a proposal would:

- Meaningfully improve care coordination and care transitions, thereby improving health outcomes for dual eligible individuals;
- Minimize burden on plans and states relative to the improvements in care coordination and transitions;
- Provide flexibility to state Medicaid agencies;
- Enable CMS to assess compliance with minimal burden on CMS, plans, and providers; and
- Be consistent with the statutory amendments made by the Bipartisan Budget Act of 2018.

We solicited comment on whether our proposal satisfied these criteria to a greater extent than the more prescriptive or alternative proposals we described in the proposed rule;[19] whether our reasoning for why our proposal was preferable to the more prescriptive or alternative proposals was sound; whether there were other minimum contacting requirements that we did not consider that were superior to our proposal; and whether our proposal provided sufficient incentives for plans and states to pursue greater levels of integration. Specifically, we considered and sought comment on the following alternatives:

- Proposing that notice requirements apply for all full-benefit dual eligible individuals' hospital and SNF admissions.
- Proposing a minimum size for the state-selected high-risk population.
- Requiring a notification for every emergency department visit, as mentioned in section 1859(f)(8)(D)(i)(I) of the Act.
- Proposing that the notification occur not later than 48 hours after the D–SNP learns of the admission or discharge.
- Requiring each D–SNP to take affirmative steps to schedule its individual health risk assessments at the same time as similar outreach is conducted by the Medicaid managed care plan, to use a combined or aligned assessment instrument, or take other steps that would minimize the burden on enrollees or providers. As we noted in the proposed rule, we continue to hear of scenarios where a D–SNP enrollee is assessed separately by the D–SNP and then again by their Medicaid MCO, even though there may be a high degree of overlap in what each organization is assessing and ultimately what each organization is requesting of the enrollee. We solicited comment on how pervasive this issue is and the extent of overlap in the assessment instruments and degree of burden on providers and beneficiaries, including a specific request for feedback on the extent to which the requirements that we proposed do not accomplish enough or should be modified to address this issue.
- Requiring D–SNPs to identify any enrollees who are in need of LTSS and behavioral health services and transmitting such information to the state Medicaid agency.
- Requiring D–SNPs to train plan staff and their network providers on the availability of LTSS and behavioral health services covered by Medicaid.
- Requiring D–SNPs to solicit state input on the plan's model of care (which is currently required and submitted to CMS pursuant to § 422.101(f)), health risk assessment instrument, and beneficiary communication materials. We sought comment regarding state burden and on compelling reasons why additional contracting requirements in this area may be necessary.
- The merits of requiring D–SNPs to share data with state Medicaid agencies or entities designated by state Medicaid

[19] We direct readers to the proposed rule, 83 FR 54997–98, for a more detailed discussion of these alternatives.

agencies that would benefit the coordination of Medicare and Medicaid items and services, as described in section 1859(f)(8)(D)(i)(I) of the Act as an example for implementing that provision. We solicited comment on whether there should be additional regulatory requirements around data sharing.

We requested feedback on our notification proposal at § 422.107(d), including the ways that state Medicaid agencies and plans would fulfill this requirement, and the additional contracting requirements we considered in the proposed rule preamble.

In addition to the new requirement for contracts between the state and MA organization at proposed § 422.107(d) for D–SNPs that are not FIDE SNPs or HIDE SNPs, we proposed to include additional specifications in the regulations governing D–SNP contracts with state Medicaid agencies at § 422.107 by amending paragraph (b) and several provisions in paragraph (c). As stated in the preamble to the proposed rule, we do not believe that these specifications materially alter these agreements; however, we proposed them in response to questions raised since the state Medicaid agency contracting requirements were promulgated in the September 2008 interim final rule (73 FR 54226). We also believed that these changes aligned with the integration requirements for D–SNPs in the Bipartisan Budget Act of 2018.

We proposed modifying the general rule for contracts with D–SNPs at § 422.107(b) to strike ''The MA organization retains responsibility under the contract for providing benefits, or arranging for benefits to be provided, for individuals entitled to receive medical assistance under Title XIX. Such benefits may include long-term care services consistent with State policy, . . .'' As discussed in the proposed rule, we believed this proposed change would be consistent with the coordination requirements in our proposed definition at § 422.2 of ''D–SNP.''

We proposed to revise the contracting requirement at § 422.107(c)(1), which currently requires the contract to document the MA organization's responsibility, including financial obligations, to provide or arrange for Medicaid benefits, to specify instead that the contract must document the MA organization's responsibility to provide, as applicable, and coordinate the delivery of Medicaid benefits, including LTSS and behavioral health services, for individuals who are eligible for such services. We solicited comment on whether our proposed amendments to this section fully communicated what we intend to require of D–SNPs or whether there were additional revisions we ought to consider to express our intent more clearly for D–SNPs, state Medicaid agencies, and other stakeholders.

In § 422.107(c)(2), we proposed to revise the current requirement that the contract between the D–SNP and the state Medicaid agency document the categories of dual eligible individuals who are eligible to enroll in the D–SNP. We proposed to revise this requirement to specify not only the categories of eligibility but also any additional criteria of eligibility to account for such conditions of eligibility under Medicaid as nursing home level of care and age. We clarified that these criteria could also include a requirement for D–SNP enrollees to enroll in a companion Medicaid plan to receive their Medicaid services.

Finally, at § 422.107(c)(3), we proposed that the contract between the D–SNP and the state Medicaid agency document the Medicaid services the D–SNP is responsible for covering in accordance with a capitated contract with the D–SNP directly or through a risk contract, defined at § 438.2, with the companion Medicaid managed care organization operated by the D–SNP's parent organization. As discussed in the proposed rule, we believe this proposed change would reduce burden on D–SNPs and would enable us to identify the particular Medicaid services that are covered under a capitated contract for FIDE SNPs and HIDE SNPs but would not limit or contravene other requirements for D–SNPs to approach their obligations to coordinate the delivery of all Medicare and Medicaid benefits. We sought comment on whether the regulatory change fully communicates what we wish to require.

We received the following comments on these proposed definitions:

Comment: We received a number of comments in support of our proposal to establish a notification requirement for any D–SNP that is not a FIDE SNP or HIDE SNP. One commenter believed the proposed requirement is consistent with the intent and language of the Bipartisan Budget Act of 2018. Several commenters supported the flexibility to allow state Medicaid agencies to build on notification processes already in place. A commenter noted that minimum contract requirements are more practical to implement than more prescriptive requirements due to variation in state capabilities and current data-sharing methods. Another commenter appreciated the flexibility states have to implement the requirement based on their needs and readiness. Another commenter believed that the notification requirement will facilitate care transitions for dual eligible individuals in instances where they are not enrolled in an aligned D–SNP and provides a framework upon which states can advance Medicare and Medicaid benefit integration in the future.

Response: We thank commenters for their support of our proposed notification requirement. We agree that the requirement is consistent with the statutory amendments made by the Bipartisan Budget Act of 2018. We intend for this notification requirement to be a catalyst for increasing care coordination during transitions of care, while minimizing plan and state burden and preserving state flexibility to develop solutions that build upon current integration efforts.

Comment: Several commenters supported our proposed notification requirement but believed that it represents a transitional step and that our integration efforts should be scaled up over time, with one commenter requesting that CMS establish timelines and benchmarks for states and plans. One commenter believed that the new statutory amendments to the Act made by the Bipartisan Budget Act of 2018 not only permit, but require, the notification requirement to be scaled up over time. A few commenters recommended that the notification requirement be broadened to include more enrollees.

Response: As we discussed in the proposed rule, our intent in establishing this notification requirement is for states and D–SNPs to begin on the path toward greater integration on a smaller scale. Not every state is similarly positioned to move towards greater integration. We note that, as processes and infrastructure mature, a state Medicaid agency may choose through its contracts with D–SNPs to scale up this notification to include additional subpopulations of full-benefit dual eligible individuals. As we gain experience with implementing the integration requirements in this final rule, we will evaluate whether further rulemaking is necessary to build on the notification requirement.

Comment: Some commenters expressed concern that CMS's proposed notification requirement will not meet the goal of promoting greater integration of Medicare and Medicaid benefits, creates unnecessary burden, or may not be the most appropriate requirement in all states. MedPAC noted that states are currently able to require D–SNPs to provide this information through their state Medicaid agency contracts, but

since few states do, states were unlikely to use this information to improve care coordination. Several commenters believed that many states may lack the capability to implement the contracting requirement and use the data in a meaningful way. Several commenters expressed concern that the requirement was too burdensome for states and would discourage states from pursuing or continuing to contract with D–SNPs. A few commenters noted that notifications of hospital or SNF admissions may not be the most useful or best way to incentivize coordinated transitions of care in every state and emphasized that states are in the best position to determine what requirements best fit their delivery system. One commenter noted that limiting the notification requirement to only one group of high-risk full-benefit dual eligible individuals would not meaningfully advance coordination efforts. Another commenter believed that the proposed requirement does not ensure both the state and D–SNP will be engaged in discharge planning in a way that ensures timely access to the most appropriate and cost effective benefits. One commenter expressed a belief that this requirement puts the state in the middle of communication between the D–SNP and enrollee's care team. Another commenter questioned whether states would utilize the information provided in the notifications. Several commenters also questioned what would happen to D–SNPs if a state was not interested in participating in the notification requirement.

Response: These commenters raise important points about our proposed notification requirement. However, we believe the requirement strikes an appropriate balance among incentivizing further integration for states and D–SNPs, limiting the administrative burdens for states and MA organizations, and ensuring flexibility in implementation to fit the needs of each state's policy environment. In addition to the notification requirement, we note that—as discussed in sections II.A.2.a.(1) and II.A.2.b.(1) of this final rule—we are also establishing through this rulemaking an explicit requirement at § 422.2 that D–SNPs coordinate dual eligible individuals' Medicare and Medicaid benefits, as well as a requirement that D–SNPs provide assistance with Medicaid appeals and grievances at § 422.562(a)(5). In implementing the statute by establishing the notification requirement, we incentivize not only D–SNPs, but also the states with which they must contract, to make incremental progress in coordinating care for dual eligible individuals. By design, the notification requirement gives the state Medicaid agency broad latitude to establish notification procedures and protocols that are within the state's capacity and consistent with the state's needs and integration goals. We believe this requirement is scalable for D–SNPs and states where no coordination activity is currently taking place. We also point to the flexibility within the notification requirement for the state to designate another individual or entity to receive the notification, therefore allowing for the timeliest action following a care transition or other significant event.

Comment: Several commenters supported the flexibility in the proposed notification requirement for the state to designate other individuals or entities to receive notification of an admission. These commenters believed that collection of this information at the state level may not be the most appropriate or useful approach. One commenter noted that Tennessee's approach, which requires D–SNPs to notify a Medicaid provider of hospitalizations and emergency department visits, better achieves the goal of improved coordination of services than a notification to the state. Another commenter requested that CMS modify the notification proposal by requiring that the beneficiary's unaligned Medicaid MCO also be notified of any admissions for beneficiaries that receive LTSS or behavioral health services.

Response: We appreciate the commenters' support for the flexibility afforded to states to designate other individuals or entities to receive notification of an admission in our proposal. We agree that in some markets, providers and other entities, such as a Medicaid MCO, may be better able to use admissions information to timely coordinate care for a beneficiary. We do not agree that CMS should finalize the regulation to require D–SNPs to notify MCOs specifically of inpatient admissions, however, but note that such delegation is already permissible under § 422.107(d). We defer to states to establish when and to whom the notification is appropriate to best achieve integration and improve outcomes for dual eligible individuals, based on how the state operates its Medicaid program.

Comment: Several commenters expressed concern that our proposed language allowing a D–SNP to authorize another entity or entities, such as the D–SNP's network providers, to notify the state Medicaid agency of inpatient admissions would create significant burden for providers. However, one commenter also acknowledged that notifications would be timelier if originated by providers. One commenter recommended removing this language from the regulatory text, while a few other commenters recommended that CMS provide guidance and provider education about the requirement. Another commenter noted that states and D–SNPs are dependent on prompt and complete claims submissions from hospitals and SNFs to achieve better care coordination and emphasized the importance of provider education about these requirements to ensure the flow of this information.

Response: In our proposed notification requirement, we provided flexibility to allow for transmission of information about hospital and SNF admissions in multiple ways because we believe the most efficient and effective processes may vary by state and evolve over time. In some cases, this might include reporting by providers and providing information to specific providers to aid in care coordination. However, our proposed requirement places the ultimate responsibility on D–SNPs and does not directly require actions by providers. When developing notification processes to meet our regulatory requirements, we expect that states and D–SNPs will consider any potential impacts on providers.

Comment: Several commenters requested that CMS provide states with technical assistance and disseminate best practices related to the notification requirement both to facilitate the contracting process and to ensure that a sufficient degree of coordination is achieved to promote successful transitions of care. These commenters' requests particularly focused on the need to develop data exchange technology, systems, and processes to achieve successful transitions of care. One commenter recommended CMS provide states with parameters for implementing the state contracting requirements to mitigate operational burden on D–SNPs while supporting implementation. Another commenter recommended CMS seek assistance from a group of plan and state stakeholders in developing this guidance and best practice models.

Response: We agree with these commenters that support for states will improve the implementation of the requirements of this final rule. As stated earlier in this final rule, the Medicare-Medicaid Coordination Office provides technical assistance to states on integration issues, including through the Integrated Care Resource Center (see

https://www.integratedcareresourcecenter.com/). We are committed to continuing our work with states to gather and disseminate best practice information and to engage stakeholders to ensure a successful implementation.

Comment: Several commenters requested that CMS establish clear guidelines and standardized formats for the proposed notification requirement, including methods, content, and timeframes for notification. One commenter requested clarification with respect to how high-risk populations should be defined. Another commenter recommended requiring that states include functional ability in their definitions of high-risk populations. A few commenters expressed concern that variation in how this requirement is implemented across states will be costly and time consuming, leading to potential problems in implementing the requirement effectively. Some commenters expressed interest in uniform requirements in order to reduce administrative burden for plans that operate in multiple states. One commenter noted that standardization of data exchange will contribute to the value of the data for benchmarking and quality improvement activities.

Response: As discussed earlier in this preamble, we intend that the proposed notification requirement provide states with discretion to develop solutions consistent with their particular policy and operational environments. We believe that a more prescriptive notification requirement would ultimately be counterproductive for both states and D–SNPs by limiting the development of solutions appropriate to each market. Regardless of the approach a state chooses to take under this final rule, our aim is to have actionable information that enables providers and payers to facilitate seamless care transitions for high-risk populations, that is, those full-benefit dual eligible individuals who are most likely to benefit from effective interventions (such as through the provision of LTSS and behavioral health services) that enable them to live independently in the setting of their choice and in a way that values their own needs and preferences. As we gain more experience with the implementation of the notification requirement in this final rule, we will share best practices and continue to provide technical assistance and guidance to states and D–SNPs.

Comment: Several commenters requested that CMS do more to establish a data-sharing system to facilitate the proposed notification requirement, citing limited ability for some states to implement data sharing mechanisms. Some commenters noted that a unified system to share data should be used by states, D–SNPs, providers, and beneficiaries. One commenter expressed support for the proposed notification requirement serving as a starting point for a robust two-way health information exchange system between D–SNPs and states to share data on dual eligible individuals' utilization of Medicare and Medicaid services. Another commenter recommended that CMS encourage states to build on current data collection and sharing efforts, such as health information exchanges (HIEs). Some commenters recommended specific data exchange solutions, such as building on the Blue Button 2.0 Framework or modifying the Transformed Medicaid Statistical Information System (T–MSIS).

Response: We believe it is most appropriate at this time to defer to state Medicaid agencies on the manner in which notification occurs and how data be exchanged. For example, in markets where there is existing infrastructure to leverage, such as a state HIE, a state may elect an approach that requires data sharing across a common platform using industry standards, including those adopted by the Office of the National Coordinator for Health IT in accordance with 45 CFR part 170, subpart B. Regardless of process, we expect that notifications occur timely in order to ensure prompt care coordination and effective care transitions. To that end, we encourage states and D–SNPs to use the most efficient notification mechanisms available, which may include the state's HIE. However, we appreciate that not every state is similarly positioned, and, therefore, if a state elected to implement this requirement on a smaller scale, targeting a small subset of high-risk beneficiaries, a solution that does not initially require automation may be more appropriate and pragmatic. We reiterate that the notification requirement we are finalizing in this rule is a first step towards improved data exchange and integration. As health information technology advances and industry standards for data exchange are established, it may be feasible to establish or leverage a standardized data-sharing system.

Comment: One commenter requested direction on how to implement the proposed notification requirement in states like Washington where high-risk dual eligible individuals are enrolled in a health home under demonstration authority.

Response: As noted previously, our final requirement at § 422.107(d) provides broad latitude to each state to determine the subset of high-risk D–SNP enrollees subject to the notification requirement. The regulation, as proposed and finalized, requires that the enrollees for which the notification must be made must be at least one group of full-benefit dual eligible and high-risk. The state is not required to specify all high-risk dual eligible individuals for this group so long as the identification of the group is consistent with the regulation's requirements.

Comment: Several commenters questioned the impact the proposed notification requirement will have on notification systems and the robust reporting requirements already in place in several states. One commenter noted that the proposed requirement would duplicate the software program currently used by Washington in which hospitals enter admissions and emergency department visit information for other providers and case managers to view. Another commenter expressed concern that the language requiring a D–SNP to notify or authorize another entity to notify a state agency may not accommodate the current Oregon Health Information Technology System, which creates a notification of admission without the D–SNP's action. This commenter recommended changing our proposed regulatory language to ensure this type of notification system meets our notification requirement such that D–SNPs would not be required to repeat a duplicate notification.

Response: We appreciate that states have different and evolving infrastructure and policies, including mandatory data sharing requirements. The notification requirement we are finalizing in this rule is not intended to impact such existing requirements, and states may continue to require additional notifications or other data sharing consistent with their state Medicaid agency contracts. We thank the commenters that raised specific operational scenarios where HIEs or other notification systems are currently in place and could be leveraged for purposes of satisfying our notification requirement. In this final rule, we are modifying the verbs used to describe the D–SNP's obligations in § 422.107(d) to clarify those responsibilities; as finalized, the D–SNP notifies or arranges for another entity to notify (instead of ''will notify or authorize another entity'' as proposed) the state Medicaid agency of hospital and SNF admissions for at least one group of high-risk full-benefit dual eligible individuals, as identified by the state Medicaid agency. We believe the phrase ''arrange for'' provides more flexibility to encompass arrangements such as those described by

the commenters. Thus, for example, a D–SNP could meet the notification requirement by arranging for another entity—for example, a hospital—to notify the state Medicaid agency or its designee when the various parties participate in an HIE or other notification system.

Comment: Several commenters raised concerns about D–SNPs' ability to fully comply with our proposed revision to § 422.107(c)(1), which codifies a requirement for D–SNPs to document their responsibility to coordinate the delivery of Medicaid benefits for their enrollees, as well as our proposed notification requirement at 422.107(d), citing potential barriers imposed by the Health Insurance Portability and Accountability Act of 1996 and 42 CFR part 2, with respect to sharing information that would allow D–SNPs to effectively coordinate and share information about behavioral health services. One commenter cited 42 CFR part 2 as preventing covered entities from effectively coordinating behavioral health services when the need for such services involves substance abuse treatment and the D–SNP cannot obtain member consent, and urged CMS to consider ways to address this issue and allow for coordinating and sharing of data without the need for written consent. Another commenter suggested that CMS work with the Office for Civil Rights and the Substance Abuse and Mental Health Services Administration on this issue.

Response: These commenters have raised important issues with respect to care coordination for individuals with substance use disorder. This final rule does not change or eliminate current requirements for D–SNPs to comply with HIPAA and 42 CFR part 2. We clarify that the requirements finalized in this rule, including the requirement codified at § 422.2 that a D–SNP coordinate Medicare and Medicaid benefits and the requirement at § 422.107(d) requiring notification of high-risk enrollee inpatient and SNF admissions, must be implemented in a way that complies with all applicable laws. As a result, we acknowledge there are limitations to D–SNPs' ability to notify states of certain inpatient admissions for high-risk enrollees with substance use disorder, as well as to their ability to coordinate these individuals' care, absent member consent for the disclosure of such information. When establishing the notification requirement in the state Medicaid agency contract, we encourage states to collaborate with D–SNPs to identify and address concerns regarding compliance with other statutes and regulations, including HIPAA and 42 CFR part 2.

Comment: Some commenters requested additional requirements for state Medicaid agency contracts between states and D–SNPs. One commenter stated that the proposed contracting requirements at § 422.107 would better meet CMS's stated goals if they were more prescriptive. Several commenters recommended additional contracting requirements to those in the proposed rule, while one commenter requested that CMS refrain from adding more contract requirements until after the implementation of the notification requirement finalized in this rulemaking. Some commenters recommended that CMS require states and D–SNPs to develop a process for coordinating Medicaid-funded services, such as LTSS and behavioral health services. One commenter recommended requiring D–SNPs to annually submit a plan for coordinating Medicaid LTSS and behavioral health services for approval by the state. A few commenters suggested requiring improved information sharing regarding Medicaid provider participation and enrollees' Medicaid and Medicare eligibility. One commenter noted that additional contracting requirements may ease administrative burdens and promote further integration and recommended that CMS clearly define minimum coordination requirements and establish uniform language and definitions.

Response: We appreciate the suggestions for modifications or additions to the state Medicaid agency contract requirements for D–SNPs currently codified at § 422.107. We are not finalizing any additional substantive changes to § 422.107 in this final rule beyond those discussed in our proposed rule. However, we will continue to evaluate D–SNPs' progress toward achieving a minimum level of integration as intended under the Bipartisan Budget Act of 2018 to determine whether additional contracting requirements might be necessary in the future. As discussed in various places in this final rule, states retain the ability to add more stringent contracting requirements in their state Medicaid agency contracts with D–SNPs in order to best achieve their specific policy goals and meet the needs of their population of dual eligible individuals.

Comments: Several commenters recommended that CMS consider new incentives that would enhance integration, such as an increase to the Federal Medical Assistance Percentage (FMAP) rate for activities related to Medicare-Medicaid integration, including for investments in state data-sharing systems and infrastructure. One commenter noted that requiring or incentivizing states to assist D–SNPs in the development of such administrative processes to assist with integration efforts would prevent states from shifting this responsibility to D–SNPs.

Response: We agree that state investments in additional data-sharing or other administrative processes may facilitate D–SNP efforts to implement the notification requirement, but also more broadly to better coordinate Medicare and Medicaid coverage. As discussed in the Collection of Information section of this final rule, we estimate that half of the cost of developing infrastructure and processes to implement the proposed notification requirement would be offset by federal financial participation for Medicaid administrative activities. However, increases to FMAP rates are beyond the scope of this rulemaking.

Comment: A few commenters supported the alternative we noted for consideration that would apply the notification requirement to all full-benefit dual eligible individuals enrolled in the D–SNP, and not just a subgroup of high-risk individuals. These commenters cited improved access to Medicaid benefits that promote care in the least restrictive environment as the reason to support the broader requirement. Another commenter requested that we establish a minimum size for the state-selected high-risk population, another alternative CMS noted for consideration in the proposed rule. This commenter noted that factors such as minimum population size impact the feasibility of implementation of this provision and would mitigate operational burden for health plans.

Response: We appreciate the commenters' requests for a broader notification requirement, but we believe that limiting the notification requirement to high-risk individuals in this final rule is preferable. Research suggests that targeting high-risk individuals is critically important to cost-effective interventions.[20] In addition, all states have some care management infrastructure for high-risk individuals in their Medicaid programs, such as through Medicaid 1915(c) HCBS waivers.[21] The notification provision at

[20] Brown, R.S., Peikes, D., Peterson, G., Schore, J. & Razafindrakoto, C.M., (2012). ''Six Features of Medicare Coordinated Care Demonstration Programs That Cut Hospital Admissions of High-risk Patients.'' *Health Affairs,* 31(6).

[21] *See: https://www.medicaid.gov/medicaid/ltss/health-homes/index.html; https://www.medicaid.gov/medicaid/section-1115-demo/demonstration-and-waiver-list/index.html;* and *Care*

§ 422.107(d) gives state Medicaid agencies the discretion to decide which group of beneficiaries is at high risk and how large or small the group(s) may be. Providing states with such flexibility to define their population of high-risk individuals will allow them to tailor the D–SNP notification requirement to align with existing infrastructure for coordinating and managing care for high-risk individuals. Such targeting will not only limit notifications to those which are most meaningful and actionable for the state, but will also reduce administrative burden and implementation costs.

Comment: One commenter encouraged CMS to require D–SNPs to provide notification of emergency department visits for unaligned D–SNP enrollees receiving LTSS and behavioral health services from fee-for-service Medicaid or an MCO.

Response: We acknowledge the potential benefits of a real-time notification of emergency department visits, but we decline to finalize a broader requirement including notification of emergency department visits at this time. We believe the greatest opportunity to target interventions and improve outcomes is after a hospital or SNF admission where there is more time to initiate discharge planning. However, as noted in the proposed rule, so long as the requirements of § 422.107(d) are met, a state Medicaid agency could choose to require a notification for full-benefit dual eligible individuals enrolled in a D–SNP who are high utilizers of emergency departments, where there may be opportunities to address barriers to accessing primary care and unmet health care needs.

Comment: One commenter recommended that CMS improve person-centered decision making during care transitions by using protocols for communication and coordination similar to interdisciplinary team models or California's guidance for MMPs on hospital discharge planning.

Response: We appreciate the commenter's suggestion and will consider this input as we develop technical assistance and identify best practices following the implementation of this final rule.

Comment: One commenter expressed support for state flexibility in determining the timeline for the notification, while several commenters expressed concerns about the lack of a specific timeliness requirement. Several commenters requested that CMS require a specific timeframe for reporting. A few commenters believed that the 48-hour requirement discussed in our proposed rule preamble as an alternative for consideration was reasonable and synchronized well with requirements for discharge notices. One commenter suggested that CMS ensure that any timeframes imposed by states begin after the health plan has received the admissions data. A few commenters expressed concern that the notifications would not be timely and therefore would not be helpful in care coordination. One commenter requested that CMS clarify its intent for requiring states to collect this admissions information.

Response: We appreciate comments on the timing and timeliness of the notification requirement. We believe that states may choose to use the notification for a variety of purposes, including coordination of care at the point of hospital or SNF discharge. When establishing a timeframe, we encourage the states to consider the current process for how D–SNPs in their markets receive admissions information to reduce burden on D–SNPs and their provider networks. Because these processes vary by state, we are not inclined to specify timing requirements for these notifications at this time. However, we may consider a timeliness standard in future rulemaking based on our experience implementing the provisions of this final rule.

Comment: Several commenters expressed support for the alternative we noted for consideration in the proposed rule that would establish requirements for coordination of individual health needs or risk assessments between D–SNPs and Medicaid MCOs. These commenters generally recommended that CMS encourage, but not require, D–SNPs to make every effort to coordinate the assessment due to concerns about feasibility. A few commenters noted that coordination could result in delays in administering the assessment. One commenter noted that guidelines for the coordination of assessments would be more appropriate in subregulatory guidance or state contracts, rather than as a regulatory requirement. Another commenter requested that CMS consider requiring D–SNPs to share assessment findings with coordinating plans. One commenter noted this could be an area for future integrated requirements for exclusively aligned plans.

Response: We agree with commenters' concerns regarding the feasibility of coordinating individual health needs or risk assessments. We believe the pervasiveness of this issue and the extent of overlap in assessment instruments varies across state lines and requires further study. We are therefore declining to add this requirement to D–SNP state Medicaid agency contract requirements at § 422.107 at this time.

Comment: One commenter supported requiring that D–SNPs identify and notify states of enrollees in need of LTSS or behavioral health services to promote care coordination and improve outcomes.

Response: We thank the commenter. Although we considered this alternative in the proposed rule, we note that D–SNPs are already required, at § 422.101(f), to develop individualized care plans and perform health risk assessments that identify the physical, psychosocial, and functional needs of each SNP enrollee. Additionally, D–SNPs have the responsibility to coordinate the delivery of Medicare and Medicaid services consistent with the D–SNP definition at § 422.2 finalized in this rule. We do not believe the burden associated with an additional requirement to proactively identify for the state enrollees in need of LTSS or behavioral health services is advisable given the potential overlap with these existing requirements. We are therefore not modifying our proposed notification requirement to include notification of enrollees in need of LTSS or behavioral health services.

Comment: A few commenters supported the alternative CMS considered in the proposed rule that states provide input on the plan's model of care, health risk assessment instrument, and beneficiary communication materials. One commenter noted this requirement would ensure that states stay active in their role as health insurance regulators and that beneficiary materials have correct state-specific information.

Response: We thank commenters for their input, but we remain disinclined to impose such a requirement on D–SNPs that do not have exclusively aligned enrollment. We believe this requirement would create additional burden for states without capitated arrangements with D–SNPs for the provision of Medicaid services, as Medicaid agencies may not see a role for themselves in reviewing such documents. We note that state Medicaid agencies can choose to require that a D–SNP provide such documents for state input through their contracts with D–SNPs, and that—as discussed earlier in this preamble—CMS has worked with several states with integrated D–SNPs to develop more streamlined and

Coordination in Managed Long-Term Services and Supports (2015, July), prepared for AARP by Truven Health Analytics. Retrieved from: *https://www.aarp.org/content/dam/aarp/ppi/2015/care-coordination-in-managed-long-term-services-and-supports-report.pdf.*

integrated beneficiary communications materials.

Comment: A few commenters supported additional or alternative data-sharing requirements for D–SNPs to comply with the statutory requirements for integration. One commenter requested that CMS provide any existing analysis on whether the notification of an admission to a hospital or SNF is more beneficial than sharing other information, such as enrollment information and care coordination contacts.

Response: While there may be additional or different requirements that would facilitate D–SNPs' integration of Medicare and Medicaid benefits, we are choosing to initially focus on a notification requirement for hospital and SNF admissions, which we believe will lead to more immediate improvements in the care transition process, while preserving state and plan flexibility and minimizing burden. After we gain sufficient experience in implementing the notification requirement we are finalizing in this rule, we will assess whether changes are necessary to achieve additional integration.

Comment: A few commenters supported inclusion of a requirement, consistent with the example included in section 1859(f)(8)(D)(i)(I) of the Act that a D–SNP demonstrate its integration of Medicare and Medicaid benefits by assigning one primary care provider for each enrollee. One commenter requested clarification as to why this specific requirement was not included in the proposed rule, noting that the primary care provider is the coordinator of the beneficiary's entire spectrum of care and a critical liaison between the beneficiary and the plan.

Response: We agree with the commenter's statement about the importance of a primary care provider, but we decline to require D–SNPs to assign a primary care provider for each enrollee as a minimum standard for integration. We considered the value of such a requirement but were unable to determine how meaningfully it would advance integration. We also note that, consistent with § 422.112(a)(2), all MA organizations offering an MA coordinated care plan, including those offering D–SNPs, must establish a panel from which an enrollee may select a primary care provider and are permitted to assign a primary care provider in limited circumstances. We are concerned that establishing a primary care provider assignment requirement may conflict with enrollee choice provisions at § 422.112(a)(2).

Comment: One commenter supported a requirement that D–SNPs submit to the state Medicaid agency the name and contact information for their designated care coordinators.

Response: We appreciate this suggestion but decline to make this change to our regulatory requirements at this time due to the burden on D–SNPs provide and update this information and on states to meaningfully use this information. We will consider this suggestion for future rulemaking.

Comment: One commenter recommend that CMS establish data reporting requirements that address integrated care and incorporate LTSS, such as requiring reporting of quarterly care coordination and LTSS referral data.

Response: We thank the commenter and will consider this suggestion for future rulemaking.

Comment: One commenter requested clarification on whether CMS intended for the notification requirement to include discharges as well as admissions.

Response: We chose to focus on notification of admissions to allow states to initiate care coordination activities prior to discharge. Our proposal deliberately did not address discharges due to concerns that care coordination activities would not be timely if they begin after a discharge takes place. However, we note that states are not precluded from adding a notification requirement for discharges through the state Medicaid agency contracts with D–SNPs under § 422.107.

Comment: One commenter recommended that CMS stop new enrollment into D–SNPs that are not contracted by the state to provide Medicaid benefits, and that CMS also require these D–SNPs to establish meaningful and timely data exchange and coordination processes with the state or MCOs for existing beneficiaries to ensure timely access to Medicaid benefits.

Response: We believe that the commenter's recommendation goes beyond section 1859(f)(8)(D)(i)(I) of the Act, which envisions a pathway for D–SNPs to remain an option in states that do not pursue a selective contracting model, subject to additional integration requirements established by CMS in this final rule. We will, however, continue to assess opportunities to promote greater levels of aligned enrollment. We note that states may establish additional requirements for data exchange and coordination in their state Medicaid agency contracts with D–SNPs.

Comment: A few commenters requested exceptions to the notification requirement. One commenter requested clarifications on possible exemptions for some non-integrated D–SNPs. Another commenter recommended that D–SNPs providing some Medicaid services, but not providing LTSS or behavioral health services, be recognized as more integrated than plans that do not provide any Medicaid services and therefore be allowed additional flexibility on the data elements D–SNPs are required to share with the state.

Response: Section 1859(f)(8)(D)(i)(I) of the Act is clear that D–SNPs that do not (i) meet the requirements of a FIDE SNP nor (ii) enter into a capitated contract with the state Medicaid agency to provide LTSS, behavioral health services, or both, must meet additional criteria for integration; CMS is establishing those criteria in this final rule. We are therefore unable to exempt D–SNPs that do not meet the definitions of either a FIDE SNP or a HIDE SNP established in this final rule from the notification requirement. We will consider the utility of establishing additional granularity with respect to D–SNP integration levels but note that such additional granularity is not relevant to D–SNPs' compliance with the statutory provisions regarding D–SNP integration.

Comment: One commenter requested that CMS extend the proposed D–SNP notification requirements to FIDE SNPs and HIDE SNPs when the affected member is not receiving all Medicaid services through the SNP.

Response: We appreciate the commenter's suggestion to hold FIDE SNPs and HIDE SNPs to the same standard as other D–SNPs required to comply with the notification requirement for their unaligned members. However, we believe that most FIDE SNPs and HIDE SNPs already demonstrate a level of Medicare-Medicaid integration through the provision of Medicaid benefits through a capitated arrangement with the state Medicaid agency, such that exchanging admission data about specified high-risk dual eligible enrollees would have less impact relative to the costs of compliance. We decline to accept the commenter's recommendation, as we believe it would be burdensome for plans that already provide a higher level of integration than plans that provide few or no Medicaid benefits to their enrollees. As discussed in section II.A.2.a.(1) of this preamble, we note that FIDE SNPs and HIDE SNPs are also required to coordinate their coverage with their members' Medicaid benefits.

Comment: Several commenters supported our proposal at § 422.107(c)(2) that the contract between

the D–SNP and the state Medicaid agency document not only the categories of dual eligible individuals who may enroll in the D–SNP but also any additional criteria of eligibility.

Response: We appreciate the commenters' support and are finalizing this provision without modification.

Comment: Several commenters supported our proposed change to § 422.107(c)(3) that would require the contract between the D–SNP and the state Medicaid agency to document the Medicaid services the D–SNP is responsible for covering in accordance with a capitated contract with the D–SNP either directly or through a companion Medicaid managed care organization operated by the D–SNP's parent organization. One of these commenters specifically noted that the revised contract requirement may help CMS achieve greater consistency in determining whether a D–SNP is a FIDE SNP or a HIDE SNP. A few commenters recommended that the D–SNP's state Medicaid agency contract also include a list of all Medicaid covered services, but specifically identify those covered by the D–SNP. One commenter recommended that in cases where the state Medicaid agency contract encompasses all the requirements in § 422.107 as amended and already clearly distinguishes between plan covered and non-covered Medicaid benefits, a separate document duplicating this information should not be required. Another commenter requested clarification regarding the intent of this provision, citing concerns that CMS' intent could be misconstrued as requiring D–SNPs to offer Medicaid benefits under a capitated contract with the state.

Response: We thank commenters for their support of this revised contracting requirement for D–SNPs. We decline to accept the recommendation that the state Medicaid agency contract also include a list of all Medicaid-covered services, including those not covered by the D–SNP or an affiliated MCO. We believe this change to the current contracting requirement will reduce burden on D–SNPs to identify and document in the contract every Medicaid-covered service. D–SNPs often submit to CMS a list of all Medicaid services in their state Medicaid agency contracts, even those for which the D–SNP is not under a capitated contract and for which the D–SNP bears no risk. We clarify that our modified requirement does not impact current processes for state Medicaid agency contract submission and approval. We also clarify that this provision in no way precludes a D–SNP that does not provide any Medicaid services—and otherwise meets all relevant regulatory requirements—from continuing to contract with CMS to operate as a D–SNP. We are also simplifying the language at § 422.107(c)(3) to ensure all potential variations of D–SNP contracting arrangements to cover Medicaid services are documented in the state Medicaid agency contract. Specifically, we are revising the requirement such that the D–SNP must document any Medicaid benefits covered by the MA organization offering the D–SNP, whether under a capitated contract with the state Medicaid agency, by the D–SNP's parent organization, or by another entity that is owned and controlled by its parent organization.

After consideration of the comments we received, we are finalizing our proposed amendments to § 422.107(b) as proposed. We are finalizing our proposed amendments to § 422.107(c)(1), (c)(2), (c)(3), (d) and (e)(2) substantively as proposed but with some minor modifications from the proposal.

- We are making a technical, non-substantive change to replace the term ''dual-eligible'' with the term ''dual eligible'' in paragraph (a), which is consistent with the revision to the section heading for § 422.107 in the proposed and final rules.
- As discussed in section II.A.2.a.(1) of this final rule, to better align with our final definition of a D–SNP, we are finalizing the regulation with a new paragraph (c)(1)(i) to clarify that the D–SNP must document its responsibility to coordinate the delivery of Medicaid benefits for individuals who are eligible for such services, and a new paragraph (c)(1)(ii) to clarify that, to the extent a D–SNP provides coverage of Medicaid benefits—including LTSS and behavioral health services—for individuals eligible for such services, it must also document in the state Medicaid agency contract its responsibility to do so.
- As proposed with minor grammatical corrections, we are finalizing paragraph (c)(2) to require the contract to document the categories and criteria for eligibility for dual eligible individuals to be enrolled under the SNP, including as described in sections 1902(a), 1902(f), 1902(p) and 1905 of the Act.
- We are finalizing paragraph (c)(3) with revisions to clarify the requirement of the contract such that the D–SNP must document any Medicaid benefits covered under a capitated contract between the state Medicaid agency and either: (1) The MA organization offering the D–SNP; (2) the D–SNP's parent organization; or (3) the another entity that is owned and controlled by the D–SNP's parent organization.

In addition, as discussed in section II.A.2.b.(2) of this final rule, we are finalizing new text in a new paragraph (c)(9) to address the requirement under section 1859(f)(8)(C) of the Act that contracts between D–SNPs that are applicable integrated plans, defined in § 422.561, and the state Medicaid agency require the use of unified grievance and appeals procedures.

- We are finalizing paragraph (d) with modifications to the regulatory text clarifying the responsibility of a D–SNP with the phrase ''the SNP notifies or arranges for another entity or entities to notify . . .'' in place of the proposed text ''the SNP will notify or authorize for another entity or entities to notify . . .'' and making edits to clarify that states can require D–SNPs to send notification of an admission to the state, individuals or entities designated by the state, or both.
- Lastly, we are finalizing paragraph (e)(2) as proposed and with a citation to paragraph (c)(9) as well as paragraph (d) to clarify that this state Medicaid agency contracting requirement is applicable beginning January 1, 2021.

(3) Conforming and Technical Changes (§§ 422.60(g), 422.102(e), 422.107(b), and 422.111(b)(2)(iii))

In the proposed rule, we also proposed to make the following conforming changes to several sections of Part 422 that address D–SNPs by adopting consistent terminology with respect to dual eligible individuals and creating cross-references to the newly proposed definitions.

- First, at § 422.60(g), which addresses CMS authority to implement passive enrollment, we proposed to use the term ''highly integrated dual eligible special needs plan'' in place of text referring to D–SNPs that meet a high level of integration, consistent with our proposed definition in § 422.2. As discussed in the proposed rule, this technical change would not materially change the plan types that are eligible for passive enrollment; the existing rule simply refers to them as D–SNPs that meet a high standard of integration under the supplemental benefits authority at § 422.102(e).
- Second, we proposed clarifying at § 422.102(e) that not only HIDE SNPs meeting minimum quality and performance standards are eligible to offer supplemental benefits, but FIDE SNPs that similarly meet minimum quality and performance standards may do so as well.

• Third, in the general rule at § 422.107(b), we proposed to substitute a ''special needs plan serving beneficiaries eligible for both Medicare and Medicaid (dual-eligible)'' with ''dual eligible special needs plan.''

• Finally, at § 422.111(b)(2)(iii), which requires D–SNPs to provide written information to dual eligible enrollees about their eligibility for cost-sharing protections and Medicaid benefits, we proposed to use the term ''dual eligible special needs plan'' consistent with the proposed definition.

We received the following comments and our responses follow.

Comment: One commenter noted their appreciation of our proposed clarification at § 422.102(e) that both FIDE SNPs and HIDE SNPs meeting minimum quality and performance standards are eligible to offer supplemental benefits. Another commenter requested that we clarify that current flexibilities with respect to supplemental benefits will continue for all FIDE SNPs and HIDE SNPs. Several commenters requested that CMS provide additional guidance about the supplemental benefits HIDE SNPs and FIDE SNPs may offer, noting recent regulatory changes that provide flexibility in the Medicare Advantage uniformity requirements and expand the definition of ''primarily health related'' benefits, as well as new requirements in the Bipartisan Budget Act of 2018 that provide additional benefit flexibility for chronically ill enrollees.

Response: We appreciate the commenters' support for the technical change we proposed at § 422.102(e), and we clarify that this conforming change does not impact current policy related to supplemental benefits for HIDE SNPs and FIDE SNPs. While we appreciate the complexities of recent legislative and regulatory changes related to permissible Medicare Advantage supplemental benefits and the need for clear guidance that several commenters raised, those comments are outside the scope of this regulation. For more information regarding newly expanded supplemental benefit offerings and flexibilities for all MA plan types, please refer to the CY 2019 and CY 2020 Call Letters.[22] We are therefore finalizing our changes to § 422.102(e) as proposed.

After consideration of the comments we received, we are finalizing § 422.102(e) without modification. We received no comments on our proposed conforming changes to § 422.60(g), the general rule at § 422.107(b), and § 422.111(b)(2)(iii) and are also finalizing those provisions without modification.

(4) Eligibility of Partial-Benefit Dual Eligible Individuals for Dual Eligible Special Needs Plans

The preamble to our proposed rule included discussion about an alternative we considered to propose limits on the enrollment of partial-benefit dual eligible individuals in D–SNPs, since there are no Medicaid services that the D–SNP is integrating or coordinating on their behalf. While we ultimately decided against proposing any such limits on enrollment in the proposed rule, we invited comments on this topic. We received the following comments, and our responses follow.

Comment: Several commenters suggested that CMS establish prohibitions on the enrollment of partial-benefit dual eligible individuals in D–SNPs. A few commenters suggested establishing separate D–SNPs exclusively for partial-benefit dual eligible individuals whose primary focus would not be on integrating Medicare and Medicaid benefits but rather on caring for a more complex population than a traditional MA plan.

MedPAC opined that D–SNPs can do little to promote greater integration for partial-benefit dual eligible individuals and noted that, based on their analysis of person-level quality data from HEDIS, D–SNPs perform about the same as regular MA plans for this population. MedPAC noted the greater likelihood of D–SNPs offering supplemental benefits attractive to partial-benefit dual eligible individuals than other MA plans. Consistent with its June 2018 report to the Congress and at its November 2018 meeting, the Commission described two potential ways of pursuing greater levels of integration: (1) Limiting enrollment in D–SNPs to dual eligible individuals who qualify for full Medicaid benefits or (2) requiring MA plan sponsors to have separate D–SNPs (distinct plan benefit packages) for full-benefit and partial-benefit dual eligible individuals.

A number of commenters opposed any limits on the enrollment of partial-benefit dual eligible individuals in D–SNPs, however. These commenters cited various rationales for the value of these beneficiaries' enrollment in D–SNPs, including the relative medical complexity of partial-benefit dual eligible individuals compared to non-dual eligible individuals; the value of the D–SNP care model, including additional care coordination, Medicare benefits, navigation assistance, individual health risk assessments, care plans, and interdisciplinary care teams; the propensity for churn between various dual eligibility categories and the value of D–SNPs in facilitating movement to full benefit dual eligibility status; and the potential for additional value for this population through new supplemental benefits flexibilities implemented by CMS that might prevent the need for medical spend-down to full benefit dual eligibility status. Several commenters recommended that CMS defer to states on defining eligibility requirements for D–SNPs. Another commenter noted that Congress did not explicitly instruct CMS to prevent partial-benefit dual eligible individuals from accessing D–SNPs. One commenter noted the variance in eligibility requirements for partial-benefit dual eligibility across states. One commenter recommended that CMS consider administrative changes to resolve the complexities related to integration presented by this population—for example for member materials and appeals and grievances.

A few commenters requested that, to the extent CMS continues to permit the enrollment of partial-benefit dual eligible individuals in D–SNPs, D–SNPs should be required to show how they will meet the needs of these enrollees a way that is distinct from the benefits that a non-D–SNP MA plan would offer, and that CMS measure and evaluate these additional benefits. These commenters also recommended that CMS place marketing restrictions on D–SNPs so they cannot primarily target partial-benefit dual eligible individuals, who may have lower acuity and less significant health care needs than full-benefit dual eligible individuals, and to carefully monitor enrollment patterns.

Response: We thank the commenters for the feedback on this issue. As we stated in the proposed rule, we continue to question the benefit that partial-benefit dual eligible individuals derive from their enrollment in a D–SNP relative to the challenges associated with allowing such enrollment. Although we did not propose, and therefore are not finalizing, any changes to how partial-benefit dual eligible individuals may enroll in D–SNPs, we share many of the concerns articulated by some comments, including those of MedPAC. CMS may consider future rulemaking in this area.

Comment: A commenter pointed to the definition of a D–SNP in the statute as limiting enrollment to only those ''special needs individuals who are entitled to medical assistance under a State plan under XIX of the Act'' and requested confirmation from CMS that we discontinue enrollment of partial-

[22] See *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html.*

benefit dual eligible individuals in D–SNPs when there is no Medicaid benefit they can coordinate for those enrollees.

Response: We note that neither the MA statute nor current MA regulations prohibit the enrollment of partial-benefit dual eligible individuals in D–SNPs, although states may choose to do so through their contracts with D–SNPs. We are not finalizing any change in that policy in this final rule.

Comment: A commenter recommended that CMS consider granting eligibility for Qualified Medicare Beneficiaries to enroll in MA-only D–SNPs and requested that reimbursement rates for such enrollees be structured to accurately reflect the resources needed to adequately provide care to such complex populations.

Response: We note that these comments are somewhat outside the scope of our proposed rule. Further, D–SNPs must provide Part D prescription drug coverage, pursuant to § 422.2, as part of a comprehensive Medicare benefit package; therefore, D–SNPs may not offer MA-only coverage. In response to concerns about the accuracy of the CMS-Hierarchical Condition Category (HCC) risk adjustment model for predicting costs of dual eligible individuals, CMS analyzed how well the model performs for various types of beneficiaries. As a result of this analysis, CMS implemented significant changes to the HCC model in CY 2017.

(5) Suspension of Enrollment for Non-Compliance with D–SNP Integration Standards (§ 422.752)

Section 50311(b) of the Bipartisan Budget Act of 2018 amended section 1859(f) of the Act by creating a new paragraph (8)(D)(ii) to permit the Secretary, for plan years 2021 through 2025, to impose an intermediate sanction of stopping all new enrollment into a D–SNP if the Secretary determines that the D–SNP is failing to comply with the integration requirements set forth in section 1859(f)(8)(D)(i) of the Act. We proposed to amend § 422.752 by adding a new paragraph (d) to require CMS to impose an enrollment suspension when CMS finds that the plan is non-compliant with the integration requirements during plan years 2021 through 2025, rather than initiating outright termination. We stressed in the proposed rule that we interpreted this proposal as leaving discretion for CMS, if the D–SNP does not submit an acceptable corrective action plan or fails to abide by the correction action plan, to determine that contract termination or other enforcement action or sanction could also be imposed. In addition, in the event that any harm to enrollees is imminent, we explained how we would retain authority to immediately terminate the contract. We also proposed in § 422.752(d) that the suspension of enrollment would continue in effect until CMS is satisfied that the deficiencies that are the basis for the sanction determination have been corrected and are not likely to recur. We stated that the procedures, remedies, and appeal rights available to plans subject to intermediate sanctions provided in § 422.756 apply to D–SNPs that are sanctioned under this new authority.

Comment: Several commenters supported CMS' interpretation of the statute to impose an intermediate sanction to suspend enrollment instead of an immediate contract termination for D–SNPs that fail to meet the integration standards by contract year 2021. A few commenters requested that CMS consider not penalizing D–SNPs when state decisions impede integration or the state does not have the interest and capacity to facilitate D–SNP compliance with the integration requirements. Some commenters recommended that CMS evaluate the implementation of these sanctions in order to make recommendations on how CMS should sanction D–SNPs that do not meet the integration standards beyond 2025. Another commenter provided recommendations, summarized elsewhere in final rule, on how CMS can support and incentivize states to move toward integration.

One commenter agreed with CMS' position that non-compliance with the integration standards should not lead directly to contract termination but noted that the enrollment sanction is at the discretion of CMS. The commenter recommended that CMS not immediately impose an enrollment sanction for minor compliance issues around the integration requirements and, rather, only impose an enrollment sanction for non-compliance that is a serious threat to the health and safety of Medicare beneficiaries and let lesser violations be handled through other compliance actions (notices of non-compliance, corrective action plans, and civil monetary penalties).

Response: We appreciate the overall support for our proposal to require CMS to impose an enrollment suspension when we find a D–SNP to be out of compliance with the integration requirements in the final rule during plan years 2021 through 2025. We disagree with the commenter urging us adopt a standard for imposing an intermediate sanction based only on whether a D–SNP's integration approach is a serious threat to the health and safety of its enrollees. As we discussed in the preamble to the proposed rule, by establishing statutory requirements that established a minimum level of integration of D–SNPs in section 50311 of the Bipartisan Budget Act of 2018, we believe the goal was for beneficiaries enrolled in D–SNPs to receive a greater level of integration of Medicare and Medicaid benefits than is the case under current regulations. Because the Bipartisan Budget Act of 2018 limited the applicability of the Secretary's authority to impose an intermediate sanction on plans that do not comply with the integration requirements to plan years 2021 through 2025, we believe that the intent of this provision is to offer an alternative to outright contract or plan termination for D–SNPs that fail to meet the new integration requirements during the period of 2021 through 2025. With respect to commenters' concerns about penalizing plans, we note that since the authority to impose the intermediate sanction is specific to a D–SNP's non-compliance with the Medicare and Medicaid integration standards finalized in this rule, we intend to consider whether imposition of intermediate sanctions would be most appropriate at the plan, rather than contract, level for each affected Medicare Advantage organization. We expect such determinations to be tied to the facts of each specific situation.

In addition to authorizing this lesser sanction, the statute requires a corrective action plan, which we believe strengthens our interpretation, as it illustrates a preference for ultimate compliance by D–SNPs with the integration requirements. The statute authorizes this lesser sanction but does not require that it be used, leaving it to our discretion whether an enrollment sanction combined with a corrective action plan is sufficient to achieve the goals of the statute. We believe that imposing an intermediate sanction to suspend enrollment establishes predictability for states, beneficiaries, and MA organizations by requiring its imposition for non-compliant plans in lieu of termination or other actions. CMS retains discretion—for example, if the D–SNP does not submit an acceptable corrective action plan or fails to abide by the corrective action plan—to determine that contract termination or other enforcement action or sanction is still possible. In addition, in the event circumstances warrant—for example, when any harm to beneficiaries is imminent—we retain authority to immediately terminate the contract. We

are therefore finalizing our proposal on intermediate sanctions without modification.

As discussed elsewhere in this final rule, CMS is committed to working with stakeholders and providing technical assistance and additional guidance to states and D–SNPs to facilitate compliance with the integration requirements in this final rule. We will evaluate application of our sanction authority and consider any additional changes or clarifications, including with respect to sanctions for those D–SNPs that fail to meet the integration requirements for plan years after 2025.

Comment: One commenter recommended that CMS' imposition of sanctions be delayed until 2023 to accommodate necessary contracting and systems changes. This commenter also recommended that CMS impose sanctions only in states where the state Medicaid agency has successfully integrated with other D–SNPs using the specific integration standards the state has selected. Another commenter urged CMS to consider the integration standards to be met, and an enrollment sanction not required, if the notification language requirement discussed in section II.A.2.a.(2) of this final rule is in the state Medicaid agency contract in 2021, even if not implemented until 2022.

Response: The Bipartisan Budget Act of 2018 specifically allows for the imposition of any enrollment sanctions related to non-compliance with the D–SNP integration standards established in this final rule be applied with respect to plan years 2021 through 2025. In addition, we note that the Bipartisan Budget Act of 2018 requires all D–SNP integration criteria established by CMS to be effective starting for the 2021 plan year. The timing for the publication of the provisions set forth in this final rule in the allows D–SNPs ample opportunity to negotiate with states and address issues requiring changes in the state Medicaid agency contracts prior to the start of the 2021 plan year. Therefore, solely including the notification requirement language in a D–SNP's state Medicaid agency contract without implementing the process as required by that state would render a D–SNP out of compliance with § 422.107(d).

After consideration of the comments we received, we are finalizing our proposal regarding CMS' imposition of intermediate sanctions for non-compliance with D–SNP integration standards without modification.

b. Unified Grievance and Appeals Procedures for Dual Eligible Special Needs Plans and Medicaid Managed Care Plans at the Plan Level (§§ 422.560–562, 422.566, 422.629–634, 438.210, 438.400, and 438.402)

Section 1859(f)(8)(B) of the Act, as added by the Bipartisan Budget Act of 2018, directs the Secretary to establish new procedures that unify, to the extent feasible, Medicare and Medicaid grievance and appeals procedures for D–SNPs. This new authority provides an important opportunity to address an area of longstanding misalignment between the Medicare and Medicaid programs. Medicare and Medicaid grievance and appeal processes have developed independently and operate entirely separately. Medicare's fee-for-service appeals processes (authorized primarily under section 1869 of the Act for Part A and B claims appeals), and MA's processes (authorized under sections 1852(f) and 1852(g) of the Act for grievance and appeal processes) are subject only to federal regulation and oversight as part of the federally-administered Medicare program. Medicaid grievances and appeals are authorized under sections 1902(a)(3) and 1902(a)(5) of the Act for Medicaid programs more generally and section 1932(b)(4) of the Act for Medicaid managed care plans. Unlike Medicare and MA, Medicaid appeals and grievance procedures are subject to both federal and state regulation and are primarily subject to state oversight and administration as part of a joint federal-state financed program. Medicare Part D grievances and appeals are authorized under sections 1860D–4(f) and (g) of the Act and are outside the scope of our authority to unify grievances and appeals under new section 1859(f)(8)(B) of the Act; we note, however, that D–SNPs are all required to provide Part D prescription drug coverage pursuant to § 422.2 (in the definition of a specialized MA plan for special needs individuals), and are therefore subject to the Part D appeals requirements in connection with Part D benefits.

Both the Medicare and Medicaid grievance and appeals systems include regulations establishing procedures for the fee-for-service programs as well as regulations governing managed care plans, including processes at the plan and post-plan levels for adjudicating appeals. Medicare rules are found at 42 CFR part 405 subpart I (general) and part 422 subpart M (Medicare Advantage); Medicaid rules are at 42 CFR part 431 subpart E (general) and part 438 subpart F (managed care). Regulations for the Medicare and Medicaid programs take broadly similar approaches to managed care appeals in that both programs establish a process for resolving a dispute at the plan level initially, followed by an opportunity for post-plan review. However, these appeals systems operate independently with sometimes subtle but important differences related to notices, adjudication timeframes, availability of benefits continuing while the appeal is pending, and levels of review. Similarly, regulations for the Medicare and Medicaid programs take different approaches with respect to some processes for grievances, including filing and adjudication timeframes and the availability of an expedited grievance process.

Although comparatively few beneficiaries file grievances or appeals,[23] these processes are vital safeguards to ensure that beneficiaries' concerns and needs are met promptly. Because of Medicare and Medicaid's misalignments in this area, beneficiaries who are dually eligible for Medicare and Medicaid can face a confusing array of choices when they seek to file a grievance or appeal. They may not know whether their complaint is tied to Medicare or Medicaid, and thus may not know where to direct their grievance. They may be uncertain if the item or service they seek is covered by Medicare, by Medicaid, or potentially by both programs, and thus may not know when or where to file an appeal following the denial of a service. The issue is particularly complicated for items and services such as home health and certain durable medical equipment that are sometimes covered by both programs but under different circumstances.

This confusion for beneficiaries and for those assisting them can result in costly and inefficient duplication of effort, as beneficiaries may file grievances and appeals under both programs when only one was necessary. Health plans and federal and state agencies may incur additional burdens and costs from having to administer parallel appeals systems. Finally, these misalignments may lead to unintended harms in the form of delayed or denied access to needed services as beneficiaries expend time and energy pursuing ultimately fruitless appeals in

[23] For example, in 2016, Medicare Part C plans reported 2.93 complaints (grievances) per 1,000 enrollees per month and 19.3 reconsideration requests (appeals) per 1,000 enrollees per month. See Analysis of Calendar Year 2016 Medicare Part C Reporting Requirements Data, available at *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartCDDataValidation.html.*

one program when they should have been pursuing them in the other.

As summarized in our proposed rule, we have made previous efforts to better align Medicare and Medicaid grievances and appeals for dual eligible individuals, including the integrated initial level of appeal in the Programs of All-inclusive Care for the Elderly (PACE). The operation of Medicare-Medicaid Plans (MMPs) in the CMS' Financial Alignment Initiative capitated model demonstrations has provided us with the most extensive experience integrating grievances and appeals for dual eligible individuals in the managed care setting. Our experience with MMPs suggests that, although implementing a new system can be challenging, once in operation, integrated grievance and appeals systems can be simpler for beneficiaries to navigate than separate systems for Medicare and Medicaid.

Under the newly enacted amendments to section 1859(f)(8)(B) of the Act, the Secretary is required to establish, not later than April 2020 and for inclusion in contracts for D–SNPs for 2021 and subsequent years, procedures unifying grievances and appeals procedures consistent with several principles:

- Under paragraph (8)(B)(ii), the new unified procedures must include provisions that are most protective for the enrollee and, to the extent feasible as determined by the Secretary, are compatible with unified timeframes and consolidated access to external review. The statute requires that the procedures take into account differences under state Medicaid plans, and be easily navigable by enrollees.
- Additionally, under paragraph (8)(B)(iii), the integrated processes implemented are required to include a single written notice that includes all relevant grievance and appeal rights; a single pathway for resolution of covered items and services; notices written in plain English and available in languages and formats that are accessible to enrollees (including in non-English languages that are prevalent in the service area of the specialized MA plan); unified timelines for processes such as filing, acknowledging, and resolving the appeal or grievance; and requirements for plans to process, track, and resolve the grievances and appeals to ensure enrollees are notified timely of decisions and can track the status of their grievance or appeal.
- Finally, under paragraph (8)(B)(iv), new grievance and appeals procedures must, with respect to all benefits under Medicare Parts A and B and Medicaid subject to appeal under such procedures, incorporate provisions under current law and implementing regulations that provide continuation of benefits pending appeal under Title XVIII and Title XIX. We address this statutory provision in section II.A.2.b.(7).

Using this statutory framework, we developed the following goals to guide development of the unified grievance and appeals provisions:

- Adopt provisions that are most protective of the enrollee;
- Reduce burden on beneficiaries (and those assisting them), plans, states, and providers; and
- Maintain state flexibility and minimize disruption by building on existing rules and policies.

These policy goals also reflect our belief that timely, efficient, accessible, and well-functioning grievance and appeals systems are critical to ensuring that beneficiaries have access to needed items and services. Such systems are especially vital for dual eligible individuals who typically lack financial resources that might enable other beneficiaries to pay out-of-pocket for needed items or services while a dispute is pending. We requested comments regarding these policy goals and the extent to which the proposed regulations are consistent with them.

Our policy goal of minimizing disruption was also informed by statutory language directing the Secretary to establish unified provisions to the extent feasible (section 1859(f)(8)(B)(i) of the Act). Consistent with this statutory standard, we primarily proposed incremental changes that are currently feasible, conform to other current law, and build upon existing systems.

Our proposals under the notice of proposed rulemaking were divided into three substantively different types:

- First, we proposed to establish requirements for all D–SNPs, relative to the role they play in assisting full-benefit dual eligible individuals, to assist with Medicaid-related coverage issues and grievances (§ 422.562(a)).
- Second, we proposed new requirements in accordance with section 1859(f)(8)(B) of the Act to create integrated grievance and appeals systems for a limited subset of D–SNPs (''applicable integrated plans''), identified using terms and concepts we propose to define in amendments to § 422.561, with the integrated processes established by proposed new regulations (§§ 422.629–422.634).
- Finally, we proposed a number of changes of a technical and conforming nature to existing provisions in parts 422 and 438 (§§ 422.560, 422.562, 422.566, 438.210, 438.400, and 438.402).

Section 1859(f)(8)(B)(i) of the Act requires the Secretary to establish unified grievance and appeals procedures for D–SNPs not later than April 2020, and section 1859(f)(8)(C) of the Act requires the use of these unified procedures in D–SNP contracts for 2021 and subsequent years. The statute does not, however, explicitly rule out the possibility of implementing such unified processes prior to 2021. As discussed in the proposed rule, we interpret the statute as permitting a state to adopt unified grievance and appeals processes for integrated D–SNPs and Medicaid plans in that state consistent with our final regulations on this topic starting as soon as the regulations establishing such procedures are final. Such a state could require establishment of unified appeals and grievance procedures consistent with CMS' regulations in its Medicaid agency contract required under § 422.107. We solicited comments on this interpretation of the statutory implementation date requirements and our proposal to make unified procedures available to states in this way before 2021.

In this final rule preamble, we summarize at a high level our specific proposals for the unified appeals and grievance processes; we direct readers to the proposed rule, 83 FR 55003 through 55013, for more detailed discussion of the proposals and our rationale for them. We received a number of comments on our proposals to implement these unified appeals and grievance procedures, both in general and with regard to specific proposals, and summarize the general comments as follows:

Comment: We received numerous comments in support of our proposal for unified plan-level appeals and grievance processes. Many commenters supported our stated policy goals and agreed that the proposed regulations were consistent with those goals. Several commenters expressed support for our policy principle of choosing the most beneficiary-friendly appeals processes and protections where there is a discrepancy between Medicare and Medicaid rules. Many commenters noted the current misalignment of administrative and operational process for beneficiaries and plans in the Medicare and Medicaid appeals processes, which confuses enrollees and reduces access to benefits, and appreciated that our proposed appeals and grievance processes begin to address some of these misalignments through a unified system that is clearer

and easier to navigate for enrollees. One commenter expressed concern that requiring D–SNPs, which typically also offer other non-D–SNP MA–PD plans, to administer two separate grievance and appeal procedures is overly burdensome. One commenter noted that it may not be possible to implement the unified appeals and grievance processes in states with consent decrees that limit plan-level appeals.

Response: We appreciate the broad support both for unified appeals and grievance processes and for the policy goals underlying our proposed process. We agree with those commenters who stated that the unified processes will be clearer and easier to navigate for enrollees. We expect the unified processes to apply to a relatively small subset of D–SNPs and states. We note that, with respect to the concern about the burden of D–SNPs administering separate grievance and appeals processes, D–SNPs that contract to provide Medicaid benefits, including applicable integrated plans that must comply with the unified appeal processes addressed in this rule, currently administer two separate processes—one for Medicare and one for Medicaid—in addition to complying with specific appeal requirements for Part D benefits. Under the unified approach we are finalizing, integrated applicable plans will only administer one process for all non-Part D benefits. Thus, while we understand that there may be some administrative burden in setting up the new system, we believe that once the system is set up, it should be more efficient for applicable integrated plans to administer than the current system. We note that drugs covered by Medicare Part D will continue to be processed under the separate Part D appeals system in 42 CFR part 423. Appeals related to non-Part D drugs covered by Medicaid for dual eligible individuals will go through the unified appeals process as outlined in this final rule for applicable integrated plans, described later in this final rule. We therefore do not believe there will be additional burden for applicable integrated plans. We also note that we will accommodate state circumstances, as needed and possible, including where a state currently operates under a consent decree.

Comment: A number of commenters noted the need for CMS to work closely with states and other stakeholders where these unified processes will be implemented to ensure a smooth implementation and transition for enrollees and set clear expectations for applicable integrated plans. Some commenters also noted the need for CMS to release additional guidance prior to the implementation date and to communicate the process clearly to enrollees. Several commenters requested that we issue subregulatory guidance specifically addressing the following topics: Allowing enrollees to raise secondary impact on health based on the financial hardship of paying for services that were not initially covered in post-service payment cases, repeat grievances, and processing prescription drug appeals in the unified processes. A commenter requested additional information on state regulations that may need to change in order for the unified processes to be implemented. Several commenters also recommended that CMS review best practices and lessons learned in the Financial Alignment Initiative to inform implementation of unified processes for D–SNPs. One commenter questioned how states will react to implementing these requirements. Another commenter noted that any new process will produce new confusion among beneficiaries.

Response: We appreciate the commenters' concerns and anticipate issuing subregulatory guidance to further clarify the unified processes. As discussed throughout this preamble, we expect to continue to engage states, plans, and other stakeholders as we implement the requirements in this final rule, including providing technical assistance to states, disseminating best practices (including from MMPs participating in the Financial Alignment Initiative), and issuing additional subregulatory guidance and model enrollee communications to ensure a smooth implementation and to reduce any potential enrollee confusion. We also note that, for most states that will be implementing this new unified process, this final rule allows CMS 18 months prior to the January 1, 2021, implementation date to work with states, plans, and other stakeholders to ensure a smooth implementation.

Comment: One comment noted the importance of provider-neutral language in the proposed rule, which is consistent with the statutory language and recognizes the important variety of providers that serve enrollees in Medicare and Medicaid.

Response: We appreciate the commenter's support of our use of the term ''provider'' in the proposed rule and note that we are maintaining the use of this term in the final rule.

Comment: One commenter observed that there is no mention of the grievance and appeals processes for network providers, noting the lack of a process for network providers under existing contract terms with managed care plans and expressing concerns about potential retaliation from managed care plans for filing appeals or complaints. The commenter urged us to develop a process for network providers to file appeals and grievances and ensure that network provider concerns are heard by states and CMS.

Response: The unified process addressed in this final rule is for coverage decisions made by the D–SNPs and the affiliated Medicaid managed care plans with exclusively aligned enrollment. As is the case under MA rules, disputes between network providers and the applicable integrated plans are governed by their contracts with plans. Some states do provide external processes for Medicaid network providers, and these processes will remain available for Medicaid-related plan-provider disputes. In addition, providers can file complaints with CMS through the Complaint Tracking Module to raise issues and concerns to CMS' attention.

Comment: One commenter requested that we include supplemental benefits and long-term services and supports (LTSS) in the unified grievance and appeals processes, similar to the current process in the Cal MediConnect Financial Alignment Initiative demonstration.

Response: We clarify that any LTSS or supplemental benefits covered by applicable integrated plans will subject to the unified grievance and appeals processes we are finalizing in this rule, with the exception that MA supplemental benefits are not subject to the continuation of benefits pending appeal process finalized at § 422.632 in this rule. Continuation of benefits pending appeal under § 422.632(b) is available only for ''benefits under Parts A and B of title XVIII and title XIX.'' Please see section II.A.2.b.(7) of the proposed and final rules for more discussion of this issue.

Comment: Several commenters requested clarification on the impact of the unified grievance and appeals processes on applicable integrated plans' Star Ratings. A commenter recommended a grace period to mitigate this impact, and another recommended that we move the measures to the display page during the transition to the new processes. Another commenter requested more information on appeals and grievance reporting processes. One commenter requested that we make timely plan-specific grievance and appeals data available to the public.

Response: These comments are not strictly within the scope of our final rule provisions establishing unified

grievances and appeals processes. We note, however, that we do not expect Star Ratings to be negatively impacted by the unified grievance and appeals processes. The Star Ratings measures focus on how timely the MA plan sends the case to the IRE when the plan upholds its initial adverse organization determination and whether the plan's decision was upheld at the IRE. Under §§ 422.590(d)(4) and 422.592, if, upon reconsideration, an MA plan upholds its initial adverse organization determination, it must submit the case file and its decision to the IRE for automatic review. Under the unified appeals process, rules governing submission of case files to the IRE when a plan upholds its initial adverse organization determination are unchanged (see § 422.634(b)). We expect that an applicable integrated plan could in fact see a reduction in cases where the IRE reverses the applicable integrated plan's integrated reconsideration determination for cases where Medicare and Medicaid benefits overlap, since the applicable integrated plan may approve the service or item under Medicaid coverage and not have to issue a denial under Medicare. The applicable integrated plans should then have fewer cases to auto-forward to the IRE, and thus fewer cases that that the IRE could overturn and negatively impact the plan's Star Ratings.

Comment: One commenter urged CMS to reconcile and align requirements across multiple proposals aimed at reducing administrative burdens on plans and beneficiaries, including those that appeared in the proposed rule and in other proposals related to MA and step therapy for Part B drugs.

Response: We appreciate this feedback and agree that internal consistency is an important consideration in reducing administrative burden and has been a priority throughout this rulemaking process.

Comment: A commenter recommended that we extend our enrollee communications requirements to integrate all member-facing materials.

Response: We appreciate the suggestion. However, the requirements of section 1859(f)(8)(B)(iii) of the Act apply only to notices required under the unified appeals and grievance processes. We are therefore not implementing requirements for other notices in this final rule. However, as discussed elsewhere in this final rule, the Medicare-Medicaid Coordination Office is working to improve and consumer test a variety of beneficiary communications materials geared toward D–SNP and MMP enrollees.

(1) Assisting With Medicaid Coverage Issues and Grievances (§ 422.562(a)(5))

As an incremental step towards improving all D–SNP enrollees' experiences with accessing Medicaid benefits, and pursuing grievances and appeals, we proposed new regulation text to require all D–SNPs to assist beneficiaries with Medicaid coverage issues and grievances, including authorizations for or appeals related to Medicaid-related services at § 422.562 by adding a new paragraph (a)(5). As discussed in the proposed rule, these new requirements are consistent with our existing guidance and expectations for D–SNPs, but we proposed regulations to define their scope and set mandatory standards to which we can hold D–SNPs accountable. We believe that all D–SNPs should assist enrollees with resolving Medicaid coverage problems, including assistance with filing grievances, requesting coverage, and requesting appeals. Such assistance is consistent with the standard we proposed as part of the definition of a D–SNP at § 422.2. As noted in section II.A.2.a.(1) of the proposed rule and this final rule, we are codifying the statutory requirement at section 1859(f)(3)(D) of the Act that D–SNPs arrange for their enrollee's Medicaid benefits as an explicit requirement that D–SNPs coordinate the delivery of Medicare and Medicaid services for individuals who are eligible for such services, whether or not the D–SNP itself contracts with the state to provide Medicaid services. We clarified in the proposed rule that the requirements at § 422.562(a)(5) were additional requirements for D–SNPs, specifically related to assisting with access to benefits, appeals, and grievances. At § 422.562(a)(5), we proposed to supplement the obligation to provide, as applicable, and coordinate Medicaid benefits by adding a requirement that when a D–SNP receives an enrollee's request for services, appeal, or grievance related to Medicaid-covered services (regardless of whether such coverage is in Medicaid fee-for-service or a Medicaid managed care plan, such as a Medicaid MCO, PIHP, or PAHP as defined in § 438.2), the D–SNP must provide a certain level of assistance to the enrollee.

In new paragraph (a)(5)(i), we proposed to describe the types of assistance we would require all D–SNPs to provide to their enrollees regarding Medicaid-related coverage issues and grievances, including authorization of services and appeals. We proposed in paragraph (a)(5)(i) to include assistance for all D–SNP enrollees, regardless of the type of Medicaid coverage in which they are enrolled.

Our proposed regulation at § 422.562(a)(5)(i) included a list of illustrative examples, at paragraphs (5)(i)(A) through (5)(i)(C), which we did not intend to be an exhaustive list of how a D–SNP would be required to comply with the assistance obligation in § 422.562(a)(5)(i).

- In paragraph (a)(5)(i)(A), we addressed explaining to a D–SNP enrollee how to request Medicaid authorization and file an appeal. Our proposed regulation text included examples of the type of assistance we expect D–SNPs to provide to their enrollees when the enrollees need information and explanations about obtaining Medicaid services. We proposed, in paragraphs (5)(i)(A)(1) through (5)(i)(A)(3), examples of the types of assistance that a D–SNP must offer, and upon acceptance or request, provide its enrollees, such as specific instructions on how to contact the entity that may cover the service (for example, the Medicaid managed care plan or a contact in the fee-for-service system), and assistance in obtaining and filling out forms necessary for the next steps in the process.
- In paragraph (a)(5)(i)(B), we proposed that D–SNPs provide assistance in the actual filing of grievances and appeals. We requested comments regarding this proposal; in particular, we requested comments regarding how D–SNPs that do not have aligned enrollment would comply with this requirement when such entities might have financial and clinical responsibility for the disputed services, potentially presenting a conflict of interest.
- In paragraph (a)(5)(i)(C), we proposed that the D–SNP assist the enrollee in obtaining documentation in support of a request for authorization or appeal.

We explained how the examples listed in proposed paragraphs (a)(5)(i)(A) through (C) were not intended to be an exhaustive list, but rather were meant to provide some leading examples of the assistance we believe any D–SNP should provide. We invited comments on this proposal, specifically whether the regulation text was clear enough that the examples are not an exhaustive list of methods of assistance that the D–SNP must offer its enrollees, as well as suggestions for other examples of assistance that we should include in regulation or address in subsequent subregulatory guidance. We also solicited suggestions for additional examples of assistance, as

well as comments on challenges D–SNPs and others envision in implementing the provisions of proposed paragraph (a)(5). In addition, we acknowledged potential challenges D–SNPs may face because Medicaid systems vary by state.

We also proposed language related to enrollees accepting the offer of assistance in proposed paragraph (a)(5)(i). In our proposal, the only obligation on D–SNPs is to offer assistance and, when a request is made or an offer of assistance is accepted, to provide it. We requested comments on whether the regulation text, as we proposed it, was the best way to achieve this goal.

In paragraph (a)(5)(ii), we proposed to specify that the D–SNP's obligation to offer assistance arises whenever the D–SNP becomes aware of an enrollee's need for a Medicaid-covered service. Our proposal included text explicitly clarifying that enrollees do not need to make a specific request to their D–SNP for assistance. As we stated in the preamble to the proposed rule, if the issue comes to the attention of the D–SNP, we would expect the plan to offer to assist the enrollee in resolving the coverage issue(s) or grievance given the D–SNP's responsibility, consistent with our proposed definition of a D–SNP at § 422.2, that such a D–SNP provide, as applicable, and coordinate the delivery of Medicare and Medicaid services for its enrollees. We requested comments on whether we should include such explicit direction to D–SNPs in the regulation to identify issues that an enrollee is having, or whether our proposed regulation text was sufficiently clear that D–SNPs will understand and meet our goal of providing assistance to an enrollee such that the enrollee can access benefits regardless of whether the benefit is covered by Medicare or Medicaid. We clarified that we were not proposing any new requirements related to assistance with Medicare covered services or services for partial-benefit dual eligible enrollees. We requested comments regarding the provisions at proposed § 422.562(a)(5)(ii) and the need for any further clarification limiting the scope of § 422.562(a)(5) to full-benefit dual eligible individuals.

In paragraph (a)(5)(iii), we proposed to provide further detail on the methods of assistance required by proposed paragraph (a)(5)(i). The methods we proposed in the regulation were intended to be examples of what a D–SNP will be required to offer and provide to enrollees and will depend, to some extent, on the needs and preferences of the enrollee. Specifically, we proposed:

- In paragraph (a)(5)(iii)(A), that a D–SNP may provide coaching to the enrollee to promote self-advocacy. We requested comments on the methods of assistance and whether further detail is needed.
- In paragraph (a)(5)(iii)(B), an explicit requirement that a D–SNP provide whatever reasonable assistance an enrollee needs in navigating the Medicaid grievance and appeals systems, such as assistance completing forms. As discussed in the proposed rule preamble, existing MA and Medicaid managed care regulations (for example, §§ 422.111(h)(1)(iii) and 438.406(a)) address the provision of interpretation services and auxiliary aids and services for enrollees who have limited English proficiency or disabilities that require accommodation. We opted not to specify the preferred technical forms of assistance that would be required under this proposal, as the evolution of technology and the increases in integration over time may change the analysis of what methods of assistance are reasonable for a D–SNP to be required to provide to its enrollees. However, because D–SNPs are already required to provide similar assistance to their enrollees in other circumstances, we stated in the proposed rule that we did not anticipate that compliance with this provision should be burdensome to plans. We requested comments on this matter, including whether and how our goals might be met with more specific regulation text.
- In paragraph (a)(5)(iv), we proposed to require that a D–SNP provide documentation to CMS upon request that demonstrates how the D–SNP is providing the assistance proposed under paragraph (a)(5)(i).
- In paragraph (a)(5)(v), we proposed to clarify that D–SNPs are not required to represent enrollees in Medicaid appeals. We requested comments regarding whether any further clarification was needed on this issue.

We received the following comments, and our responses follow.

Comment: We received a significant number of comments in support of the proposed requirement in § 422.562(a)(5) to require all D–SNPs to provide assistance to D–SNP enrollees with Medicaid coverage issues and grievances. Many commenters were supportive of our efforts to improve D–SNP enrollees' experience and require all D–SNPs to provide a minimum level of assistance to their enrollees while granting D–SNPs flexibility in complying with the proposed requirements. A subset of commenters, while supportive of our proposal, recommended that CMS provide more specificity regarding what D–SNP assistance looks like and additional guidance on how plans can work with Medicaid agencies to obtain information on the Medicaid coverage of their enrollees.

Response: We appreciate the support we received for our proposed requirement that D–SNPs provide assistance to enrollees with Medicaid coverage issues and grievances. We believe these requirements constitute an incremental, but important, step in improving all D–SNP enrollees' access to the benefits under the Medicare and Medicaid programs. We address commenters' specific requests for clarification and guidance in subsequent responses in this section.

Comment: Several commenters expressed concerns that D–SNPs do not always have sufficient insight into whether certain Medicaid benefits are covered under the state's Medicaid program if the D–SNP does not provide those benefits directly. Many commenters noted that data sharing with states is essential for D–SNPs to access information regarding enrollees' Medicaid enrollment status—for example, whether they are enrolled in Medicaid fee-for-service or a Medicaid managed care organization (MCO), and the specific MCO they are enrolled in—in order to be fully informed about enrollees' coverage. A number of commenters recommended CMS consider issuing additional guidance to facilitate state sharing of Medicaid provider and enrollment information. One commenter suggested that CMS should create a centralized enrollment database that D–SNPs can query for Medicaid plan information regarding unaligned D–SNP enrollees. Another commenter suggested that in order to streamline the process and facilitate its implementation, CMS consider partnering with states to develop standardized resource lists with critical information on key Medicaid contacts that can be shared with enrollees and D–SNPs to streamline the navigation process and mitigate operational burden.

Response: We agree with commenters that information on how D–SNP enrollees receive their Medicaid coverage is essential for effectively fulfilling both the requirement to assist with Medicaid coverage and grievance issues and the requirement we finalized in the definition of a D–SNP at § 422.2 to coordinate Medicare and Medicaid coverage that these plans do not provide directly. We also recognize that, especially for states that do not contract

with D–SNPs to deliver Medicaid benefits, providing such information may be an operational challenge that is not among these states' priorities. We agree that it would be useful to provide states with technical assistance that would facilitate the exchange of information and help D–SNPs effectively coordinate their enrollees' Medicaid coverage.

At the same time, we do not believe that the absence of such information sharing relieves D–SNPs of their responsibility to coordinate Medicaid benefits they do not directly provide, nor prevents them from providing the types of assistance with Medicaid coverage issues and grievances that we outlined in the proposed rule. While we do not intend to penalize D–SNPs for not having in place a real-time data exchange with states on D–SNP enrollees' Medicaid coverage, we emphasize that the obligation for Medicaid coordination rests on the D–SNPs, and it is therefore incumbent on D–SNPs to develop mechanisms to coordinate Medicaid coverage and assist with Medicaid appeals and grievance issues. There are other methods that D–SNP staff can use to obtain information to better assist their members with Medicaid coverage issues, appeals, and grievances. For example, many states have data systems that providers use to obtain information on patients' Medicaid coverage; D–SNP personnel may be able to similarly access information in order to better assist enrollees. In some circumstances, a plan can assist a member simply by questioning the enrollee about their Medicaid coverage, or by jointly calling Medicaid customer service to obtain coverage information. As D–SNPs implement these provisions, we will gather and share best practices to help ensure robust implementation of these requirements.

Comment: A commenter indicated that, in certain circumstances, the state Medicaid agency is the only source that can clarify or have up-to-date information for the member. The commenter stated that D–SNPs should have the ability to direct members to state Medicaid agencies as needed.

Response: We wish to clarify that our proposal would not prevent D–SNPs from directing enrollees to state Medicaid agencies. Instead, our proposal requires that the D–SNP provide reasonable assistance in identifying the specific contacts within the state Medicaid agency, and helping the enrollee find the correct contact information, when referral of an enrollee to Medicaid resources is appropriate.

Comment: A few commenters recommended that CMS modify its proposal so that D–SNPs would be responsible for assisting members with appeals and grievances and other matters related only to services available through the D–SNP and that are clearly within the purview of the plan.

Response: We disagree with these commenters. Despite the valid data-sharing challenges, we believe it is reasonable to require that D–SNPs, as plans focused on serving dual eligible individuals, take steps to assist enrollees with obtaining Medicaid covered services and resolving Medicaid grievances, consistent with the requirement codified in this final rule in § 422.2 that D–SNPs coordinate the delivery of Medicare and Medicaid services for individuals eligible for such services. This would necessarily mean that the D–SNP take steps to gain access to information about the Medicaid benefits available to the D–SNP's enrollees. Moreover, providing such assistance is often in a D–SNP's financial interest, such as when an enrollee's access to Medicaid-covered services like personal care services and other home and community based services (HCBS) could prevent a hospitalization or address an enrollee's condition before it escalates into a need for medical services.

Comment: Several commenters requested clarification of whether the proposed regulation would require a FIDE SNP to offer to assist a dual eligible individual in appealing its own reduction of Medicaid LTSS services. The commenter believed this would be burdensome and could present a conflict for the plan.

Response: We clarify that a FIDE SNP that covers the Medicaid service through a capitated contract with a state also has an obligation to assist a dual eligible individual in appealing its own reduction or denial of Medicaid services, including LTSS, under its Medicaid MCO contract. The definition at § 422.2 finalized elsewhere in this rule requires that FIDE SNPs have Medicaid MCO contracts. As a Medicaid MCO, the FIDE SNP has an obligation under § 438.406(a) to provide reasonable assistance to its members in completing forms and taking other procedural steps related to a grievance or appeal. Therefore, FIDE SNPs already have an obligation to assist with Medicaid appeals. We do not agree that there is any undue burden or conflict under either the D–SNP or Medicaid MCO requirements to assist with appeals when that assistance results in a FIDE SNP providing coverage upon adjudication of the appeal. These requirements are, in the first instance, a component of the Medicaid MCO requirements to implement an appeals process, and, in the second instance, consistent with the requirement codified elsewhere in this final rule that D–SNPs coordinate Medicaid benefits. The new requirements we are finalizing at § 422.562(a)(5) of this final rule are applicable to all D–SNPs and to all D–SNP enrollees, whether or not they are enrolled in the Medicaid MCO offered by the D–SNP, and thereby effectively extend and complement the existing MCO requirements under § 438.406(a). Further, we note that § 422.562(a)(5)(v) expressly provides that the D–SNP does not have any obligation to represent an enrollee in a Medicaid appeal.

Comment: Several commenters emphasized that other entities have an important role in providing enrollees assistance with Medicaid coverage issues and grievances. Several of the commenters stressed the important role of the state ombudsman. One commenter proposed that CMS add language to the regulation text stating that the D–SNP must make available to their enrollees specific contact information for organizations providing free legal services and for any applicable ombudsman programs. Another commenter suggested that D–SNPs be required to make a written referral for the enrollee to the state's Medicaid managed care ombudsman, particularly when the D–SNP has a financial and/or clinical responsibility for the disputed services. One commenter highlighted the fact that the ombudsman offices are specifically funded to assist beneficiaries in filing grievances and appeals, and frequently coordinate with State Health Insurance Assistance Programs (SHIPs). The same commenter stated that many community-based organizations already receive federal funding to provide coaching to promote self-advocacy, and D–SNPs should not duplicate these services.

Response: We agree with commenters that ombudsman programs, SHIPs, legal services organizations, and other community organizations have an important role in providing assistance with Medicaid coverage and grievances and believe that referrals to such organizations can be an appropriate method for D–SNPs to provide the required assistance in certain circumstances. We recognize that such organizations often have limited capacity and encourage D–SNP partnerships with such organizations to help ensure the referrals are to organizations with the capacity to help.

Comment: Several commenters proposed requiring D–SNPs to provide

assistance in a language and format needed to effectively assist enrollees and in compliance with all language and disability access provisions.

Response: The language suggested by the commenter is very similar to obligations already required of Medicaid managed care organizations at § 438.406(a), which includes obligations to provide interpreter services and auxiliary aids to assist enrollees with grievances and appeals. MA plans also have existing obligations under Title VI of the Civil Rights Act of 1964 to take reasonable steps to ensure meaningful access by individuals with limited English proficiency and under section 504 of the Rehabilitation Act of 1973 to take appropriate steps to ensure effective communication with individuals with disabilities, including the provision of auxiliary aids and services. Section 1557 of the Affordable Care Act places similar civil rights obligations on covered entities.

Comment: Several commenters requested that CMS be mindful of dual eligible individuals' choices and recommended that CMS not penalize plans for not providing assistance when enrollees decline such assistance.

Response: If an enrollee does not want the D–SNP's help in resolving an issue, then the D–SNP would not be obligated under our proposal to provide assistance.

Comment: A few commenters recommended expanding the proposal to include providing assistance with Medicaid eligibility, and one commenter noted that case managers are in a good position to help enrollees with these issues. One commenter suggested CMS should explicitly require assistance in resolving issues related to Medicaid eligibility as a fourth requirement at § 422.562(a)(5)(i).

Response: We believe this recommendation is beyond the scope of our proposed requirement, which focuses on assistance with grievance and coverage appeals and not Medicaid eligibility. However, states may choose to require assistance with eligibility issues in their state Medicaid agency contracts with D–SNPs.

Comment: Several commenters recommended that CMS provide states and D–SNPs with technical assistance on implementing these provisions. One commenter stated that CMS should consider establishing a technical expert panel to make recommendations to CMS on appropriate practices and then develop guidance that establishes guiding principles for enrollee assistance, provides examples, and identifies related issues for states and Medicaid plans to consider. Another commenter suggested that CMS consult with states and D–SNPs in developing additional guidance to help evaluate recommended pathways for specific situations. Another commenter recommended states provide clear guidance to D–SNPs operating in the state to define the level of assistance they should provide, including applicable examples.

Response: We are committed to providing technical assistance to states and to sharing best practices with D–SNPs to implement these requirements based on consultations with stakeholders and evolving practice in this area. We expect that the best approaches will be specific to the Medicaid coverage in specific states and how these states use D–SNPs to integrate coverage.

Comment: Several commenters were supportive of our proposal at § 422.562(a)(5)(i)(A) that D–SNPs provide reasonable assistance to an enrollee and explain to an enrollee how to make a request and how to file an appeal following an adverse benefit determination. Several commenters also appreciated that the D–SNP's only obligation would be to offer assistance with filing an appeal and, upon acceptance of the request, provide its enrollees such assistance in obtaining and filling out forms as necessary for the next steps in the process. Many commenters appreciated that the proposed rule recognizes that some enrollees will wish to self-advocate and can receive support from the plan for their efforts. A few commenters believed plans must empower their staff to act in the best interests of the enrollee and that D–SNPs should establish appropriate staff training and procedures to ensure that those staff provide the same reasonable assistance that the dual eligible individual might receive from a similarly charged independent assister (which enrollees could continue to work with should they choose).

Response: We appreciate the commenters' support of CMS's approach to broadly requiring D–SNPs to provide assistance to dual eligible individuals with Medicaid grievances and appeals. D–SNPs can provide assistance in many ways, including advising enrollees to call providers and the questions to ask, assisting enrollees with medical documentation requests, identifying necessary forms to file, and referring enrollees to an organization with more expertise (such as a state ombudsman and other relevant assistance programs). We do not seek to be overly prescriptive in the types of assistance a D–SNP must provide, and our examples are not intended to be exhaustive. Further, we note that the regulation, as proposed and as finalized in this rule at § 422.560(a)(5)(v), does not require the D–SNP to represent its enrollees in Medicaid matters.

Comment: Many commenters recommended that CMS clarify what constitutes ''reasonable assistance.'' A few commenters requested additional guidance on ''coaching the enrollee to promote self-advocacy.'' Some commenters noted that it is ultimately the enrollee's responsibility to ensure that they take all procedural steps and provide and submit documentation as part of the appeals process. Other commenters requested more guidance on the expectations and extent of assistance D–SNPs must offer and give their enrollees.

Response: We emphasize that our requirements describe the D–SNP's responsibility to provide assistance and do not include a requirement to resolve the coverage issue or to represent the enrollee. Not all enrollees would need significant assistance; for many enrollees, simply receiving information under paragraph (a)(5)(i) would be sufficient. Some dual eligible individuals are highly adept at advocating for themselves, and may require only modest assistance—for example, a phone number or direction to an appropriate website—or help with technical terms in explaining why they need a specific piece of equipment. Other enrollees may need encouragement and coaching to advocate for themselves, such as talking through the steps the enrollee will take to seek resolution of the issue, or role playing to practice how to talk to a representative of the Medicaid agency or a Medicaid managed care plan. We encourage D–SNPs to provide such coaching to empower dual eligible individuals to advocate for themselves when appropriate. When a D–SNP enrollee needs a higher level of assistance with the act of filing a Medicaid grievance or appeal, the D–SNP should provide that help. However, the D–SNP is not obligated to represent the enrollee in Medicaid appeals nor advocate for coverage, as stated in paragraph (a)(5)(v). Plans can provide specific contact information, explain to enrollees the roles of the Medicaid program, and generally offer different levels of assistance based on the individual's needs.

Comment: Another comment sought an explanation of the phrase, ''becomes aware of an enrollee's need for a Medicaid-covered service.''

Response: There are a number of ways in which a D–SNP could become aware of the need for assistance. A non-

exhaustive list includes: During a health risk assessment when an enrollee shows a need for more LTSS than she currently receives through Medicaid; during a request for coverage of a Medicaid-covered service made to the D–SNP; and during a call to the D–SNP's customer service line. As the above list illustrates, the offer of assistance from the D–SNP is not dependent on an enrollee's specific request for assistance.

Comment: Many commenters agreed with the proposed provision at § 422.562(a)(5)(i)(C) requiring plans to assist an enrollee in obtaining documentation to support a request for authorization of Medicaid services or a Medicaid appeal, such as medical records. One commenter requested additional clarification from CMS on the extent of responsibility that D–SNPs will assume when obtaining documentation, including the specific types of documentation that D–SNPs might be able to provide. Several commenters questioned whether CMS was imposing a requirement on D–SNPs that duplicates the existing regulations that require Medicaid MCOs to assist enrollees with grievances and appeals.

Response: CMS believes the assistance requirement for D–SNPs is commensurate with the assistance a Medicaid MCO is required to provide for appeals and grievances at § 438.406(a), which includes reasonable assistance in completing forms and taking other procedural steps related to a grievance or appeal; however, while there may be some areas of overlap, the new MA requirement at § 422.562(a)(5) is not inappropriately duplicative. Not all D–SNPs are Medicaid MCOs, PIHPs, or PAHPs subject to the requirements under § 438.406(a). Even some D–SNPs, such as FIDE SNPs, that are also Medicaid MCOs may have some members who are not also enrolled in the Medicaid MCO, or there may be Medicaid services that are carved out of the Medicaid MCO's benefits and delivered through Medicaid FFS or a separate Medicaid plan. The assistance requirement for D–SNPs that we are finalizing here is an implementation of the overriding requirement on D–SNPs under section 1859(f)(3)(D) of the Act to coordinate Medicaid benefits. To the extent the assistance in grievances actually provided by a Medicaid MCO obviates the need for any additional assistance by the D–SNP in a grievance or appeal, such assistance would no longer be required to be provided by the D–SNP. To the extent the D–SNP enrollee requires additional advice or assistance with completing forms, or seeking documentation from relevant providers, the D–SNP should offer to provide such assistance and provide it when the enrollee agrees.

Comment: Several commenters were concerned with how D–SNPs should document and report to CMS that assistance was offered and whether or not an offer of assistance was accepted. A few commenters requested additional information on the documentation and reporting requirements that CMS will establish and whether such documentation will be reviewed as part of the audit protocols for D–SNPs. One commenter requested CMS remove the requirement at § 422.562(a)(5)(iv) that requires a D–SNP to provide documentation to CMS that demonstrates how the D–SNP is providing the assistance, citing concerns with administrative burden on plans.

Response: We agree that documentation of the assistance D–SNPs provide their enrollees with Medicaid coverage and grievances should not be overly burdensome to plans. The documentation requirement (including any potential reporting to CMS) in § 422.562(a)(5)(iv) does not prescribe certain types of assistance in all cases. Particularly in the initial years of implementation, when plans are developing processes to best implement these requirements, our goal is to provide plans with flexibility on the type of assistance they provide in individual cases and to monitor compliance with this requirement at a high level. We would not, for example, require proof that a beneficiary had declined an offer of assistance. We plan to detail the scope and content of the documentation requirements in subregulatory guidance, and it is likely that the subregulatory guidance will be made available for stakeholder comment before it is finalized.

Comment: Several commenters suggested that CMS take steps to ensure that D–SNPs that provide assistance with Medicaid coverage issues are not penalized in CMS audits or in the MA Star Ratings measure that is based on beneficiary complaints (''Complaints About the Health Plan'') when the final result—the coverage decision made by a party other than the D–SNP—is not to the beneficiary's satisfaction. Another commenter recommended that CMS protect D–SNPs from ''liability'' for providing assistance with Medicaid coverage and grievances.

Response: In general, we do not believe that D–SNPs providing their enrollees with assistance navigating their Medicaid coverage will trigger an increase in beneficiary complaints. Rather, we expect D–SNP enrollees will appreciate the assistance that their D–SNP provides. Nonetheless, we will review our criteria to ensure we are capturing complaints appropriately and will consider any future changes to these criteria that may be necessary. Outside of these areas, we are unclear how providing such assistance would increase D–SNPs' ''liability.''

After considering the comments we received and for the reasons provided in the proposed rule and our responses to those comments, we are finalizing the text proposed for codification at § 422.562(a)(5) with one technical modification. At paragraph (5)(iii)(B), we are modifying the regulatory text to clarify that the requirement that D–SNPs provide reasonable assistance in completing forms and procedural steps applies specifically to Medicaid appeals and grievances. We believe the additional clarification provided by our responses to the comments in this final rule should give D–SNPs a clearer understanding of the scope of their responsibilities under the regulation and the various methods and resources D–SNPs can use to fulfill the requirements. We recognize that there will be a joint learning process with states, MA organizations, dual eligible individuals, and their advocates on the processes that can facilitate effective implementation of these requirements. We expect to provide technical assistance to states and D–SNPs to help with implementation. In addition we plan to provide subregulatory guidance as necessary, including regarding CMS oversight of D–SNP performance in this area. We note that, unlike the remainder of the appeals and grievances provisions finalized in section II.A.2.b of this final rule, the requirements at § 422.562(a)(5) will be applicable to all D–SNPs and will be applicable beginning January 1, 2020.

(2) Statutory Basis and Scope for Unifying Grievances and Appeals (§ 422.560)

In § 422.560, we proposed to add new paragraphs (a)(4) and (b)(5) to address the statutory basis and scope of our proposal to establish unified grievance and appeals processes for a subset of D–SNPs. Specifically, we proposed a new paragraph (a)(4) to cite section 1859(f)(8) of the Act and provide that the procedures under that section apply in place of otherwise applicable grievance and appeals procedures with respect to items and services provided by certain D–SNPs. We also proposed to add new paragraph (b)(5) to identify the scope of the new proposed regulations—that is, requirements for applicable integrated plans with regard to unified appeals and grievance procedures. The substance of these proposals is addressed in sections

II.A.2.b.(3) through (11) of the proposed and final rules.

We received no comments on our proposed changes to § 422.560 and are finalizing the regulation text at paragraph (b)(5) as proposed. However, we are making a non-substantive technical change to paragraph (a)(4) to clarify that the unified appeals and grievance procedures finalized in this rule are applicable beginning January 1, 2021. We are also making a technical change to correct an inadvertent omission in the proposed rule. Section 1859(f)(8)(C) of the Act states that, effective in 2021, contracts between D–SNPs and state Medicaid agencies must require the use of the unified grievance and appeals process. In order to reflect this requirement in regulation, as noted in section II.A.2.a.(2) of this final rule, we are finalizing a new paragraph at § 422.107(c)(9) that requires that contracts between D–SNPs that are applicable integrated plans, defined in § 422.561, and the state Medicaid agency require the use of unified grievance and appeals procedures.

(3) Definitions of ''Applicable Integrated Plan'', ''Integrated Appeal'', ''Integrated Grievance'', ''Integrated Organization Determination'', and ''Integrated Reconsideration,'' and General Requirements for Applicable Integrated Plans (§§ 422.561 and 422.629(a)–(k))

A central challenge to implementing unified grievance and appeals systems for D–SNPs and the Medicaid managed care organization operated by such plan's parent organization is the variety of enrollment scenarios across states. There are only a limited number of D–SNPs in which aligned enrollment, as defined in § 422.2 of this final rule, is possible—that is, a situation when a full-benefit dual eligible individual is enrolled in a D–SNP and receives coverage of Medicaid benefits from the D–SNP's MA organization or from a Medicaid managed care organization, as defined in section 1903(m) of the Act, operated by the D–SNP's parent organization or by another entity that is owned and controlled by the D–SNP's parent organization. Even fewer D–SNPs operate in states where that state Medicaid agency mandates such aligned enrollment. With exclusively aligned enrollment, all of the enrollees of the D–SNP also receive Medicaid services through the D–SNP or an affiliated Medicaid managed care organization operated by the D–SNP's parent organization.

The bulk of D–SNP enrollment, however, is not exclusively aligned. In most states, the majority of D–SNP enrollees have Medicaid coverage either through a different organization's Medicaid MCO, in a prepaid ambulatory or inpatient health plan (PAHP or PIHP), or through a state's Medicaid fee-for-service system. In these circumstances, the D–SNP has no control over the Medicaid grievance and appeals processes. Even a D–SNP that has a Medicaid managed care organization operated by such plan's parent organization available to its enrollees, but whose members may instead enroll in other Medicaid plans, can only unify the procedures for Medicaid appeals and grievances of those enrollees who are also simultaneously enrolled in the Medicaid managed care organization operated by such plan's parent organization.

We proposed to add definitions for new terms to govern the integrated grievance and appeals processes. In § 422.561 we proposed a new definition for ''applicable integrated plan,'' which is the specific type of D–SNP and affiliated Medicaid plan that would be governed by the new integrated grievance and appeals regulations. In our definition of applicable integrated plan, we proposed to include only a subset of D–SNPs, that is, only FIDE SNPs and HIDE SNPs with exclusively aligned enrollment, terms that were also proposed (see section II.A.2.a.(1) of the proposed rule) and are finalized with limited modifications elsewhere in this rule (see section II.A.2.a.(1) of this final rule). We proposed that the affiliated Medicaid plan be a Medicaid managed care organization, as defined in section 1903(m) of the Act, that is offered by: (1) The D–SNP with exclusively aligned enrollment; (2) the parent organization of such D–SNP; or (3) another entity that is owned and controlled by the parent organization of such D–SNP. Thus, as we stated in the proposed rule, our proposed unified grievance and appeals procedures would apply only to the enrollees of the subset of D–SNPs that are FIDE SNPs or HIDE SNPs with exclusively aligned enrollment and the affiliated Medicaid managed care organizations through which such enrollees receive their Medicaid services. As we noted in our discussion of the proposed definition of aligned enrollment in section II.A.2.a.(1) of the proposed rule, we would not consider a D–SNP's companion Medicaid plan to be an applicable integrated plan where it is a PIHP or PAHP in the state's Medicaid program. We solicited comments on our proposed definition of an applicable integrated plan and how it reflects which plans and entities would have to use the proposed unified grievance and appeals procedures. We sought comment on whether limiting our proposed policies to MCOs, rather than including PIHPs and PAHPs, was appropriate in light of the statute and our policy goals. We also clarified which proposed appeal and grievance procedure requirements for D–SNPs would not apply to applicable integrated plans; D–SNPs that are not applicable integrated plans would continue to establish and administer appeal and grievance systems that comply with the existing requirements for MA plans.

For the purpose of differentiating the terminology and procedures within this framework, we proposed to establish definitions for ''integrated organization determination,'' ''integrated appeal,'' ''integrated reconsideration,'' and ''integrated grievance'' and apply them exclusively to applicable integrated plans and the unified appeal and grievance procedures.

Under our proposal, integrated organization determinations would encompass both Medicare organization determinations, as described in § 422.566, and adverse benefit determinations, as defined in § 438.400(b); however, these determinations would be made by applicable integrated plans and would therefore be subject to the integrated organization determination procedures in proposed §§ 422.629, 422.631, and 422.634. These would be the first decisions made by the applicable integrated plan regarding coverage, approval, or payment for a covered service.

Similarly, we proposed that integrated reconsiderations would be the appeal of the applicable integrated plan's adverse integrated organization determination with respect to the health care services the enrollee believes he or she is entitled to receive. Under our proposal, an integrated reconsideration would be the same as an MA plan's reconsideration (in § 422.580) of an organization determination (defined in § 422.566) and the appeal (defined in § 438.400(b)) of an adverse benefit determination made by a Medicaid managed care plan. Integrated reconsiderations would encompass both Medicare reconsiderations, as described in §§ 422.578, 422.580, 422.582, and 422.584, and appeals, as defined for the Medicaid managed care context in § 438.400(b). However, these determinations would be made by applicable integrated plans and therefore subject to the integrated reconsideration procedures in proposed § 422.629 and §§ 422.632 through 422.634.

We proposed defining integrated appeals to encompass integrated reconsiderations and any additional post-plan level unified appeal processes that may be implemented in the future.

Additionally, we proposed to define an integrated grievance as a dispute or complaint that would be defined and covered, for grievances filed by an enrollee in non-applicable integrated plans, under § 422.564 or §§ 438.400 through 438.416. Integrated grievances would not include appeals procedures or QIO complaints, as described in § 422.564(b) and (c), respectively. An integrated grievance made by an enrollee in an applicable integrated plan would be subject to the integrated grievance procedures in §§ 422.629 and 422.630.

Our proposed definitions for integrated grievance, integrated organization determination, and integrated reconsideration were intended to replicate the scope and meaning of the parallel terms in parts 422 subpart M and part 438 subpart E regarding the appeals and grievance procedures required of, respectively, MA organizations and Medicaid managed care plans because we were proposing that these regulations and procedures would take the place of those part 422 and part 438 procedures for applicable integrated plans. We solicited comment on whether our proposal adequately accomplished this.

We proposed at § 422.629 to establish general requirements for applicable integrated plans, as defined in § 422.561. In the proposed rule, we generally explained how we balanced existing Medicare and Medicaid requirements, including existing state Medicaid flexibilities. In paragraphs (a) and (b), we proposed language that sets forth the scope of the requirements and general process that applicable integrated plans must implement. In paragraph (a)(1), we proposed to specify that the proposed rules apply in lieu of the general requirements for MA organizations at §§ 422.564, 422.566(c) and (d), and 422.568 through 422.596, and Medicaid managed care plans at §§ 438.404–438.424, and encompass integrated grievances, integrated organization determinations, and integrated reconsiderations. In paragraph (b), we set forth the general requirement that applicable integrated plans create integrated processes to administer these grievance and appeals requirements.

In proposed paragraph (c), we addressed an overarching question about whether a state may establish requirements that are different for the applicable integrated plan(s) using the state Medicaid agency contract with the D–SNP required under § 422.107. Specifically, we proposed to apply the flexibility offered to states under Medicaid regulations, which establish a floor for enrollee protections while offering states flexibility to impose more stringent requirements for timeframes and notices so long as they are more protective of beneficiaries. By preserving state flexibility in adopting more stringent, beneficiary-protective requirements, we believe that we were adhering to the direction set forth in sections 1859(f)(8)(B)(ii)(I) and (II) of the Act for us to take into account differences in state plans under Title XIX. Finally, in paragraph (c), we proposed to codify the opportunity for states to establish standards that differ from the standards set forth in these regulations in its state Medicaid agency contract, per § 422.107, with the applicable integrated plans. We solicited comments on our proposed approach, and specifically how we proposed to allow state flexibilities to be incorporated into the unified procedures for an applicable integrated plan.

In paragraph (d), we proposed that the applicable integrated plan provide the enrollee who is requesting the integrated reconsideration a reasonable opportunity, in writing and in person, to present evidence and testimony and make legal and factual arguments in support of their appeal. We also proposed to require that applicable integrated plans inform enrollees of the limited time available for these opportunities in cases were the timeframe is expedited, similar to § 422.586 and § 438.406(b)(4).

In paragraph (e), we proposed to require applicable integrated plans to provide reasonable assistance to the enrollee with respect to completing and submitting their integrated appeals and integrated grievances, as well as on navigating this process. This proposal would impose on applicable integrated plans a similar standard as applies to Medicaid managed care plans pursuant to § 438.406(a).

We proposed at paragraph (f) a general rule, using cross-references to the requirements in §§ 422.560, 422.561, 422.562, 422.566, and 422.592 through 422.626, to specify the regulations that apply to the applicable integrated plan for grievance and appeals processes unless otherwise noted.

We proposed at paragraph (g) to require applicable integrated plans to send the enrollee an acknowledgement of receipt in writing for all integrated grievances and integrated reconsiderations. We proposed to adopt the standard currently in § 438.406(b) for applicable integrated plans and to clarify that the acknowledgement should be in written form.

In paragraph (h), we proposed to adopt Medicaid's grievance and appeals recordkeeping requirements, as required for Medicaid managed care plans at § 438.416, to require applicable integrated plans to maintain records of integrated appeals and grievances and review them as part of their ongoing monitoring procedures.

We proposed in paragraphs (i) and (j) to incorporate similar provisions as are imposed on Medicaid managed care plans pursuant to §§ 438.410(b) and 438.414 regarding relationships between the plan and its contracted network providers. Specifically, in paragraph (i), we proposed to prohibit an applicable integrated plan from taking any punitive action against a provider for requesting an integrated organization determination or integrated reconsideration, similar to the provisions in §§ 422.570(f) and 438.410(b). We also proposed requiring, in paragraph (j), such a plan to disclose information about its appeals and grievances procedures at the time it enters into a contract with a provider or subcontractor. We proposed to include specific topics which must be covered in this information to providers, and these specific topics are the same as in existing Medicaid regulations (see § 438.414, which cites to § 438.10(g)(2)(xi) for this purpose).

In paragraph (k), we proposed regulatory standards controlling who must review an integrated organization determination. In developing our proposal, we sought to combine the MA and Medicaid managed care requirements for who must review an organization determination. In paragraph (k)(1), we proposed to include the requirement from Medicaid (§ 438.406(2)(iii)) that any individual who reviews an integrated appeal or grievance must consider all information submitted by the enrollee, regardless of whether the information was previously made available to the plan. In paragraph (k)(2), we proposed to include the requirements for reviews of Medicaid grievances (from § 438.406(b)(2)) for who can review a grievance to integrated grievances.

In paragraph (k)(3), we proposed to include the existing requirements from MA (§ 422.566) for who can review an organization determination. We also proposed language that, in accordance with current MA regulations (§ 422.566(d)), requires that physicians or other health care professionals who review integrated organization

determinations have an unrestricted license and be acting within the scope of that license.

In paragraph (k)(4) we proposed to combine existing MA and Medicaid requirements for who can review a reconsideration or adverse benefit determination since both sets of existing regulations have relevant requirements.

We explained in the proposed rule (83 FR 55003 through 55006) how we applied the direction in section 1859(f)(8)(B)(ii)(I) of the Act to adopt the existing procedures that were more protective of enrollees and explained the rationale for our specific proposals in paragraphs (a) through (k) of proposed § 422.629. Where MA and Medicaid managed care rules are similar, our proposals tracked closely to existing MA and Medicaid managed care rules. Where MA and Medicaid managed care rules differ, we considered which rule was more protective of enrollees and proposed rules that would follow the more protective approach.

We summarize the comments we received on proposed § 422.629(a) through (k) and respond to them as follows:

Comment: Many commenters agreed with our approach to limit the unified appeals and grievance processes to applicable integrated plans. A subset of commenters, while supportive of our proposal, encouraged CMS to extend the unified processes to all D–SNPs, or at least to all FIDE SNPs and HIDE SNPs that are not exclusively aligned, to cover more dual eligible individuals. Several of these commenters recommended that, if CMS is unable to extend the unified process beyond what was proposed, we should continue to review lessons learned and best practices from our implementation of the unified processes and potentially extend the processes in the future as overall integration efforts advance. A commenter recommended that, if we are not able to extend the unified processes beyond applicable integrated plans at this time, we encourage states to facilitate cooperation between D–SNPs and other entities covering benefits for the D–SNPs enrollees. A commenter suggested that, if we did not extend the unified processes to additional plans, we at least make it optional for states and plans other than applicable integrated plans. Another commenter recommended that we restrict the unified processes to exclude HIDE SNP enrollees, due to lower level of benefits integration. A few commenters requested that CMS clarify the impact of this unified process on MMPs in the Financial Alignment Initiative demonstrations.

Response: We appreciate the broad support for the unified appeals and grievance processes we proposed. While we appreciate the support for extending these requirements to additional D–SNPs and dual eligible individuals, we do not believe it is feasible at this time to implement fully unified grievance and appeals systems for D–SNPs and Medicaid managed care plans that do not have the same enrollees or where the organizations offering the D–SNPs and Medicaid plans are unaffiliated or even competitors. We note that states may include additional integration requirements in their state Medicaid agency contracts with D–SNPs. We disagree with the commenter that suggests excluding HIDE SNPs with exclusively aligned enrollment from the definition of an applicable integrated plan, because when a HIDE SNP meets the definition of exclusively aligned enrollment, as defined in § 422.2, the plan covers Medicare and Medicaid benefits (including at least some LTSS or behavioral health services) for their dual eligible enrollees. We also clarify that this rule will not impact the appeals or grievance processes for MMPs, which will continue to be governed by the demonstration three-way contracts and demonstration-specific guidance. MMPs will continue to operate within existing waivers of part 422, as outlined in the memoranda of understanding for each demonstration.

Comment: A commenter requested that CMS clarify the relationship between the terms ''aligned enrollment,'' ''exclusively aligned enrollment,'' and ''applicable integrated plan,'' specifically, the relationship between the plan-specific nature of ''aligned enrollment,'' the state policy-specific nature of ''exclusively aligned enrollment,'' and whether it is actually CMS' intent that the term ''applicable integrated plans'' be a function of state policy and not of individual plan structure. The commenter further requested clarification as to whether it is CMS' intent to use this concept of ''exclusively aligned enrollment'' as a policy benchmark for states to meet, and, if so, whether CMS intends to somehow influence states toward that goal. A commenter also recommended that CMS clarify whether a HIDE SNP or FIDE SNP operating in a state without exclusively aligned enrollment cannot or should not unify their appeals and grievances in the fashion outlined in this section.

Response: We acknowledge that exclusively aligned enrollment is directly related to state policy choices to require such alignment. Exclusively aligned enrollment, as defined in § 422.2 in this final rule, occurs when the state requires a D–SNP operating in the state to enroll only dual eligible individuals who are also enrolled in an MCO (that has an MCO contract under section 1903(m)(2) of the Act) that is offered by the D–SNP's MA organization, the D–SNP's parent organization, or by another entity that is owned and controlled by the D–SNP's parent organization. In effect, exclusively aligned enrollment means that Medicare benefits, MA supplemental benefits, and comprehensive Medicaid benefits (which are the benefits that an MCO contract covers) are provided by one entity (the D–SNP) or closely affiliated entities that share a parent organization for all members. Applicable integrated plans are the D–SNP and MCO in this exclusively aligned enrollment arrangement. Aligned enrollment—in contrast to *exclusively* aligned enrollment—occurs when some, but not all, of the D–SNP's enrollees are covered under this arrangement.

While CMS intends to continue to provide technical assistance to states on the value of integration and exclusively aligned enrollment, we believe that it is most feasible at this time to impose the unified processes only on those plans that have the ability to unify such processes for all of their members. Therefore, only applicable integrated plans are required to comply with the regulations we proposed and are finalizing, with some modifications, in this final rule. D–SNPs, including HIDE SNPs and FIDE SNPs, that do not meet the definition of an applicable integrated plan must comply with the MA appeal and grievance system requirements in §§ 422.560 through 422.626. We also note that a state may establish additional integration requirements through its state Medicaid agency contract with D–SNPs.

Comment: We received several comments supporting our proposed definitions at § 422.561, as well as a few requests for additional clarification, including whether the definition of an integrated organization determination includes prior authorizations. One commenter expressed concern that, if integrated organization determinations do include prior authorizations, the 72-hour resolution timeframes for an expedited integrated organization determination may not be a fast enough resolution timeframe in all cases.

Response: Integrated organization determinations include prior authorizations because prior

authorizations are included in the definitions of organization determinations under § 422.566, adverse benefit determinations under § 438.400(b), and actions in § 431.201. We also note that, for resolution of an expedited integrated organization determination, the timeframe requirement is that resolution must be as expeditiously as the enrollee's health condition requires, but not to exceed 72 hours; thus, 72 hours is only a maximum timeframe, and an applicable integrated plan must take each enrollee's unique circumstances into consideration in processing and deciding an integrated organization determination. This is consistent with the requirement timeframes under both MA and Medicaid (see §§ 422.572(b) and 438.210(d)(2)).

Comment: We received a number of comments on our proposed requirement at § 422.629(c) allowing states flexibility in implementing standards for timeframes or notice requirements that are more protective for the enrollee. A number of commenters supported our proposal as a way to extend enrollee protections currently available under Medicaid in some states. Some commenters opposed or expressed concerns related to allowing state flexibility. One commenter requested clarification on whether the proposed procedures would supersede or override any conflicting current Medicaid state law or rules and federal statutes and rules related to D–SNPs and under what process any of those potential conflicts could be addressed. A few commenters noted that allowing states to shorten timeframes for resolving appeals can be detrimental to a plan's ability to collect necessary information and make fully informed decisions. A few commenters expressed concern about the burden and complexity associated with requiring applicable integrated plans to implement different timeframes for entities that operate in many states. A commenter questioned how CMS would make decisions about which state flexibilities to allow and which not to allow. One commenter expressed concern that states would not be able to implement the intent of Congress and CMS without additional guidance, or that CMS would not be able to accommodate state variations without impacting or delaying the intent of the overall process to provide simplification and clarity for beneficiaries. A few commenters encouraged CMS to work with states and stakeholders, including through a stakeholder panel, to implement this requirement.

Response: We appreciate commenters' varied perspectives on this issue. As discussed earlier in this preamble, the statute requires that we take into account differences in state plans and that we implement standards most protective of enrollees (see sections 1859(f)(8)(B)(ii)(I) and (II) of the Act). Medicaid regulations governing managed care plans currently allow variation from federal regulations as long as the state policy complies with federal standards, and thus we are designing the unified process for applicable integrated plans to include similar state flexibilities. In effect, the federal regulations we proposed and are finalizing operate as the minimum requirements on unified grievance and appeals procedures; states may use the contract they have with the D–SNP under § 422.107 and the state Medicaid contract with the Medicaid managed care plan to require timeframes that are more protective of the enrollees in the applicable integrated plans. We also note that the unified process will impact a relatively small universe of states and plans. The proposed unified process will apply for enrollees in applicable integrated plans in lieu of current federal Medicare and Medicaid regulations. With respect to the burden and complexity of administering these unified processes, D–SNPs that contract to provide Medicaid benefits, including applicable integrated plans that must comply with the unified appeal processes addressed in this rule, currently administer two separate processes—one for Medicare and one for Medicaid—in addition to complying with specific appeal requirements for Part D benefits. Under the unified approach, they will only administer one process for all non-Part D benefits. Thus, though there may be some initial burden in implementing the new unified processes, in the long term we expect the administrative burden on applicable integrated plans to be reduced.

With respect to when the state flexibility will be allowed, to the extent that a state statute or rule sets a standard that is more protective of enrollees with respect to timeframes or notices than the unified rules we are establishing in this final rule, which is the standard set by Congress in the statute, then that state standard will apply under the flexibility we are finalizing at § 422.629(c) in the unified processes, as it would currently in the state's Medicaid program. With respect to how CMS will accommodate such flexibilities, the flexibilities will need to be stated in the state's contracts with the applicable integrated plan (meaning both the contract with the D–SNP under § 422.107 and the state contract with the Medicaid MCO). States will then need to ensure compliance with state-specific requirements. We expect that any state requirements that differ from the requirements as written in this rule will reflect state-specific Medicaid requirements, and will therefore ensure the same degree of protection as that afforded to all Medicaid beneficiaries in the state. CMS is committed to continuing our work with states based on their specific policy priorities following the implementation of this final rule, including any necessary changes to state regulations or processes, and we will work to ensure changes and updates are communicated to the public.

Comment: One commenter stated that our proposed requirement, at § 422.629(g), to send written acknowledgements of all integrated reconsiderations was likely to cause confusion for enrollees and increase administrative burden for applicable integrated plans.

Response: Sections 1859(f)(8)(B)(iii)(IV) and (V) of the Act, as added by section 50311(b) of the Bipartisan Budget Act of 2018, specifically call for unified timelines and procedures for acknowledgement of appeals and grievances, and procedures to ensure enrollees are notified of and can easily determine the status of the grievance or appeal. We believe that that written acknowledgement best meets these requirements and therefore decline to make any changes to the requirement that applicable integrated plans send written acknowledgment of each integrated reconsideration. We note that applicable integrated plans have flexibility to tailor the acknowledgement to the enrollee's case to improve clarity and help avoid confusion. This requirement parallels the Medicaid regulation at § 438.406(b), and we note that MA guidance also addresses written acknowledgement of oral requests for reconsideration (see Parts C & D Enrollee Grievances, Organization/Coverage Determination, and Appeals Guidance § 50.2.1).[24]

Comment: A commenter suggested that we consider ways to ensure that plans are consistently and uniformly capturing and logging beneficiary requests for appeals and grievances and that applicable integrated plans are, at a minimum, required to provide oral notification of resolutions.

[24] See *https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf.*

Response: We are finalizing recordkeeping requirements at § 422.629(h) to help ensure consistency in recordkeeping and documentation of integrated grievances and appeals, including the date that the applicable integrated plan notified the enrollee of the resolution at § 422.629(h)(vii), as well as other minimum data elements. We also note that applicable integrated plans are required to provide the resolution of each integrated grievance to the enrollee, per § 422.630(e), which we address in detail in section II.A.2.b.(5) of this final rule. We will monitor the need for additional guidance on this issue during and after implementation of the unified appeals and grievance processes required by this final rule.

Comment: We received several comments supporting the proposed prohibition, at § 422.629(i), on applicable integrated plans taking punitive action against providers for supporting enrollees' integrated organization determinations or integrated reconsiderations. One commenter recommended that we clarify that this prohibition extends to an applicable integrated plans' contracted and delegated entities.

Response: We appreciate commenters' support for this requirement and note that it is our expectation that applicable integrated plans will ensure that contracted and delegated entities follow this requirement, since the managed care plan must ensure that requirements are met completely by its delegated or subcontracted entity and/or individual under current Medicaid rules (§ 438.230(b)) and current MA rules (§ 422.504(i)).

Comment: One commenter noted support for our proposed requirement, at § 422.629(j), for applicable integrated plans to provide information about the integrated grievance and appeals systems to all providers and subcontractors at the time they enter into a contract, and requested that we extend the provision to require annual refresher trainings.

Response: We appreciate the commenter's support. Both Medicaid and MA have general requirements about providing information, but no specific requirements with respect to frequency (see §§ 438.414, and 422.202(b)). We decline to incorporate the commenter's suggested requirement at this time because annual refresher training is beyond what current Medicaid or MA regulations require in connection with training on appeals and grievances processes. We believe such a requirement would be unduly prescriptive and constrain plans' flexibility in informing and training their providers and subcontractors. However, we do expect that applicable integrated plans will provide information and training to providers and subcontractors as often as is necessary to ensure requirements are well understood and met by all delegated entities.

Comment: One commenter supported the proposed requirement at § 422.629(k)(3) related to the specific individuals who can review an organization determination. A commenter recommended that we strike ''nor a subordinate of any such individual'' in the requirement at § 422.629(k)(4) related to who, at the applicable integrated plan, can review integrated reconsiderations.

Response: We appreciate the commenter's support for this requirement, but we decline to make this change, since our proposed rule applied the requirement in the Medicaid managed care regulations and we do not see a reason to set a new, different standard for review under the unified appeals process. We believe that prohibiting subordinates of someone who had already made a decision in a case is appropriate, since the goal of the requirement is to help ensure a new, objective review of the case, and a subordinate may believe a conflict of interest in this respect.

After review of the comments and for the reasons set forth in the proposed rule and our responses to the related comments, we are finalizing the definitions at § 422.561 of applicable integrated plan, integrated appeal, integrated grievance, integrated organization determination, and integrated reconsideration substantively as proposed with minor technical and grammatical modifications to the definition of an integrated organization determination to improve readability. We are finalizing the general provisions at § 422.629(a) through (k) requiring use of unified appeals and grievance processes by applicable integrated plans substantively as proposed with a minor modifications in paragraph (a) to make a non-substantive technical change to clarify that the unified appeals and grievance procedures finalized in this rule are applicable beginning January 1, 2021, and to clarify that § 422.618(a) does not apply to applicable integrated plans and to remove the designation of the single paragraph as (a)(1).

(4) Parties and Authorization for Filing Appeals (§ 422.629(l))

In proposed at § 422.629(l), we addressed who is able to request integrated grievances, integrated organization determinations, and integrated reconsiderations. Proposed § 422.629(1) used the heading ''Parties.'' Although not explicitly stated in the preamble of the proposed rule, we intended the heading to signal that such individuals would be parties to the resulting integrated grievance, integrated organization determination, and integrated reconsideration.

We also proposed in § 422.629(l)(1)(ii) to combine the MA and Medicaid requirements, such that a treating provider or authorized representative can file an appeal on behalf of an enrollee. Our proposal primarily adopted the MA rules at § 422.566(c) and § 422.582(a) that allow a treating provider to file a request for an organization determination or standard reconsideration on behalf of an enrollee without written authorization from the enrollee, but also require that the provider notify the beneficiary. In order to mitigate the risk that a provider would file an appeal against an enrollee's interest and without an enrollee's consent, particularly to take advantage of the provisions that allow a benefit to continue while the appeal is pending, we proposed that the appealing provider obtain the enrollee's written consent before requesting an integrated reconsideration if continuation of benefits is requested under § 422.632. Our proposed regulation text at § 422.629(l)(1)(ii) also incorporated the MA provision at § 422.574(b) that allows a provider to become an assignee of the enrollee and thereby become a party to the organization determination and redetermination if the provider waives any right to payment from the enrollee for the service that is the subject of the appeal.

We summarize the comments we received on proposed § 422.629(l) and respond to them as follows:

Comment: We received broad support for our approach to authorization for filing grievances, integrated organizations, and integrated reconsiderations. Most commenters agreed that our proposal presented a workable compromise between MA and Medicaid rules that should protect enrollees' rights and minimize the potential for inappropriate appeals. A few commenters expressed concern that allowing providers to pursue appeals without first obtaining enrollees' written consent would create a risk of conflicts of interest and potentially be used to manipulate negotiated rates.

Response: We thank commenters for their broad support of our approach. Because we are adopting existing MA rules for circumstances where written

consent is not required when requesting integrated reconsiderations, we believe the potential for conflicts of interest under our proposal are no greater than they are under MA. Moreover, because we believe the most significant potential for inappropriate provider-filed appeals exists when aid (that is, coverage and payment) pending integrated reconsideration is requested, requiring enrollees' written consent in these cases should mitigate these risks. Our proposal reflected this concern by limiting a provider's ability to seek benefit continuation pursuant to § 422.632 to only when the provider had received the written request of the enrollee in proposed § 422.629(l)(1)(ii); we are finalizing this specific provision in a new paragraph (l)(1)(iv).

Comment: One commenter expressed concern that requiring enrollees' written consent for provider-filed appeals requesting continuation of Medicare services would confuse enrollees and providers and raise the risk that enrollees would miss out on the opportunity to request continuation of benefits for Medicare-related appeals. Instead, the commenter recommended allowing providers to file requests for integrated reconsiderations on behalf of enrollees without enrollees' written authorization in these cases.

Response: We appreciate this concern but disagree with the recommendation. We believe the provision requiring enrollee authorization for provider-filed appeals requesting benefits pending appeal is necessary to mitigate against potential conflicts of interest. Although it may be theoretically possible to exclude Medicare-related appeals from the requirement for written enrollee consent in integrated reconsiderations, implementing such an exception would likely be more confusing for providers and enrollees in an integrated appeals system. We are therefore not adopting this suggestion, but we encourage plans, enrollees and their advocates, and providers to advise us regarding any difficulties implementing this provision.

Comment: One commenter requested that we clarify who is a party to the integrated reconsideration, similar to what currently exists in § 422.582.

Response: Proposed § 422.629(1) used the heading ''Parties'' and identified who could request an integrated grievance, integrated organization determination, and integrated reconsideration. Although not explicitly stated in the preamble, we intended the heading to be clear that such individuals would be parties to the resulting integrated grievance, integrated organization determination, and integrated reconsideration. We are finalizing the proposal with additional language clarifying, at § 422.629(l)(1), that all of the individuals listed in that paragraph are parties to the integrated grievance, integrated organization determination, and integrated reconsideration.

In addition, we are deleting the language proposed at § 422.629(l)(3) regarding which parties can request an expedited integrated organization determination and expedited integrated reconsideration. The same provisions are also at § 422.631(c)(1) for expedited integrated organization determinations and at § 422.633(e)(1) for expedited integrated reconsiderations, and including duplicative provisions at § 422.629(l)(3) created the potential for confusion.

Comment: Several commenters requested clarification regarding whether non-treating providers would be authorized to file appeals without an enrollee's written consent.

Response: Under § 422.578, only treating providers are permitted to file reconsideration requests on behalf of enrollees without obtaining the enrollees' written consent. We did not intend to broaden the ability of providers to file appeals on behalf of enrollees beyond what is permitted in MA or change the right of assignees of an enrollee to be parties to an appeal. We are therefore finalizing regulatory text in paragraph (l)(1)(ii) that an assignee of an enrollee includes a physician or provider that has furnished or intends to furnish a service to the enrollee and has waived the right to payment from the enrollee for the service. However, we are moving the provision regarding the need for physicians and providers to provide notice to the enrollee when filing a request for an integrated reconsideration on behalf on an enrollee to a new paragraph (l)(3) along with additional clarifying language. In this new paragraph (l)(3), we clarify that only treating providers may request an integrated pre-service reconsideration on behalf of enrollees without obtaining the enrollees' written consent, but must also provide notice to the enrollee of that request. Finally, for additional clarity, we are also finalizing a new paragraph (l)(1)(iv) in this final rule that explicitly states that any providers that furnish or intend to furnish a service to the enrollee may request an integrated organization determination or, subject to the requirements of paragraph (l)(3), an integrated reconsideration. This provision is similar to the MA provision at § 422.566(c)(1)(ii), and upon consideration of comments requesting clarity on the role of treating and non-treating providers, we believe it will be helpful to include this provision explicitly in this final rule. We are also moving the requirement that a provider requesting continuation of benefits on behalf of an enrollee must obtain the enrollee's written consent from proposed paragraph (l)(1)(ii) to the new paragraph (l)(1)(iv), as this new paragraph explicitly addresses the rights of treating providers in connection with integrated appeals. We are not finalizing in this new paragraph (l)(1)(iv) the requirement that was proposed at (l)(1)(ii) in the proposed rule that an authorized representative also needs to obtain written consent when requesting continuation of benefits because authorized representatives have—by definition—obtained authority to act on enrollees' behalf.

Comment: Several commenters requested clarification regarding whether our proposal for provider authorization applies both to pre-service and post-service appeals.

Response: MA rules at § 422.578 specify that the procedures permitting treating providers to request reconsiderations on an enrollee's behalf without the enrollee's consent apply only to pre-service appeals. As with the limitation to treating providers, we did not intend to broaden providers' appeal rights in this area beyond existing MA rules. We are therefore removing the regulatory text at § 422.629(l)(1)(ii) and adding to the new paragraph (l)(3) in this final rule regulatory text clarifying that the ability of providers to file for an integrated reconsideration without obtaining the enrollee's written consent applies only to pre-service integrated reconsiderations.

Comment: One commenter supported our proposal but suggested adding an explicit requirement that providers obtain enrollees' consent and provide enrollees with status updates during the appeal process. Another commenter made a related suggestion that providers requesting integrated reconsiderations on behalf of enrollees be required to sign and document that they have informed the enrollees of the filing of the appeal.

Response: We disagree that more explicit restrictions and obligations need to be part of the regulation. The final regulation at § 422.629(l)(3) states that, as under the MA regulation at § 422.578, only treating providers may request an integrated reconsideration on behalf on an enrollee without the enrollee's written consent upon providing notice to the enrollee. Pursuant to § 422.578, a treating provider may, upon providing notice to the enrollee, request a pre-service,

standard reconsideration on the enrollee's behalf; any provider acting on behalf of an enrollee may request that the standard reconsideration be expedited, and § 422.584 does not require notice to the enrollee of the request that the reconsideration be expedited. MA rules at § 422.578 do not impose additional explicit obligations on plans requiring specific documentation or monitoring of communications between providers and enrollees to establish that notice to the enrollee has been provided in these situations. Instead, MA policy provides plans with flexibility in how to ascertain whether a provider has adequately informed an enrollee of the request for reconsideration (see Parts C & D Enrollee Grievances, Organization/ Coverage Determination, and Appeals Guidance, § 50.1).[25] We believe similar flexibilities should apply to integrated reconsiderations. For example, if there are no records indicating contact between the provider and enrollee, the plan should take reasonable steps to confirm that the provider has informed the enrollee. Such steps could include asking the provider either directly or on the form used to request the reconsideration, or looking to see that the enrollee is copied on correspondence. The plan may also contact the enrollee to confirm.

Comment: One commenter requested clarification regarding whether the provider authorization rules in this section will also apply to expedited integrated reconsideration requests.

Response: As under MA rule at § 422.578, the rules regarding a provider requesting a reconsideration on an enrollee's behalf apply both to standard and expedited integrated reconsideration requests. The new paragraph § 422.629(l)(3) we are finalizing in this rule states explicitly that the rule applies to both standard and expedited integrated reconsideration requests. We note that if there is a request for benefits pending appeal, then the enrollee's written consent is required under the provision we are finalizing at § 422.629(l)(1)(iv). In such a circumstance, the provider may file the expedited request without a request for aid pending appeal in order to get the reconsideration request filed as soon as possible. The provider may then follow up with written authorization to request continuing benefits on the enrollee's behalf after securing the enrollee's consent to that request so long as the time period for requesting continuing benefits has not expired.

After consideration of the comments and for the reasons provided in the proposed rule and our responses to the comments, we are finalizing § 422.629(l) with some modifications. Specifically—

- We have revised paragraph (l)(1) to more clearly state that that the individuals and entities identified in that section are parties to the case;

We moved the provisions addressing the ability of providers to file appeals on behalf of enrollees that were proposed at paragraph (l)(1)(ii) to a new paragraph (l)(3), and we have deleted references to authorized representatives in that paragraph.

- We have added a new paragraph (l)(1)(iv) to expressly permit any treating provider to request an integrated organization determination and integrated reconsideration. We have also moved the provisions addressing the obligation of providers to obtain written consent of enrollees when requesting continuation of benefits that were proposed at paragraph (l)(1)(ii) to the new paragraph (l)(1)(iv);
- In paragraph (l)(2), which addresses the use of the term ''enrollee,'' we have replaced the words ''this section' in the proposed rule with ''§§ 422.629 through 422.634'' because our intent is that the use of the term enrollee as described in this paragraph apply to the entire integrated grievance and appeal process. As proposed, we are concerned the reference to ''this section'' was ambiguous and therefore are clarifying it; and
- We have deleted the proposed paragraph (l)(3) because that language was redundant with provisions codified in §§ 422.631 and 422.633.

(5) Integrated Grievances (§ 422.630)

At § 422.630, we proposed to largely parallel Medicare and Medicaid requirements where these requirements are the same with regard to the treatment of integrated grievances. Where MA includes a requirement that Medicaid does not, or vice versa, or where the MA and Medicaid regulations conflict, we proposed applying the requirement that best aligns with the principles and statutory requirements discussed in section II.A.2.b. of the proposed rule. For integrated grievances, we specifically proposed:

- At paragraph (a), to establish the general purpose of the regulation, similar to § 438.402(a) and § 422.564(a), by requiring that an applicable integrated plan provide meaningful procedures for timely hearing and resolving integrated grievances filed by an enrollee. We proposed to define the scope of the required procedures as being applicable to any grievances between the enrollee and the plan or any entity or individual through which the applicable integrated plan covers health care services. We proposed this requirement for the applicable integrated plan to be responsible for ensuring timely and appropriate resolution of a grievance even if the grievance pertains to an act or decision by one of the applicable integrated plan's providers of health care services. In the regulation text, we proposed that the integrated grievance procedures applied to ''grievances between enrollees and the applicable integrated plan or any other entity or individual through which the applicable integrated plan provides health care services.''
- At paragraph (b), to provide that an enrollee may file a grievance at any time, paralleling the current Medicaid regulation at § 438.402(c)(2).
- At paragraph (c), to allow grievances to be filed with the applicable integrated plan orally or in writing, in alignment with MA and Medicaid requirements; we also proposed to allow integrated grievances related to Medicaid benefits to also be filed with the state in states that have processes in place for that in accordance with § 438.402(c)(3).
- At paragraph (d), we proposed to largely parallel the MA requirements (at § 422.564(f)) to authorize an enrollee to file an expedited grievance when the complaint involves the applicable integrated plan's decision to extend the deadline for certain appeals or refusal to grant a request for an expedited integrated organization determination or expedited integrated reconsideration.
- At paragraph (e)(1), to parallel MA's maximum 30-day timeframe for resolving the grievance and MA's requirements, at § 422.564(e)(1), for how the applicable integrated plan must respond to grievances, depending on how the grievance is received and the basis upon which the enrollee filed the grievance. Although not discussed in the preamble to the proposed rule, the proposed regulation text would require the applicable integrated plan to resolve an integrated grievance as expeditiously as the case requires based on the enrollee's health status and within 30 days, which is the current requirement under Medicare (see § 422.564(e)(1)).
- At paragraph (e)(2), to include a provision, paralleling provisions in MA (§ 422.564(e)(2)) and Medicaid managed care (§ 438.408(c)(1)), permitting the applicable integrated plan to extend the time period in which a determination on an integrated grievance must be

[25] See *https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf.*

issued to the enrollee by up to 14 days. We proposed combining MA and Medicaid requirements, such that applicable integrated plans must notify enrollees immediately, but no later than within 2 calendar days, which we believe to be in line with the principles identified in section 1859(f)(8)(B)(iii) of the Act for timely, clear notification to enrollees.

We invited comments on these topics, specifically whether the proposed regulation text accurately incorporated the standards from the underlying part 422 or part 438 regulation that are more beneficial to the enrollee. We also solicited comment on whether we adequately captured all relevant enrollee protections currently available under MA and Medicaid. We summarize and respond to the comments on these specific proposals as follows:

Comment: Many commenters supported our proposed integrated grievance process, including provisions for an expedited grievance process, the 14-day extension period for resolving integrated grievances, the clarification that applicable integrated plans must resolve grievances involving any entity or individual through which the applicable integrated plan provides health care services, requiring responses to grievances within 30 days, and allowing enrollees to file at any time. A few commenters opposed the proposal to allow enrollees to file integrated grievances at any time, and recommending that CMS instead limit enrollees to filing integrated grievances within 60 days, to be consistent with the current MA requirement.

Response: We appreciate the support for our proposed integrated grievance requirements. We decline to establish in this final rule a timeframe for enrollees to file a grievance. While we understand the commenters' desire to be consistent with such limits in the MA program, our proposed requirements were developed consistent with the statutory requirement that we implement standards most protective of enrollees (see section 1859(f)(8)(B)(ii)(I) of the Act). The relevant Medicaid regulation (§ 438.402(c)(2)(i)) allows a grievance to be filed at any time, while the MA regulation (§ 422.564(d)(a)) limits grievance filing to within 60 days of the event at issue. Not having a time limit for enrollees to file grievances is most protective for enrollees by eliminating barriers to filing.

In addition, we note that the language as we proposed in § 422.630(a) with respect to the types of benefits for which the applicable integrated plans is responsible for resolving integrated grievances was limited to disputes involving entities that provide ''health care services,'' which is the MA rule at § 422.564(a). Our intent was that an applicable integrated plan be responsible for resolving grievances pertaining to all its contracted providers, including those that provide items and services that might not be strictly considered health care services, such as Medicaid non-emergency transportation. Using a broader term will ensure that the right to file an integrated grievance with an applicable integrated plan includes grievances that could be filed for all Medicare and Medicaid covered benefits. Therefore, we are revising § 422.630(a) to state that the applicable integrated plan is responsible for resolving grievances between enrollees and entities through which the plan provides ''covered items and services.'' We are adopting the provision as set forth in the proposed rule with this minor revision as noted.

Comment: Several commenters supported the proposal to allow enrollees to file Medicaid-related grievances with the state. A few commenters requested clarification on which integrated grievances could be filed with the state. Another commenter suggested that CMS go further and allow integrated grievances to be filed with providers and 1–800–Medicare, and a few commenters recommended that CMS ensure that there is a ''no wrong door'' policy such that if an enrollee files a grievance with the wrong entity, it is not just dismissed.

Response: We appreciate commenters' broad support for this provision. We appreciate the importance of a ''no wrong door'' policy, and we intend to work closely with states that permit enrollees to file Medicaid grievances with the state to ensure that applicable integrated plans have the guidance they need regarding policies and procedures for these instances. Further, we will consider comments about establishment of ''no wrong door'' processes for all enrollees in applicable integrated plans; we note that CMS has established an online system for Medicare beneficiaries to submit complaints and concerns about the Medicare program, including MA plans. Additionally, 1–800–Medicare currently accepts complaints related to Medicare, and CMS ensures resolution of them.

With regard to the ability to file grievances with providers, we do not believe additional regulatory provisions are needed. We expect that, as currently is the case, most enrollees will submit grievances directly to the applicable integrated plan. Under § 422.629(j), applicable integrated plans will be required to provide information about the integrated grievance and appeals system to all contracted providers (as noted in the proposed rule, this requirement already exists for Medicaid MCOs). This information should enable contracted providers to direct enrollee grievances properly to the applicable integrated plan when necessary. In addition, plans may delegate responsibility for handling grievances to provider groups consistent with existing Medicare policy (see § 422.504(i) and the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, § 10.4.3 [26]). In those circumstances, the plan remains ultimately responsible for ensuring that contracted entities comply with all rules governing responding to grievances.

With regard to comments about filing grievances with the state, we clarify that the regulation is designed to provide a means for the state to address Medicaid grievances. If a grievance contains aspects related to both Medicare and Medicaid benefits, the state can review the Medicaid benefit portions, but should ensure that the Medicare benefit portions are appropriately transferred to the applicable integrated plan for review. If a grievance related to Medicaid benefits is filed with both the state and the applicable integrated plan, we expect the two entities to be in communication to ensure the grievance is resolved, as would occur now for Medicaid managed care grievances.

Comment: One commenter requested that we require all responses to grievances to be in writing. Several other commenters suggested that we not require written acknowledgement of all grievances.

Response: We do not believe that a written response to all integrated grievances is necessary; such a standard is not imposed under current requirements for MA plans or for Medicaid managed care plans. As proposed and finalized in this rule, the regulation (§ 422.630(e)(1)) requires applicable integrated plans to respond in writing to integrated grievances when: (1) The integrated grievance was filed in writing; (2) the enrollee requests a written response to an integrated grievance that was orally submitted; and (3) the integrated grievance was related to quality of care. The regulation permits applicable integrated plans to respond in writing or orally to integrated grievances that are filed orally, unless the enrollee requests a

[26] See *https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf.*

written response. Additionally, the applicable integrated plan must send the enrollee a written notice when it extends the timeframe for responding to the integrated grievance (consistent with § 422.630(e)(2)(ii), it may extend the timeframe by up to 14 calendar days). Consistent with § 422.629(c) as finalized, there is flexibility for states to set standards that are more protective of enrollees in connection with timeframes and notices; a state could, at its discretion, require that applicable integrated plans provide the disposition of all grievances in writing. Such a requirement would need to be specified in the state Medicaid agency contract with the D–SNP. We note that an applicable integrated plan, consistent with § 422.629(g), must send a written notice acknowledging receipt of the grievance; in this notice, a plan could also note that the grievance is considered resolved if the applicable integrated plan has previously provided the enrollee an oral resolution to clarify the status of the grievance for the enrollee. Accordingly, we are adopting without change the provision as set forth in the proposed rule.

Comment: Several commenters requested clarification on the requirement that applicable integrated plans notify enrollees within 2 calendar days when an extension is being taken.

Response: We clarify that the applicable integrated plan must notify the enrollee that an extension is being taken within two calendar days of when the applicable integrated plan, after justifying the need for the extension and documenting how the delay is in the enrollee's interest, makes the decision to extend the timeframe. We are finalizing the regulation text at § 422.630(e)(2)(ii) with additional text to clarify this timing.

Comment: A commenter suggested that we implement integrated reporting in the Complaint Tracking Module (CTM) for grievances in the CMS Health Plan Management System (HPMS) and give states access to track all grievances and resolutions for transparency and monitoring.

Response: We appreciate the comment and will consider it as we move forward with implementation. If such a step is operationally feasible, we do not believe it would require additional regulatory language.

For the reasons provided in the proposed rule and our responses to the comments, we are finalizing the requirements at § 422.630 substantively as proposed with some minor modifications as follows:

- We are revising the regulatory text at paragraph (a) by replacing ''health care services'' with ''covered items and services'' in order to ensure that grievances pertaining all Medicare and Medicaid covered benefits are included in the requirement;
- We are finalizing the regulatory text in paragraph (d) with revisions to streamline the regulation text and, at paragraph (d)(2), to clarify the terms used; and
- We are revising paragraph (e)(2)(ii) to clarify how long the plan has to notify the enrollee when it extends the time the resolve a grievance.

(6) Integrated Organization Determinations (§ 422.631)

In proposed § 422.631, we specified the procedures applicable integrated plans would follow in making integrated organization determinations. In paragraph (a), we proposed that, as part of a unified process, all requests for benefits covered by applicable integrated plans must be subject to the same integrated organization determination process.

In paragraph (b), we proposed to adopt the MA provisions at § 422.568(a) allowing an enrollee to request an integrated organization determination either orally in writing, but requiring requests for payment to be made in writing.

In paragraph (c), we proposed to articulate the standard for making an expedited organization determination. Both MA (at § 422.570(c)) and Medicaid (at § 438.210(d)(2)) have similar standards for an expedited organization determination, including who can file it (proposed in § 422.631(c)(1)) and how it should be decided (proposed in § 422.631(c)(3)). At paragraph (c)(2), we proposed that the request to expedite the appeal can be made orally or in writing.

In paragraph (d), we proposed rules regarding timeframes and notices when resolving integrated coverage determinations. In paragraph (d)(1), we proposed to require that an applicable integrated plan send a written integrated notice when the organization determination (standard or expedited) is adverse to the enrollee. We proposed to include text specifically identifying as adverse determinations requiring a notice any decision to authorize a service or item in an amount, duration, or scope that is less than the amount requested or previously requested or authorized for an ongoing course of treatment. We also proposed to include text specifying, consistent with Medicaid managed care requirements (§ 438.404(c)(5)), that the applicable integrated plan must send an integrated determination notice when the plan fails to make a timely decision because failure to make a decision within the required timeframe is a denial (and thus an adverse determination). The proposed notice would include information about the determination, as well as information about the enrollee's appeal rights under both Medicare and Medicaid. We also proposed that the notice be written in plain language and available in a language and format that is accessible to the enrollee; this proposed requirement is consistent with section 1859(f)((8)(B)(iii)(III) of the Act.

In paragraph (d)(2), we proposed timelines for sending this notice that largely align with both existing Medicare and Medicaid requirements. We proposed, in paragraph (d)(2)(i)(A), to require that applicable integrated plans send a notice of an integrated organization determination at least 10 days before the date of action if a previously authorized benefit is being reduced, suspended, or terminated, with some exceptions in accordance with §§ 431.213 and 431.214; we briefly explained the exceptions available in accordance with §§ 431.213 and 431.214 in the proposed rule (83 FR 55008). We proposed, in paragraph (d)(2)(i)(B), to require that applicable integrated plans send the notice as expeditiously as the enrollee's health condition requires but no later than 14 calendar days from receipt of the request for a standard integrated organization determination. We further proposed to permit extensions, in paragraph (d)(2)(ii), in circumstances that largely parallel those that exist in Medicare and Medicaid currently. In paragraph (d)(2)(iii), we proposed requirements for notice to be provided to the enrollee in cases of extension; these proposed requirements also largely parallel current MA and Medicaid requirements at § 422.572(b)(2) and § 438.404(c)(4)(i), respectively. Proposed § 422.631(d)(2)(iii)(A) largely parallels § 422.572(b)(2), which provides more specific direction on timing of the notice. We also proposed in paragraph (d)(2)(iii)(B) regulatory text controlling when the notice of the integrated organization determination must be sent in cases where the applicable integrated plan makes the decision to extend the timeframe.

In paragraph (d)(2)(iv)(A), we proposed the deadline for issuing notice of expedited integrated organization determinations. Both MA and Medicaid require expedited organization determinations (or adverse actions) as expeditiously as the enrollee's health condition requires but not later than within 72 hours of the request, with the possibility of extending that timeframe

by 14 calendar days. We proposed, at paragraph (d)(2)(iv)(B), to mirror the MA requirements (§ 422.570(d)), with required procedures when an applicable integrated plan denies a request for expediting an organization determination. In paragraph (d)(2)(iv)(C), we proposed to include requirements, which parallel MA requirements (§ 422.572(d)), for applicable integrated plans when obtaining necessary information from noncontract providers.

We received the following comments on the proposals at § 422.631 and our responses follow.

Comment: We received many comments related to the notice requirement in proposed § 422.631(d)(1). Several commenters supported the notice of the integrated organization determination, the required content we proposed, and the requirement that it be written in plain language and available in the language and format that is accessible to the beneficiary. Several commenters requested clarification regarding whether the existing Integrated Denial Notice used by MA plans (Form CMS–10003–NDMCP) would be used to satisfy the requirement for notice of the integrated organization determination. Several other commenters also suggested that CMS develop a model notice to serve as the integrated organization determination notice for applicable integrated plans to use. A commenter recommended that the notice only be required to be sent when there is a denial of the service or item by all coverage sources (that is, Medicare and Medicaid).

Response: We intend to develop a separate model notice that will be used exclusively for integrated organization determinations and that will be specifically tailored to contain information relevant to the unified appeals process we are finalizing in this rule. As finalized in § 422.631(d)(1), the new integrated notice will be sent in cases where a service or item is being denied under Medicare and Medicaid. In addition, as is the case with the current MA Integrated Denial Notice (Form CMS–10003–NDMCP), we will develop instructions for appropriate use of the new model notice. The instructions will also explain how plans should tailor the model notice to explain the outcome to the enrollee in situations where a notice is required. As we note in the Collection of Information section in this final rule, this model notice, and its associated requirements and burden, will be submitted to OMB for approval separately from this final rule once we develop the model and accompanying analyses. The OMB approval process will include a public comment period.

Comment: A commenter recommended that we also make the integrated organization determination notice available for use by plans other than applicable integrated plans.

Response: We decline to accept the commenter's suggestion. We intend to tailor the model notice specifically to the unified appeals process, and information and procedures relevant to that process, we are finalizing in this rule. We do not believe the model notice will be appropriate for enrollees outside the unified process and, as such, the model notice for integrated organization determinations will be specifically tailored for use by applicable integrated plans.

After consideration of the comments and for the reasons set forth in the proposed rule and our responses to the related comments, we are finalizing § 422.631 substantively as proposed, but with minor modifications to streamline the regulatory text at paragraph (d) as follows:

- We are finalizing proposed paragraph (d)(1) as three new paragraphs, paragraphs (d)(1)(i) through (iii) and making minor grammatical changes.
- We are renumbering proposed paragraphs (d)(1)(i) through (viii) in the final rule as paragraphs (d)(1)(iii)(A) through (H).

(7) Continuation of Benefits Pending Appeal (§ 422.632)

At § 422.632, we proposed rules to implement the provisions added to section 1859(f) of the Act by section 50311 of the Bipartisan Budget Act of 2018 pertaining to continuation of benefits pending appeal under Titles XVIII and XIX, specifically the new provision at section 1859(f)(8)(B)(iv) of the Act. We explained in detail in the proposed rule (83 FR 55008 through 55009) how we interpret this provision as requiring CMS to apply continuation of benefits to all Medicare Parts A and B and Medicaid benefits under our proposed unified appeals processes.

Based on that interpretation, we proposed that the existing Medicaid standards applicable to Medicaid managed care plans for continuation of benefits at § 438.420 apply to applicable integrated plans for Medicare benefits under Parts A and B and Medicaid benefits in our proposed integrated appeals requirements at § 422.632. Under our proposal, if an applicable integrated plan decides to stop (as a termination or suspension) or reduce a benefit that the enrollee is currently authorized to receive, the enrollee could request that the benefit continue to be provided at the currently authorized level while the enrollee's appeal is pending through the integrated reconsideration. The enrollee would be required to make a timely request for the continuation. We proposed, at paragraph (a), a definition for ''timely files.'' This proposed definition mirrored the definition at § 438.420(a), with minor revisions to make the text applicable to applicable integrated plans instead of Medicaid managed care plans.

We proposed, at paragraph (b), to require a previously authorized service covered under Medicaid or Medicare Part A or Part B, excluding supplemental benefits as defined at § 422.102, to be continued pending an appeal of a termination of those services. We proposed to require that the continuation of these services as a covered benefit would be conditioned on meeting the same five criteria listed in § 438.420:

(1) The enrollee files the request for an integrated appeal timely in accordance with § 422.633(e);

(2) The integrated appeal involves the termination, suspension, or reduction of previously authorized services;

(3) The services were ordered by an authorized provider;

(4) The period covered by the original authorization has not expired; and

(5) The enrollee timely files for continuation of benefits.

Because proposed paragraph (b) repeated that language at section 1859(f)(8)(B)(iv) of the Act that limits the continuation of benefits to only benefits under Parts A and B of title XVIII and title XIX of the Act, we noted in the preamble to the proposed rule that MA supplemental benefits would not be subject to the proposed rule (83 FR 55009).

We proposed, at paragraph (c), to require that an applicable integrated plan continue such services pending issuance of the integrated reconsideration. We noted in the proposed rule that for Medicaid managed care plans that are not applicable integrated plans, continuation of these services after the integrated reconsideration and pending resolution of the state fair hearing is controlled by § 438.420(c). Proposed § 422.632(c)(2) provided that continuation of services would end when the applicable integrated plan issues an adverse integrated reconsideration. If the applicable integrated plan finds in favor of the enrollee, benefits would continue in accordance with the favorable integrated

reconsideration. In proposed § 422.632(c)(3), we proposed requirements for Medicaid-covered benefits to continue after the applicable integrated plan issues an adverse integrated reconsideration, mirroring the requirements currently in Medicaid managed care regulations (see § 438.420(c)(2)). The enrollee must make the request and file for a state fair hearing within 10 calendar days after the applicable integrated plan sends the notice of the integrated reconsideration. We also proposed to mirror requirements from § 438.420 for how long Medicaid-covered benefits must continue by requiring that the benefits continue until the enrollee withdraws the request for the state fair hearing or until the state fair hearing decision is issued.

In proposed paragraph (d), we addressed whether an applicable integrated plan can seek recovery for the costs of services provided while an appeal is pending. We proposed not to follow Medicaid's regulations that allow states to determine whether or not a plan, or the state, can seek recovery for the costs of services provided pending appeal. We noted there is no analogous process in Medicare, as continuation of benefits pending appeal is very limited in Medicare and generally only available in cases involving QIO review of inpatient discharges. Instead, drawing in part on the experience of a number of Financial Alignment Initiative demonstrations, we proposed to prohibit recovery of the costs of services provided pending the integrated reconsideration and, for Medicaid-covered benefits, any state fair hearing, to the extent that services were continued solely under § 422.632, for all applicable integrated plans and state agencies.

We solicited comment generally on our proposal regarding continuation of benefits and also requested comments on alternatives, including regarding the feasibility of treating Medicare and Medicaid benefits differently for the purpose of recovery of costs. We summarize the comments on this topic and respond to them as follows:

Comment: Most commenters supported our overall interpretation of the statute extending Medicaid's approach of providing aid pending appeal to items and services covered under Medicare Part A and Part B. One commenter, in supporting our overall approach, urged us to monitor for any unexpected cost consequences to D–SNPs resulting from the rule and encouraged us to ensure that any additional costs resulting from the policy are allowable for bid purposes. Another commenter objected to the entire approach based on concerns about potential cost implications to the integrated D–SNPs subject to the provision. One commenter disagreed with our approach, stating that we should make no changes to Medicare's coverage of items and services pending appeal, although this commenter provided no statutory basis for their perspective.

Response: We appreciate the strong support for our overall approach. As we discussed in the preamble to the proposed rule, we believe the most logical reading of the statutory language directs us to extend Medicaid's aid pending appeal procedure to Medicare Part A and B services covered by applicable integrated plans. Regarding costs, MMPs in the Financial Alignment Initiative have operated under similar rules and have not reported any significant resulting adverse impact on cost. The Regulatory Impact Analysis for our proposed rule, on which we received no comments related to this specific proposal, projected a minimal cost to plans from extending the Medicaid aid pending appeal procedure to Medicare Parts A and B services. We will provide further guidance on this topic for plans as part of the bid submission process.

Comment: We received many comments regarding our approach to recovery of the costs of services provided pending appeal. Many commenters supported our proposal as consistent with the statute, clearer to administer than alternatives, and most protective of beneficiaries. A significant number of other commenters, however, expressed concern that our approach could increase costs and recommended instead that states retain the flexibility to pursue recovery of costs at their discretion.

Response: We thank the commenters for their comments on this issue. After careful consideration of the commenters' perspectives, we are finalizing our proposal with some modifications to § 422.632(d) regarding recovery of the costs. We are finalizing the proposed regulation regarding recovery of costs at the integrated reconsideration level, which is now codified at § 422.632(d)(1). We believe it is highly desirable to have one single rule regarding recovery of costs apply to all services provided pending the issuance of the integrated reconsideration decision pursuant to section 1859(f)(8)(B)(iv) of the Act, rather than to treat Medicare-related and Medicaid-related services differently. We believe that it is simpler and more protective of beneficiaries to prohibit the recovery of the costs of all services provided by an applicable integrated plan pending an integrated reconsideration pursuant to a request filed under § 422.632. All services, both Medicare-related and Medicaid-related, provided by applicable integrated plans through the end of the integrated reconsideration process are considered to be furnished under the requirements of § 422.632 and are therefore not subject to recovery of costs.

However, we find it persuasive that, for cases where a plan's denial is ultimately affirmed, eliminating the ability of states to recover the costs of Medicaid services provided by the applicable integrated plan after the integrated reconsideration is final and pending a state fair hearing could create significant inconsistencies for state Medicaid appeal processes and potentially discourage states from pursuing exclusively aligned enrollment and thereby adopting integrated appeals. Moreover, because our entire integrated process extends only to the integrated reconsideration stage and not to the state fair hearing process, this rule limiting recovery of costs is also limited to costs incurred for continuation of services pending the integrated reconsideration stage. We are therefore designating the text in proposed paragraph (d) as (d)(1) in this final rule with revised text limiting that rule to recovery of costs for services continued pending the integrated reconsideration. We are also finalizing a new provision at paragraph (d)(2) to provide states with the flexibility to recover the costs of services continued pending the state fair hearing phase of an appeal (that is, after the date of the integrated reconsideration decision and until the decision is issued on the state fair hearing), consistent with state rules and with § 438.420(d). We believe this addition should mitigate concerns about costs to states. We also note a number of Financial Alignment Initiative demonstrations do not allow recoupment of costs and MMPs have not reported any adverse financial impact, suggesting a minimal impact on costs from limiting recovery of costs. In summary, under § 422.632(d)(1) and (d)(2), recovery of costs is not permitted for services provided pending the integrated reconsideration. If an enrollee requests a state fair hearing after an adverse integrated reconsideration, then state Medicaid procedures regarding continuation of benefits and recovery of costs will apply. We will work with states and plans to ensure that enrollees are fully informed of these rules. Finally, we note that this provision is

unrelated to the requirement at § 422.634(e) requiring a plan or state to pay the costs of benefits provided in the event a plan's initial decision is reversed at the integrated reconsideration or fair hearing stage. The obligations at § 422.634(e) are similar to those under Medicaid at § 438.424(b) governing effectuation of a decision, and apply to any services the enrollee receives while the appeal is pending, whether or not continuation of benefits was requested under § 422.632.

Comment: A commenter requested that CMS clarify whether services were required to continue pending IRE review. We received a number of comments recommending that we should require coverage of aid pending appeal for Medicare Parts A and B services to extend through the IRE level (and in some comments, through the administrative law judge (ALJ) or higher appeal levels as well), rather than stopping after the integrated reconsideration level. One commenter expressed concern that stopping before the IRE level would discourage appeals. Others encouraged continuation through the IRE level to ensure external review of all appeals before services ended.

Response: The regulation, as proposed and finalized at § 422.632(c)(2), requires integrated applicable plans to continue Medicare Part A and Part B and Medicaid benefits through the issuance of an integrated reconsideration decision under § 422.633(f)(4). If the applicable integrated plan affirms its decision at the integrated reconsideration level and the case involves Medicaid benefits, an enrollee may request a state fair hearing as described in § 422.634(b)(2). From that point forward, existing Medicaid rules apply, including § 438.420 that requires Medicaid managed care plans—regardless whether they are applicable integrated plans—to continue provision of Medicaid benefits on certain terms through the state fair hearing process. We decline at this time to require continuation of Medicare services through the IRE level, and will retain our rule as proposed that requires continuation of Medicare Parts A and B services only through the integrated reconsideration level. Section 1859(f)(8)(B)(iv) of the Act provides authority to extend benefits pending appeal in the context of the unified appeal procedures we are adopting in this rule. We are not at this time integrating IRE review into a unified appeal process; therefore, we believe we lack statutory authority to extend benefits pending to the IRE level review under the unified appeal process. In addition, most of the Financial Alignment Initiative demonstrations have not included aid pending appeal through the IRE level. As a result, we have little experience with either the operational complexities or the financial impact of such a policy. Finally, because IRE review is automatic for all adverse Medicare plan reconsiderations under § 422.592, there is not a risk that enrollees will end their appeal prior to the IRE review. We believe the more prudent course is to implement aid pending appeal for services through the integrated reconsideration level as we have proposed. We may consider the feasibility of broadening the unified appeal process to include IRE review and continuation of benefits through additional appeal levels in future rulemaking.

Comment: A few commenters recommended that continuation of benefits pending appeal also apply to supplemental benefits provided by applicable integrated plans.

Response: We decline to adopt this recommendation and believe that it is not consistent with the statute. Section 1859(f)(8)(B)(iv) of the Act, added by the Bipartisan Budget Act of 2018, authorizes continuation of benefits for integrated appeals is limited to benefits under Medicare Parts A and B as well as Medicaid, but does not include MA supplemental benefits, which are offered under Part C of the Act (specifically section 1852(a)(3) of the Act). We therefore do not have the authority to require continuation of supplemental benefits pending appeal. Plans may continue such benefits voluntarily, however, and states may include conditions affecting coverage of such benefits in their contracts with D–SNPs, so long as enrollees are made aware of any potential risk of financial liability.

Comment: A few commenters suggested that we establish an expedited process for integrated reconsiderations when continuation of benefits pending appeal is requested in order to minimize the risk of payment discrepancies.

Response: We decline to adopt this suggestion. We note that continuation of services pending appeal has long been part of Medicaid appeals and no special expedited process exists for such cases. We do not see a reason for treating integrated reconsiderations differently in this regard. In addition, applicable integrated plans may prioritize resolution of integrated reconsiderations where services are continuing, so long as these plans follow all procedural rules and ensure that enrollees have a full opportunity to present their case. Further, the requirement to expedite certain integrated reconsiderations based on the enrollee's health status (discussed in section II.A.2.b.(8) of this final rule) applies regardless whether benefits are continued under § 422.632.

Comment: A few commenters requested that we add language that would allow plans to dismiss an integrated reconsideration request if an enrollee becomes eligible for a service while the integrated reconsideration is pending.

Response: We decline to make this addition. There are no regulations in the MA program or Medicaid managed care program that address dismissals of reconsiderations or appeals in these circumstances, and we do not believe that we should create a new procedure unique to integrated reconsiderations here. We note that the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, § 50.8, does include guidance regarding dismissal of pre-service reconsideration requests when a service has been provided before the reconsideration is completed. We will consider if additional guidance is needed in this area for integrated reconsiderations when continuation of services is requested.

After considering the comments and for the reasons set forth in the proposed rule and our responses to the comments, we are finalizing § 422.632 as proposed with modifications to paragraph (d). In newly designated paragraph (d)(1), we are making technical changes to the proposed regulation text to clarify that an applicable integrated plan or a state agency may not pursue recovery of costs for services continued pending the integrated reconsideration. In new paragraph (d)(2), we are finalizing a provision that authorizes states to recover the costs of Medicaid services provided during the state fair hearing phase of an appeal (that is, after the date of the integrated reconsideration decision and until the decision is issued on the Medicaid state fair hearing), consistent with state rules and with § 438.420(d).

(8) Integrated Reconsiderations (§ 422.633)

In proposed § 422.633, we laid out our proposed provisions for an integrated reconsideration process for applicable integrated plans. As with other provisions, we compared relevant Medicare and Medicaid provisions, and where they differ, we chose to adopt the policy that is most protective of the beneficiary.

In paragraph (a), consistent with current MA and Medicaid regulations (§§ 422.590 and 438.402(b), respectively), we proposed that

applicable integrated plans may only have one plan level of appeal beyond the initial decision (the integrated organization determination).

In paragraph (b), we proposed to adopt a rule similar to § 438.402(c)(1)(i)(B) regarding the permissibility of external medical reviews: Medicaid managed care plan enrollees may be offered an opportunity to elect external medical review under a state external review process. Under our proposal, the ability to elect external medical review would apply only to Medicaid covered services that are the subject of an adverse integrated reconsideration issued by an applicable integrated plan because D–SNPs, like all MA plans, are not subject to state external review procedures.[27]

In paragraph (c), we proposed a right for each enrollee, and their representatives, to receive a copy of the enrollee's case file (including medical records and evidence considered, generated, or relied on by the integrated applicable plan in making the integrated organization determination) free of charge, consistent with the protection for Medicaid enrollees under § 438.406(b)(5).

In paragraph (d)(1), we proposed timelines for filing for a standard integrated reconsideration that, consistent with both MA (at § 422.582(b)) and Medicaid managed care (at § 438.402(c)(2)(ii)) regulations, would require that an integrated reconsideration be filed within 60 days of the date of the denial notice. We proposed, in paragraph (d)(2), that oral inquiries seeking to make an integrated reconsideration be treated as integrated reconsiderations; this is generally consistent with § 438.406(b)(3). We did not propose to include the language in § 438.406(b)(3) requiring beneficiaries to provide written confirmation of oral requests because such a requirement would be inconsistent with MA policy that directs plans that do accept oral requests for reconsideration to provide written confirmation to the beneficiary (see Parts C & D Enrollee Grievances, Organization/Coverage Determination, and Appeals Guidance, § 50.2.1). We proposed, in paragraph (d)(3), to include current requirements from MA (at § 422.582(c)) that allow for extending the timeframe for an enrollee, or a physician acting on behalf of an enrollee, to file a late reconsideration.

In paragraph (e), we proposed to address procedures for filing expedited integrated reconsiderations, consistent with current MA and Medicaid rules. The proposed language in paragraphs (e)(1) and (e)(2) aligns with § 422.584 in permitting the enrollee or health care provider to file a written or oral request for an expedited reconsideration. The proposed language in paragraph (e)(3) aligns with § 422.584 in setting the standard that the applicable integrated plan must use in deciding whether to expedite the integrated reconsideration.

In paragraph (e)(4), we proposed notice requirements related to requests for expedited integrated reconsiderations. We proposed requirements that parallel Medicaid managed care requirements for notice to the enrollee when the request for an expedited integrated reconsideration is denied (§ 438.410(c)(2))—specifically, that the plan must give prompt oral notice and written notice within 2 calendar days and transfer the matter to the standard timeframe for making an integrated reconsideration (that is, the timeframe specified in paragraph (f)(1)). We proposed to apply the MA requirements for what applicable integrated plans must include in the written notice to enrollees when the request to expedite the integrated reconsideration is denied (§ 422.584(d)(2)).

In paragraph (e)(5) we proposed to include requirements, which mirror MA requirements (§ 422.590(d)(3)), for applicable integrated plans when obtaining necessary information from noncontract providers. These requirements specify that the applicable integrated plan must reach out to a noncontract provider within 24 hours of the initial request for an expedited integrated reconsideration.

In paragraph (f), we proposed timelines and procedures for resolving an integrated reconsideration request. We proposed specific requirements for applicable integrated plans. Both MA (at § 422.590(a)) and Medicaid (at § 438.408(b)(2)) require resolution of pre-service standard appeal requests within 30 calendar days. We proposed the rules in paragraph (f)(1), that parallel MA (at § 422.590(a)) and Medicaid (at § 438.408(b)(2)) with the addition of a provision mirroring § 422.590(a)(2), that the integrated reconsideration decision be issued as expeditiously as the enrollee's health requires but no later than 30 calendar days from the date the applicable integrated plan receives the request for the integrated reconsideration.

In § 422.633(f)(1), we proposed to require that all integrated reconsiderations—pre-service and post-service—be resolved as expeditiously as the enrollee's health requires and within 30 calendar days from the date the applicable integrated plan receives the request for the integrated reconsideration. We noted that this timeframe is consistent with Medicaid managed care requirements for both pre- and post-service requests at § 438.408(b)(2) and with pre-service requests under MA at § 422.590(a). We deviated from the MA requirements for post-service cases involving denial of payment, as current MA requirements provide 60 calendar days for MA plans to resolve these cases.

In paragraph (f)(2), we proposed to establish the timeframes for expedited reconsiderations, which parallel both MA (at § 422.590(d)(1)) and Medicaid (at § 438.408(b)(3)) regulations for managed care plans in requiring the applicable integrated plan to resolve the expedited reconsideration as expeditiously as the enrollee's health requires and within 72 hours from the date the applicable integrated plan receives the request for the integrated reconsideration. We also proposed to apply the Medicaid managed care requirement (at § 438.408(d)(2)(ii)) by requiring that applicable integrated plans make reasonable efforts to give enrollees oral notice of the resolution in expedited cases, in addition to sending the written notice within 72 hours of receipt of the request.

In paragraph (f)(3)(i), we proposed criteria for an applicable integrated plan to extend the timeframe for resolving either a standard or expedited reconsideration. We proposed to adopt a standard similar to current MA and Medicaid rules, allowing 14-day extensions upon request of the enrollee (or the enrollee's representative) and generally using the standard in § 438.408(c) that the plan must show that the extension is in the enrollee's interest and that the information is necessary. We also proposed to use the MA standard that the timeframe may be extended if there is a need for additional information and there is a reasonable likelihood that receipt of such information would lead to approval of the request. We clarified in the preamble of the proposed rule that an applicable integrated plan could not extend the timeframe for making an integrated reconsideration in order to develop or find information to justify a denial of coverage.

In paragraph (f)(3)(ii), we proposed requirements for the notice that applicable integrated plans must send to enrollees when the plan extends the timeframe for making its determination, in accordance with the requirements in this paragraph. We proposed to require that the applicable integrated plan make reasonable efforts to give the enrollee

[27] Section 1856(b)(3) of the Act preempts state regulation of MA plans.

prompt oral notice and give the enrollee written notice within 2 calendar days. These requirements align with current Medicaid managed care regulations at § 438.408(c)(2). We also proposed that the notice of the extension include the reason for the delay and inform the enrollee of the right to file an expedited grievance if the enrollee disagrees with the decision to extend the timeframe.

In paragraph (f)(4), we proposed requirements for providing appellants with notices regarding the resolution of reconsiderations. We proposed to require that applicable integrated plans send notices within the resolution timeframes established in this section for all integrated reconsideration determinations, paralleling the current Medicaid managed care regulations which require notices of all determinations. We also proposed to include language requiring that the notice be written in plain language and available in a language and format that is accessible to the enrollee consistent with section 1859(8)(B)(iii)(III) of the Act. We also proposed, in paragraphs (f)(4)(i) and (ii), to adopt the standards similar to those governing the content of a notice found in § 438.408(e)—namely, that the plan must provide to the enrollee a notice of the integrated reconsideration for an adverse decision that includes the reason for the decision and the date of completion. We proposed in paragraph (f)(4)(ii)(A) that, for integrated notices not resolved wholly in the enrollee's favor, the notice include an explanation of the next level of appeal under both Medicare and Medicaid, and the steps the enrollee must take to further pursue the appeal. We explained our expectation that the integrated notice will enable the enrollee to understand which program covers the benefit at issue. We also proposed in paragraph (f)(4)(ii)(B) that the notice include specific information about the ability to request continuation of Medicaid-covered benefits pending appeal.

We summarize and respond to the comments on proposed § 422.633 as follows:

Comment: Many commenters supported our proposed requirements related to integrated reconsiderations, including the timeframes for applicable integrated plans to resolve integrated reconsiderations. One commenter specifically supported the inclusion of post-service appeals in the expedited integrated reconsiderations process, at § 422.633(e), noting significant financial need that may be present for dual eligible individuals. Another commenter supported the requirement at § 422.633(f)(1) to use the same timeframes and processes for pre-service and post-service appeals to simplify the process for enrollees. One commenter opposed requiring post-service appeals to follow the same decision timing as pre-service appeals, requesting that CMS instead apply the MA rules, which allow 60 days for decision in post-service appeals cases to allow applicable integrated plans more time to gather necessary information, including from enrollees, and potentially leading to fewer plan denials of integrated reconsiderations.

Response: We appreciate the support for our proposed integrated reconsideration requirements. We clarify that the post-service appeals timing applies to appeals from noncontracted providers as well as to enrollees. We understand the concern related to obtaining all necessary information to make a determination for post-service integrated reconsiderations; however, we decline to make a change to our proposed requirements. As we noted in the proposed rule (83 FR 55010–55011), Medicaid regulations at § 438.408(b)(2) do not distinguish between pre-service and post-service appeals—all appeals must be resolved within 30 calendar days. We do not believe the volume of post-service appeals, which would generally be only for payment, is high for dual eligible individuals, and we believe it is more protective of enrollees to have all integrated reconsiderations resolved in 30 calendar days, particularly given what may be significant financial needs for these individuals.

Comment: Several commenters expressed support for our proposed requirement, at § 422.633(c), that applicable integrated plans provide the enrollee or the enrollee's representative with a copy of the enrollee's case file for free, to help eliminate barriers to enrollees in obtaining this information. A few commenters suggested we establish specific timeframes for when the case file should be provided to ensure that it is provided timely, and a commenter suggested that we require the case file be sent automatically whenever an appeal is filed, arguing that such a requirement would be consistent with Medicaid rules.

Response: We decline to modify the regulation text at § 422.633(c) to establish specific timeframes for provision of the case file, since we are adopting the existing requirements related to case files for Medicaid managed care plans at § 438.406(b)(5); that Medicaid managed care regulation does not include timeframes for sending the case file but requires instead that the records and information be provided sufficiently in advance of the resolution timeframe for appeals. As proposed and finalized, § 422.633(c) uses the same standard. We believe this is sufficient and decline to establish a specific deadline for provision of these records and information. We also decline to specify that a plan send a case file for every appeal filed. Rather, we believe that making it clear to appellants that they may request the case file at no charge (for example, as part of the denial notice) will be less burdensome for all parties.

Comment: Several commenters supported the requirement at § 422.633(d)(2) for applicable integrated plans to accept oral requests without requiring written follow up from the enrollee, noting that this requirement helps eliminate barriers for enrollees in filing appeals. One commenter opposed this requirement. One commenter requested that applicable integrated plans have discretion, as MA plans currently do under guidance in the Parts & D Enrollee Grievances, Organization/ Coverage Determination, and Appeals Guidance § 50.2.1, to require written follow-up when enrollees file oral appeals because oral appeals can be difficult to define, track, and standardize.

Response: We thank the commenters for their support of this requirement, and decline to make any changes to it at this time. We assume the comment related to the guidance interpreting § 422.568(a)(1) and providing discretion to MA plans on whether to allow oral reconsiderations referred to the previous version of the CMS Medicare Managed Care Manual, Chapter 13, § 70.2, which stated that an MA plan may choose to accept an oral reconsideration. Similar guidance was published more recently (February 22, 2019) in an updated version of the Parts C & D Enrollee Grievances, Organization/Coverage Determination, and Appeals Guidance, § 50.2.1. We agree that this requirement is an important way to remove barriers to filing appeals for enrollees related to language, literacy, housing, and behavioral health concerns. We believe that requiring applicable integrated plans to allow oral appeals from enrollees without requiring the enrollee to follow up in writing is most consistent with the provision in section 1859(f)(8)(B)(ii)(I) of the Act requiring us to adopt provisions that are most protective for enrollees. In addition, we have recently proposed making a similar change for similar reasons to the Medicaid managed care rule at § 438.402(c)(3)(ii) (see Medicaid and Children's Health Insurance Program

(CHIP) Managed Care (CMS–2408–P), 83 FR 57264, 57283 (November 14, 2018)).

Comment: One commenter requested that, for expedited integrated reconsiderations, we clarify our regulations to align with current MA guidance and explicitly state that applicable integrated plans have three calendar days to mail written notification when verbal outreach to a member is successful.

Response: We decline to adopt this suggestion. Under § 422.633(f)(4), as proposed and finalized in this rule, the applicable integrated plan must send a written determination notice within the resolution timeframes regulations. For expedited integrated reconsiderations, these requirements are located at § 422.633(f)(2). In order to clarify the regulation text and conform it to the preamble of the proposed rule, we are finalizing paragraph (f)(2) with revised text stating that the applicable integrated plan must resolve the expedited integrated reconsideration as expeditiously as the enrollee's health condition requires but no later than 72 hours from the receipt of the request. Pursuant to paragraph (f)(4), this timeframe will also apply to the required written notice to the enrollee. We are also revising the language in the final rule regarding expedited integrated reconsiderations under § 422.633(f)(2) to clarify that the applicable integrated plan must make reasonable efforts to provide prompt oral notice of the determination in addition to providing the written notice, which aligns with Medicaid rules that require oral notification as a separate requirement that is not tied to the timing of the written notification (see § 438.408(d)(2)(ii)).

Comment: One commenter requested that we clarify when the timeline begins for the applicable integrated plan to notify an enrollee of the decision to extend the timeframe for deciding the integrated reconsideration.

Response: We clarify that the applicable integrated plan must notify the enrollee that an extension is being taken within two calendar days of when the applicable integrated plan, after considering the factors outlined in § 422.633(f)(3)(i), makes the decision to take an extension. We are finalizing revised regulation text at § 422.633(f)(3)(ii) to clarify this timing.

Comment: A few commenters supported the requirement at § 422.633(f)(4) that applicable integrated plans send a written determination in all cases when an integrated reconsideration is filed. They also supported the content requirements for the written determination notice. One commenter noted that this notice should include information on how to get assistance with the next level of appeal.

Response: We thank the commenters for their support of this requirement, and we agree that information on how to get assistance with the next step in the appeal process is important and useful information for the enrollee and would be beneficial to include in the notice. We are adding this content requirement to the regulation at § 422.633(f)(4)(ii)(A). This information may include the name and contact information of, for example, the State Health Insurance Assistance Program (SHIP), a state ombudsman program if one exists, or a legal aid office. State Medicaid agencies may also have appropriate local referrals.

For the reasons set forth in the proposed rule and our responses to the related comments, we are finalizing § 422.633 substantively as proposed, but with some minor modifications from proposed text as follows:

- At paragraph (c), we are revising the last sentence to clarify that the records must be provided sufficiently in advance of the resolution timeframe for the integrated reconsideration, or subsequent appeal;
- At paragraphs (d)(1) and (d)(2), we are including headings to aid the reader;
- At paragraph (f)(1), we have modified the regulatory text to clarify that an applicable integrated plan has a maximum of 30 calendar days to resolve the integrated reconsideration, but must resolve it more quickly if the enrollee's health requires faster resolution. As finalized, this language exactly parallels the language from the MA requirement at § 422.590(a);
- At paragraph (f)(2), we have modified the regulatory text to clarify that an applicable integrated plan has a maximum of 72 hours to resolve the expedited integrated reconsideration, but must resolve it more quickly if the enrollee's health requires faster resolution. As finalized, this language exactly parallels the language from the MA requirement at § 422.590(d)(1). We also clarify in paragraph (f)(2) that an applicable integrated plan must make reasonable efforts attempt to provide prompt oral notice of the determination in addition to providing the written notice;
- At paragraph(f)(3)(ii) we clarify the timeframe for the applicable integrated plan to notify the enrollee that an extension is being taken; and
- At paragraph (f)(4), we are finalizing regulatory text as proposed with a modification to clarify that the notice of resolution the applicable integrated plan sends must be a written notice, and to add, at paragraph (f)(4)(ii)(A), a requirement that the notice of resolution contain information on how the enrollee can obtain assistance in pursuing the next level of appeal under each program.

(9) Effect (§ 422.634)

We proposed, at § 422.634(a), to use the same standard as in existing MA and Medicaid regulations related to a plan's failure to made a timely determination. If an applicable integrated plan fails to make a timely determination at any point in the appeals process (for an integrated organization determination or an integrated reconsideration), that failure would constitute an adverse determination, such that the enrollee could move forward with the next level of appeal procedures (see §§ 438.400(b)((b), 438.402(c)(1)(i)(A), 438.408(c)(3), 422.568(f), and 422.572(f)).

We proposed, at § 422.634(b), to establish the next steps in the appeals process if the enrollee receives an adverse decision from the applicable integrated plan on the integrated reconsideration. For cases involving Medicare benefits, we proposed, for applicable integrated plans at § 422.634(b)(1)(i), to codify the requirement that adverse reconsiderations be reviewed and resolved by an IRE, consistent with section 1852(g)(4) of the Act and existing § 422.592. In § 422.634(b)(1)(ii) and (iii), we proposed to mirror existing MA regulations (§ 422.590(a)(2) and (d)(4))[28] with requirements for applicable integrated plans to forward the case file to the independent entity within set timeframes for both standard and expedited integrated reconsiderations.

At § 422.634(b)(2), we proposed that for cases involving Medicaid benefits, the enrollee may initiate a state fair hearing no later than 120 calendar days from the date of the applicable integrated plan's notice of resolution. We also proposed to include the requirement that a provider who has not already obtained the written consent of an enrollee must do so before filing a request for a state fair hearing. We explained in the proposed rule how we intended the timeframe to mirror the appeal right and requirement in the Medicaid managed care regulation at § 438.408(f)(2) and (3).

We proposed, at § 422.634(c), language providing that determinations are binding on all parties unless the case

[28] In the proposed rule (83 FR 55010), we erroneously cited to § 422.590(d)(3) instead of (d)(4) and use the correct reference here.

is appealed to the next applicable level of appeal. We also proposed to specify that this means that, in the event that an enrollee pursues an appeal in multiple forums simultaneously (for example, files for an external state medical review and an integrated reconsideration with the applicable integrated plan, and the integrated reconsideration decision is not in the enrollee's favor but the external state medical review decision is), an applicable integrated plan would be bound by, and must implement, decisions favorable to the enrollee from state fair hearings, external medical reviews, and independent review entities (IRE). As we explained in the proposed rule, for Medicare benefits, the adverse integrated reconsideration would be automatically forwarded to the IRE, pursuant to § 422.634(b)(1), and thus the IRE's determination in those cases would ultimately be binding.

We proposed, at § 422.634(d), requirements for how quickly services must be put in to place for an enrollee after he or she receives a favorable decision on an integrated reconsideration or state fair hearing. In the first sentence of paragraph (d), we proposed that if an applicable integrated plan, or a state fair hearing with regard to a Medicaid benefit, reverses a decision to deny, limit, or delay services that were not furnished while the appeal was pending, the applicable integrated plan must authorize or provide the disputed services as expeditiously as the enrollee's condition requires but not later than 72 hours. We intended this to mean that when an integrated organization determination or integrated reconsideration decision is favorable to the enrollee for any covered services, and, for Medicaid benefits, when a state fair hearing reverses an applicable reconsideration (that is, makes a decision that is favorable to the enrollee with regard to Medicaid benefits), the same timeframe for the applicable integrated plan to provide the benefits would apply. We also proposed to cross-reference the existing MA regulations at §§ 422.618 and 422.619 that provide how and when disputed Medicare benefits must be provided when an integrated reconsideration denying benefits is reversed at the post-plan level of appeal. Finally, we also proposed in this paragraph to maintain the same effectuation timelines for reversals by the Medicare independent review entity, an administrative law judge or attorney adjudicator at the Office of Medicare Hearings and Appeals, or the Medicare Appeals Council as apply to other MA plans.

We proposed, at § 422.634(e), for Medicaid-covered benefits, to parallel Medicaid requirements from § 438.424(b) governing how services that were continued during the appeal must be paid for, if the final determination in the case is a decision to deny authorization of the services. For Medicare-covered services, we proposed that the applicable integrated plan will cover the cost of the benefit.

We received the following comments regarding our proposed provisions at § 422.634, and our responses follow.

Comment: A commener supported the proposed requirements at § 422.634. Another commenter requested that we align our requirement at § 422.634(b)(2) with the proposed Medicaid managed care rule to allow states to give enrollees between 90 and 120 days to file for a state fair hearing.

Response: We thank the commenter for their support. Our intent in proposed § 422.634(b)(2) was to follow the timeframes in the existing Medicaid managed care requirements. Because we have proposed a revision to the Medicaid managed care rules (see Medicaid and Children's Health Insurance Program (CHIP) Managed Care (CMS–2408–P), 83 FR 57264 (November 14, 2018)), we are revising the requirement at § 422.634(b)(2) to refer to the timeline requirements in § 438.408(f)(2) rather than stipulating those timelines in our final regulations. By finalizing this cross-reference, the timeframe for an enrollee to request a state fair hearing will be the same regardless of whether the enrollee is appealing a decision by an applicable integrated plan or a Medicaid managed care plan.

After considering the comments and for the reasons set forth in the proposed rule and our responses to the related comments, we are finalizing § 422.634 substantively as proposed, but with some clarifying modifications at paragraphs (a), (b), and (d). In paragraph (a)(2), we are adding a citation to the parallel Medicaid managed care rule at § 438.408(f) for the timeframe for an enrollee to request a state fair hearing. In paragraph (b)(2), we have revised the text to cite to the state fair hearing in the timeframe specified in § 438.408(f)(2), rather than cite a specific timeframe, to ensure alignment with Medicaid managed care rules as described above. In paragraph (d), we are finalizing the first sentence with revisions to clarify that the applicable integrated plan's reversals—of integrated organization determinations and integrated reconsiderations, as well as of state fair hearing reversals—must be effectuated by the applicable integrated plan within 72 hours rather than the MA timeframe in § 422.618(a). The regulation text specifies that state fair hearing decisions are only with regard to Medicaid benefits. Post-plan level appeal decision on Medicare benefits (that is, by the Part C independent review entity, an administrative law judge or attorney adjudicator at the Office of Medicare Hearings and Appeals, or the Medicare Appeals Council) must be effectuated in accordance with §§ 422.618, and 422.619.

(10) Unifying Medicare and Medicaid Appeals Subsequent to Integrated Reconsideration

The new section 1859(f)(8)(B)(ii) of the Act directs us to include, to the extent we determine feasible, consolidated access to external review under an integrated process. We interpret ''external review'' in this statutory provision as meaning review outside the plan, including by a government agency or its designee. For MA, this includes the independent review entity (IRE) and ALJ review described in §§ 422.592 through 422.602. For Medicaid, this includes the state fair hearing process described in Part 431 Subpart E, as well as any additional external review offered under state law.

We believe that such a process could offer benefits to beneficiaries, plans, states, and the federal government. Currently, once a D–SNP or Medicaid managed care plan makes a final decision on an appeal, the federally-administered Medicare and state-administered Medicaid appeals processes are entirely separate. Although they have some common principles, such as ensuring access to an independent administrative hearing, they differ in many respects. In the proposed rule (83 FR 55012 through 55015), we detailed the considerable challenges of unifying D–SNP and Medicaid appeals subsequent to the reconsideration level.

Based on these complexities, we stated in the proposed rule our belief that it is not feasible to propose a unified post-plan appeals process (that is, adjudication of appeal subsequent to an applicable integrated plan's integrated reconsideration of an initial adverse determination) at this time. Instead, we solicited comments on viable paths forward given the constraints presented by the statutory mandates for the MA and Medicaid appeals processes and our experience gained through demonstrations. We received comments from six commenters. Overall, the commenters expressed support for continued efforts

to move forward in this area in the future. We thank these commenters for the time and effort expended on providing us with comments on the establishment of a unified post-plan appeals process in potential future rulemaking. We will take the comments into consideration as we continue work on this issue.

(11) Conforming Changes to Medicare Managed Care Regulations and Medicaid Fair Hearing Regulations (§ 422.562, § 422.566, § 438.210, § 438.400, and § 438.402)

We proposed a number of changes to Medicaid managed care, Medicaid fair hearing, and Medicaid single state agency regulations to conform with our proposed unified grievance and appeals provisions. Following is a summary of these proposed changes.

- In § 422.562(a)(1)(i) and (b), we proposed to add cross references to the proposed integrated grievance and appeals regulations along with new text describing how the provisions proposed in this rule for applicable integrated plans would apply in place of existing regulations.
- In § 422.566, we proposed to add additional language to paragraph (a) to establish that the procedures we proposed in this rule governing integrated organization determinations and integrated reconsiderations at proposed § 422.629 through § 422.634 apply to applicable integrated plans in lieu of the procedures at §§ 422.568, 422.570, and 422.572.
- In § 438.210(c) and (d)(4), we proposed to add cross references to the proposed integrated grievance and appeals regulations along with new text describing how the provisions proposed in this rule for applicable integrated plans would apply in place of existing regulations to determinations affecting dual eligible individuals who are also enrolled in a D–SNP with exclusively aligned enrollment, as those terms are defined in § 422.2. In § 438.210(f), we proposed to make these Medicaid changes applicable to applicable integrated plans no later than January 1, 2021, but, consistent with our discussion earlier on the effective dates of our proposed unified appeals and grievance procedures overall, we would not preclude states from applying them sooner.
- In § 438.400, we proposed adding a new paragraph (a)(4) to include the statutory basis for the proposed integration regulations (section 1859(f)(8) of the Act). We also proposed to amend § 438.400(c) to clarify that these Medicaid changes apply to applicable integrated plans no later than January 1, 2021, but, consistent with our discussion elsewhere in this final rule, we would not preclude states from applying them sooner.
- In § 438.402, we proposed amending paragraph (a) to allow a Medicaid managed care plan operating as part of an applicable integrated plan to the grievance and appeal requirements laid out in §§ 422.629 through 422.634 in lieu of the normally applicable Medicaid managed care requirements.

We received the following comments, and our responses follow.

Comment: We received several comments related to the effective date for the unified grievance and appeals procedures, including our statement in the proposed rule that states could require applicable integrated plans to implement such procedures prior to January 1, 2021, using the state Medicaid managed care contract and the contract with the D–SNP required under § 422.107. Some commenters objected to earlier implementation, noting the many processes that applicable integrated plans will need to complete, such as systems changes, staff training, policy and procedure development and implementation, and developing enrollee communication materials, as well as the need for CMS to release further guidance prior to the effective date. One commenter noted that applicable integrated plans need all final guidance from CMS one year prior to implementation. Another commenter supported early implementation, provided such early implementation would be on a trial basis only, and plans would not be subject to intermediate sanctions, penalties, or audits.

Response: We understand the commenters' concerns about the need for sufficient time to implement the unified grievance and appeals processes we are finalizing in this rule. As we stated in the proposed rule, these processes will apply to a relatively small subset of states and plans, and while early implementation at state option is possible, we do not anticipate many states implementing the processes earlier than required (that is, beginning January 1, 2021) for many of the reasons cited by these commenters. However, CMS will work closely with any state interested in early implementation to ensure that impacted applicable integrated plans have the guidance they need.

For the reasons explained in the proposed rule and our responses to comments, we are finalizing substantively as proposed the conforming changes to §§ 422.562, 422.566, 438.210, 438.400, and 438.402. We are making the following additional non-substantive changes to the noted regulations:

- We are modifying the regulatory text at § 422.562(a)(1)(i), (b)(1), (b)(2), (b)(3), (b)(4)(i), and (b)(4)(ii), and at § 422.566(a), to clarify that the effective date of the unified appeals and grievance processes finalized in this rule is January 1, 2021. We are also making a minor grammatical change to § 422.566(a) to make the language addressing applicable integrated plans a separate sentence.
- We are changing ''MA plans'' to ''Medicare Advantage plans'' in § 438.400(a)(4) because the term ''MA plans'' is not defined Part 438.
- We are finalizing § 438.402 substantively as proposed, but with some modifications to clarify that, for post-plan appeals of Medicaid benefits, state fair hearing processes and requests are subject to § 438.408(f).
- We are changing ''section'' to ''part'' in § 438.400(c)(2) to clarify that the provisions affecting applicable integrated plans throughout Part 438 are applicable no later than January 1, 2021.

3. Prescription Drug Plan Sponsors' Access to Medicare Parts A and B Claims Data Extracts (§ 423.153)

a. Background

This final rule sets forth the manner in which CMS will implement section 50354 of the Bipartisan Budget Act of 2018 (BBA), Public Law 115–123, enacted on February 9, 2018. Section 50354 amends section 1860D–4(c) of the Social Security Act by adding a new paragraph (6) entitled ''Providing Prescription Drug Plans with Parts A and B Claims Data to Promote the Appropriate Use of Medications and Improve Health Outcomes''. Specifically, section 1860D–4(c)(6)(A), as added by section 50354 of the BBA, provides that the Secretary shall establish a process under which the sponsor of a Prescription Drug Plan (PDP) that provides prescription drug benefits under Medicare Part D may request, beginning in plan year 2020, that the Secretary provide on a periodic basis and in an electronic format standardized extracts of Medicare claims data about its plan enrollees. Such extracts would contain a subset of Medicare Parts A and B claims data as determined by the Secretary. In defining the specific data elements and time frames for the Parts A and B claims data included in such extracts, hereinafter referred to as ''Medicare claims data,'' the Secretary is instructed, at section 1860D–4(c)(6)(D) of the Social Security

Act, to include data ''as current as practicable.''

Section 1860D–4(c)(6)(B) of the Act, as added by section 50354 of the BBA, further specifies that PDP sponsors receiving such Medicare claims data for their corresponding PDP plan enrollees may use the data for: (i) Optimizing therapeutic outcomes through improved medication use; (ii) improving care coordination so as to prevent adverse healthcare outcomes, such as preventable emergency department visits and hospital readmissions; and (iii) for any other purposes determined appropriate by the Secretary. Finally, section 1860D–4(c)(6)(C) states that the PDP sponsor may not use the data: (i) To inform coverage determinations under Part D; (ii) to conduct retroactive reviews of medically accepted conditions; (iii) to facilitate enrollment changes to a different PDP or a MA–PD plan offered by the same parent organization; (iv) to inform marketing of benefits; or (v) for any other purpose the Secretary determines is necessary to include in order to protect the identity of individuals entitled to or enrolled in Medicare, and to protect the security of personal health information.

b. Provisions of the Proposed Rule

To implement the new statutory provision at section 1860D–4(c)(6) of the Act, as added by section 50354 of the BBA, we proposed to add a new paragraph (g) at § 423.153. We summarize our proposals and comments received and provide our responses and final decisions.

c. Purposes and Limitations on the Use of Data

In accordance with section 1860D–4(c)(6)(B) of the Act we proposed to limit the purposes for which PDP sponsors are permitted to use the Medicare claims data. Consistent with the statute, we proposed at § 423.153(g)(3) that PDP sponsors would be permitted to use Medicare claims data to optimize therapeutic outcomes through improved medication use, and to improve care coordination so as to prevent adverse health outcomes. In addition, we proposed to permit PDP sponsors to use Medicare claims data for the purposes described in the first or second paragraph of ''health care operations'' under 45 CFR 164.501, or that qualify as ''fraud and abuse detection or compliance activities'' under 45 CFR 164.506(c)(4). We also proposed to permit disclosures that qualify as a ''required by law'' disclosure as defined at 45 CFR 164.103.

In accordance with section 1860D–4(c)(6)(C) of the Act, we proposed specific limitations on how Medicare claims data provided to the PDP sponsors may be used. Consistent with statutory limitations, we proposed that PDP sponsors must not use Medicare claims data provided by CMS under this subsection for any of the following purposes: (1) To inform coverage determinations under Part D; (2) to conduct retroactive reviews of medically accepted indications determinations; (3) to facilitate enrollment changes to a different prescription drug plan or an MA–PD plan offered by the same parent organization; or (4) to inform marketing of benefits.

Section 1860D–4(c)(6)(C)(v) of the Act provides that the Secretary may place additional limitations on the use of Medicare claims data as necessary to protect the identity of individuals entitled to, or enrolled in, benefits under Part D, and to protect the security of personal health information. Therefore, we also proposed to require that the PDP sponsor contractually bind its Contractors that will be given access to Medicare claims data, and to require those contractors to contractually bind any further downstream data recipients, to the terms and conditions imposed on the PDP Sponsor. In addition, we proposed to allow CMS to refuse future releases of Medicare claims data if it determines or has a reasonable belief that the PDP sponsor has made unauthorized uses, reuses, or disclosures of prior data received under this provision. We also proposed that a PDP sponsor would have to complete a data attestation as part of the data request process to ensure an understanding of the purposes for which the Medicare claims data may be used and the limitations on its reuse, and redisclosure.

Comment: A commenter recommended CMS explore ways to share the same Parts A and B claims data with Medicare Advantage (MA) plans and Cost plans.

Response: We appreciate the suggestion that CMS explore ways to share the same Medicare data with MA plans and Cost plans. While we understand that this data may be helpful to MA and Cost plans, section 1860D–4(c)(6)(A) only provides that the Secretary shall establish a process for the sponsor of a Prescription Drug Plan (PDP) sponsor. We are continuing to evaluate additional pathways for data sharing and may consider data sharing with MA plans and Cost plans in the future.

Comment: A commenter requested additional clarification on how the data could be used for fraud and abuse detection purposes. Specifically, the commenter requested that CMS clarify that while PDP sponsors may not use the Parts A and B data to change individual coverage determinations decisions alone, they may review this data as part of an effective fraud and abuse detection program.

Response: We appreciate the request to clarify the relationship between the prohibition that PDP sponsors must not use the Medicare claims data provided under this provision to change individual coverage determination decisions with the permissible use of the Medicare claims for fraud and abuse detection or compliance activities. As stated earlier, the statutory language prohibits the use of the Medicare claims data to inform coverage determinations under Part D and to conduct retroactive reviews of medically accepted determinations. There are a number of fraud and abuse detection or compliance activities that the Medicare claims data can be used for that would not impact an individual Medicare enrollee's coverage determination under Part D. For instance, the PDP sponsor could use the Medicare claims data to create algorithms that detect fraud and abuse and this information could be used to inform future policies or procedures. PDP sponsors also could use the Medicare claims data for internal and external audits or to identify fraud and abuse activities by providers and suppliers. We also encourage the PDP sponsors to refer to the current compliance and fraud, waste, and abuse programs that are in place under the Part D Sponsor compliance program and the suggested elements that CMS has provided to Part D sponsors to consider when developing these programs.

Comment: Most commenters supported CMS's proposal for the permitted uses of the data. A few commenters suggested additional permissible uses of the data. A commenter suggested that CMS allow the use of Medicare claims data for value-based contracting. Another commenter encouraged CMS to include, as a permissible use, use of the data to make favorable coverage determination decisions. Finally, a commenter suggested that CMS permit plan sponsors to use the data for any other purpose for which protected health information can be used under HIPAA, including as de-identified data.

Response: We thank commenters for their support of the proposal. When we considered expanding the permitted uses of the data provided to the PDP sponsors beyond the statutory uses, we took into account a number of factors.

First, we examined the purpose for which Medicare claims data is provided, namely to promote the appropriate use of medications and improve health outcomes. Second, we considered the statutory limitations imposed on the use of the data, specifically that the data not be used to inform coverage determinations or to conduct retroactive review of medically accepted indications. Finally, we took into account that this is a new data disclosure. Therefore, we decided to make the additional permitted uses narrow. While we will not expand the permitted uses as suggested at this time, we will continue to assess whether additional permissible uses of the data should be proposed in future rulemaking.

Comment: A commenter requested CMS release more specific guidance on how the data could potentially be used and provide for additional comment opportunities so feedback can be shared with CMS.

Response: We thank the commenter and believe that the rule provides adequate information on the limits and permissible uses of the data under this section. We will continue to assess the program to determine if additional guidance is needed and welcome stakeholders to provide additional feedback or seek clarification on program requirements. If CMS makes future changes to the regulatory requirements of this program, then stakeholders will be able to provide feedback during that rulemaking process.

Comment: A few commenters recommended that CMS not expand the permissible uses beyond what was explicitly provided for in statute. These commenters were concerned that the expanded uses conflict, or have the potential to conflict, with the directive in the statute that PDPs may not use this information ''to inform coverage determinations under Part D'' or to conduct retroactive reviews of medically accepted indications. In particular, they were concerned about the use of the data for fraud and abuse detection and compliance activities. They encouraged CMS to limit disclosures under this authority to those expressly allowed by statute, to monitor plan's use of the data, and only consider expansion after the Secretary has evaluated plans' actual use of this data as well as the agency's audit and review capacity.

Response: We thank commenters for this feedback. Section 1860D–4(c)(6)(B)(iii) of the Act states that the Secretary can determine if there are other appropriate purposes for which the data can be used. Therefore, consistent with this statutory authority, we proposed to narrowly expand on the permitted uses of the Medicare claims data based on the factors discussed earlier. In terms of concerns about the use of the data for fraud and abuse detection and compliance activities, we clarified previously that the use of the claims data would still need to comply with the statutory limitations on the use of the data at § 423.153(g)(4). These fraud and abuse activities would not focus on an individual Medicare enrollee's Part D coverage, but rather, these fraud and abuse detection and compliance activities would be aimed at plans and providers/suppliers. In addition, as discussed in the proposed rule, we believe that PDP sponsors are required to comply with the applicable HIPAA rules, so they would have extensive experience ensuring that data is only used and disclosed as permitted or required by applicable laws. We believe that PDP sponsors understand and will abide by their obligations regarding the permitted uses and limitations on the use of Medicare data provided under this provision.

Comment: A few commenters disagreed with the limitations on using these data for coverage determinations and to conduct retroactive reviews of medically accepted indications determinations. A commenter stated that with access to claims data, PDP sponsors would be better positioned to identify appropriate interventions related to medication adherence, opioid overutilization, risk adjustment and other medication management related requirements of PDP sponsors. Another commenter stated that because plan sponsors that offer standalone Part D benefits (PDP sponsors) have no contracts with prescribing providers, they currently have no mechanism for ensuring that medications are appropriate. They further asserted that access to claims data would allow PDP sponsors to validate whether prescriptions are medically supported, as well as to identify other interventions related to opioid overutilization, medication adherence, risk adjustment and other functions related to requirements for Part D sponsors.

Response: We appreciate the feedback on the limitations on the use of the data; however, the statutory language at section 1860D–4(c)(6)(C) of the Act states that PDP sponsors must not use Medicare claims data provided by CMS under this subsection for any of the following purposes: (1) To inform coverage determinations under Part D; (2) to conduct retroactive reviews of medically accepted indications determinations; (3) to facilitate enrollment changes to a different prescription drug plan or an MA–PD plan offered by the same parent organization; or (4) to inform marketing of benefits.

Comment: A number of commenters requested clarification that the permissible uses and limitations provided in this rule only apply to the Medicare data received under this provision and not to Medicare data that is obtained through other data disclosure pathways. For instance, a commenter requested that CMS clarify that Medicare data obtained through different sources may still be used for coverage determinations and to determine medically accepted indications. Another commenter requested clarification on how the permissible and impermissible use of this claims data will be taken into account for purposes of audits and other reviews—specifically, they requested confirmation that PDP sponsors will not be penalized for failing to implement Medically Accepted Indications (MAI) and other restrictions, even if the plan sponsor has Medicare claims data on hand since PDP sponsors are explicitly prohibited from using the Medicare claims data provided under this provision to conduct retroactive reviews of medically accepted indications determinations.

Response: We appreciate the request for clarification. The limitations and permissible uses of the Medicare claims data at § 423.513(g)(3) and (4) only apply to the data received under the authority of section 1860D–4(c)(6) of the Act. Medicare claims data provided to PDP sponsors under another program or pathway are subject to those program requirements. PDP sponsors are not permitted to use the Medicare claims data provided under this provision for any of the impermissible purposes specified by the statute at section 1860D–4(c)(6)(C). Therefore, we do not see how a PDP sponsor would be held accountable for not using that Medicare claims data in a manner that conflicts with the statutory requirements.

Comment: We received several comments on the requirement that PDP sponsors complete a data attestation as part of the data request process. A few commenters questioned whether an attestation is sufficient to ensure compliance and urged CMS to monitor Part D plan sponsors' use of the data to ensure restrictions are enforced. A commenter expressed concern that PDP sponsors do not need to show with any specificity how they intend to use the data or the results that they expect. Another commenter recommended CMS

not adopt an attestation requirement given the statutory obligations on plans relating to their use of the Medicare data. Another commenter mentioned that they would provide comments on the data attestation as part of the PRA process.

Response: Section 1860D–4(c)(6)(C)(v) of the Act provides that the Secretary may place additional limitations on the use of Medicare claims data as necessary to protect the identity of individuals entitled to, or enrolled for, benefits under Part D, and to protect the security of personal health information. In proposing additional limitations on the use of the Medicare data, we sought to balance the burden on PDP plans with CMS' commitment to ensuring beneficiary-level data is protected by strict privacy and security requirements. We believe that the data attestation requirement is a means of ensuring an understanding of, and compliance with, the terms and conditions of data access and seeks an appropriate balance. In terms of monitoring, we will pursue any complaints regarding a PDP sponsor's violation of program requirements. We would emphasize that CMS may refuse to make future releases of Medicare claims data to a PDP sponsor if the Agency makes a determination or has a reasonable belief that unauthorized uses, reuses, or disclosures have taken place. We believe this approach to monitoring is sufficient since we believe that PDP sponsors are required to comply with the HIPAA rules. Therefore, they have experience ensuring that data can only be used and disclosed for specific purposes. We believe that PDP sponsors understand and will abide by their obligations regarding the permitted uses and limitations on the Medicare data under this provision. However, as this program is implemented, we will continue to monitor and assess our program compliance policies to determine if additional oversight or guidance materials are needed on the use of the data.

In terms of the PRA process, we published a stand-alone 60-day **Federal Register** notice that set out the requirements and burden associated with the request and attestation (November 30, 2018; 83 FR 61638). We are also realigning the provision with this rulemaking by setting out such requirements and burden in section III.B.4 of this final rule. In this regard we will not be publishing a stand-alone 30-day **Federal Register** notice.

Comment: A commenter requested clarification as to PDP sponsors' access to the data (for example, single point person or multiple individuals within the PDP permitted to access the data extract).

Response: As discussed earlier, we believe that PDP sponsors are required to comply with the HIPAA Rules, including Privacy, Security and Breach Notification requirements. They are accustomed to dealing with limitations on the use and disclosure of data. We expect that they will designate a data custodian as the recipient, and establish policies and procedures as to use and disclosure that will comply with all applicable law, including this program's data usage limitations, and the limits on use and disclosure under the HIPAA regulations, including the minimum necessary concept.

We are finalizing the policy as proposed.

d. Data Request

Section 1860D–4(c)(6)(A) of the Act provides that the Secretary shall establish a process under which a PDP sponsor of a prescription drug plan may submit a request for the Secretary to provide the sponsor with standardized extracts of Medicare claims data for its enrollees. Therefore, we proposed at § 423.153(g)(1) to establish a process by which a PDP sponsor may submit a request to CMS to receive standardized extracts of Medicare claims data for its enrollees. We proposed to accept data requests on an ongoing basis beginning January 1, 2020. We proposed to require that such data requests be submitted in a form and manner specified by CMS. Consistent with the discretion accorded to the Secretary under section 1860D–4(c) (6)(D) of the Act, we proposed not to allow PDP sponsors to request data for subsets of their enrolled beneficiary populations. We proposed allowing requests to be submitted without an end date, such that the request, once reviewed for completeness and approved, would remain in effect until one or more of the following occur: the PDP sponsor notifies CMS that it no longer wants to receive Medicare claims data, CMS cancels access to Medicare claims data when a PDP sponsor leaves the Part D program, or CMS concludes or has a reasonable belief, at its sole discretion, that the PDP sponsor has used, reused or disclosed the Medicare claims data in a manner that violates the requirements of section 1860D–4(c)(6) of the Act and § 425.153(g). Upon receipt of the request from the PDP sponsor and the PDP's execution of an attestation discussed earlier, and review for completeness and approval of the application by CMS or its contractor, we proposed that the PDP sponsor would be provided access to Medicare claims data. We note that access to Medicare claims data will be further subject to all other applicable laws, including, but not limited to, the part 2 regulations governing access to certain substance abuse records (42 CFR part 2).

Comment: One commenter expressed concern about providing information on the entire membership on a continuous basis regardless of whether the Part D plan needs the complete data set or membership.

Response: We believe that in order to accomplish the purposes of the statute to promote the appropriate use of medications and improve health outcomes that the PDP sponsor will need Medicare claims data for all of its enrollees. We also believe that this approach is consistent with the discretion afforded to the Secretary under section 1860D–4(c)(6)(D) of the Act.

Comment: A commenter requested that CMS clarify how this will comply with the regulations governing the disclosure of substance use disorder data and address whether PDP sponsors will be required to scrub the substance use disorder data from the extract.

Response: In compliance with the part 2 regulations governing access to certain substance abuse records (42 CFR part 2), we do not anticipate providing substance use disorder data to PDP sponsor under this program.

We are finalizing the policy as proposed.

e. Data Extract Content

Section 1860D–4(c)(6)(D) of the Act provides the Secretary with the discretion to determine the time frame and claims data under Parts A and B to be included in the standardized extracts provide to PDP sponsors. To develop a proposed data set to include in the standardized extracts of Medicare claims data, we first considered what Medicare claims data PDP sponsors might require if they were to undertake the activities expressly permitted by section 1860D- 4(c)(6)(B) of the Act. In doing so, we attempted to limit the data set to the minimum data that we believe PDP sponsors would need to carry out those statutory activities and the additional activities we proposed to permit under § 423.153(g)(3). That is, we sought to establish data access limits that would comport with the HIPAA Privacy Rule's minimum necessary concept at 45 CFR 164.502(b) and 164.514(d), and CMS' policy-driven data release policies.

We proposed that data from all seven claim types, including inpatient, outpatient, carrier, durable medical equipment, hospice, home health, and skilled nursing facility data, would be

required to carry out the permitted uses of the data under section 1860D–4(c)(6)(B) of the Act and the proposed provision at § 423.153(g)(3). Because section 1860D–4(c)(6) of the Act focuses on providing Medicare claims data to promote the appropriate use of medications and improve health outcomes, we proposed to initially include the following Medicare Parts A and B claims data elements (fields) in the standardized extract: An enrollee identifier, diagnosis and procedure codes (for example, ICD–10 diagnosis and Healthcare Common Procedure Coding System (HCPCS) codes); dates of service; place of service; provider numbers (for example, NPI); and claim processing and linking identifiers/codes (for example, claim ID, and claim type code). We proposed that CMS would continue to evaluate the data elements provided to PDP sponsors to determine if data elements should be added or removed based on the information needed to carry out the permitted uses of the data. Any proposed changes would be established through rulemaking.

We next considered the beneficiary population for which we should draw the identified data elements, and what time span of data would best serve PDP sponsors while honoring the requirement at section 1860D–4(c)(6)(D) of the Act that the data should be as current as practicable. Therefore, because only the most timely data is needed for care coordination purposes, we proposed at § 423.153(g)(2) to draw the standardized extracts of Medicare claims data for items and services furnished under Medicare Parts A and B to beneficiaries who are enrolled in a Part D plan offered by the Part D sponsor at the time of the disclosure. We proposed to make standardized data extracts available to eligible PDP sponsors at least quarterly, as described earlier, but only on a specified release date that would be applicable to all eligible PDP sponsors. We also anticipate that Medicare claims data would be provided at least quarterly with approximately a 3-month lag from the last day of the last month of the prior quarter. In addition, given the permitted uses of the data, we proposed to use a standard format to deliver the resulting data to each PDP sponsor with standard format extracts, meaning that CMS would not customize the extracts for a PDP sponsor. We believe that these standardized data extracts would provide PDP sponsors with the minimum data necessary to carry out the permitted uses specified in section 1860D–4(c)(6)(B) of the Act and as proposed at § 423.153 (g)(3). We solicited comments about the proposed frequency and contents of the standardized data extracts.

Comment: We received a few comments seeking clarification on the standardized data extract. A commenter requested clarification about the inclusion of Part A and B data furnished by MA plans. Another commenter requested clarification that the data feed includes enrollees who may not be new to Medicare coverage, but are new to the health or PDP sponsor. A commenter requested the inclusion of Part D claims data for lives enrolled in or attributed to MA Plans and ENHANCED Track ACOs.

Response: We appreciate commenters' request for clarification. We proposed at § 423.153(g)(2) to draw the standardized extracts of Medicare claims data for items and services furnished under Medicare Parts A and B to beneficiaries who are enrolled in a Part D plan offered by the Part D sponsor at the time of the disclosure. The standardized data extract only includes Parts A and B claims data furnished under Medicare as there are no Part A and B data for MA plans. The standardized extract also does not include Part D data. We would also clarify that the standardized data extract will include all enrollees for a PDP sponsor at the time of the disclosure. Therefore, if an enrollee is new to the PDP sponsor, but not to Medicare, that enrollee will be included in the standardized extract.

Comment: A commenter recommended that CMS provide itself flexibility to not have to amend the rules every time it changes the data elements included in the data extract.

Response: We appreciate the commenter's suggestion, however, CMS believes that it is necessary to provide stakeholders with the opportunity to comment on any proposed data variables to ensure they are necessary to carry out the statutory activities and the additional activities that are proposed to be permitted under § 423.153(g)(3).

Comment: Several commenters were supportive of the data elements that were proposed. However, a commenter suggested that Hierarchical Condition Category (HCC) and Prescription Drug Hierarchical Condition Category (RxHCC), which are risk adjustment scores, would also be beneficial as they could be used to assess the degree of morbidity and potential morality associated with a beneficiary to determine whether there is a need for outreach or interventions, which would improve medication outcomes, and for identifying potential fraud and abuse.

Another commenter suggested the inclusion of national drug codes (NDC), lab results, and patient reported outcomes to support the evaluation of effectiveness of value-based contracts.

Response: We appreciate the suggested additions to the data variables. We do not believe that the HCC and RxHCC risk scores that are used to set payment rates are consistently informative for the purposes for which data is made available under this regulation, namely to provide PDPs with information that allows them to optimize therapeutic outcomes through improved medication use, and to improve care coordination so as to prevent adverse health outcomes. The claims data that will be provided under this regulation will provide a comprehensive clinical picture of each member, including utilization, cost, and diagnostic information. We do not believe that risk scores would provide significant information above and beyond what the claims data will provide. Further, risk scores for a year are not finalized until after that year is complete, and therefore, to the extent they theoretically could be pertinent for some aspect of care coordination, would not be complete until after treatment decisions have been made. We also note that if a PDP sponsor were to want the risk score of their members, they receive their Part D risk scores monthly, along with a report of the specific HCCs that contribute to those scores. If they believe that Part C risk scores would be helpful—that is, risk scores that predicted relative expected expenditures for Part A and B services—they would have the data available to them to calculate these risk scores with the claims data. With respect to the NDC, Part A claims data do not include NDC, and only very rarely is the NDC included on the Part B claims data. The statute instructs the Secretary to provide claims data, in which NCDs are generally not available. Therefore, we do not have the authority under this program to supplement the claims data made available under this provision. Finally, CMS also does not have access to lab results or patient reported outcomes in parts A and B claims data, and therefore would be unable to provide that information.

Comment: One commenter suggested adopting an existing standard format for Parts A and B data after soliciting and considering stakeholder feedback.

Response: We anticipate that the data will be provided in standard data format. CMS will publish the standard format publicly once it is finalized. As this provision is implemented, we will continue to seek feedback on the data format.

Comment: A number of commenters urged CMS to make data available as real-time and with as short of a lag time as possible, for instance on a monthly basis.

Response: We recognize that more timely data with a shorter lag time would be helpful to PDP sponsors in achieving the goals of this program. Currently, our infrastructure only supports delivery of quarterly data extracts that have roughly a five-month lag time. Our goal is to provide the Medicare data as timely and with as little of a lag in the claims data as possible and are striving to meet this goal.

Comment: A few commenters suggested providing historical data for enrollees. A commenter suggested providing historical data as it is critical to support the execution of value-based contracts and suggested a look back period of at least a year, similar to the Enhanced Medication Therapy Management (EMTM) program. Another commenter suggested providing historical data for the creation of value-based care tools to avoid counter indications. Another commenter recommended a 14-month look back similar to the Bundled Payment for Care Improvement Initiative (BPCI).

Response: Section 1860D–4(c)(6)(D) of the Act provides that the Secretary shall make standardized extracts available to PDP sponsors with data that is the most current as practicable. While we understand that historical data may assist PDP sponsors, we must adhere to the statutory language. As this program matures, PDP sponsors will amass historical data.

Comment: A commenter suggested the use of an Application Programming Interface (API) given the volume of Medicare claims data that will be provided to PDP sponsors. This commenter also suggested leveraging the process established through Blue Button 2.0 to allow beneficiaries to release Parts A and B claims directly to PDP plan sponsors.

Response: We appreciate this comment and will explore leveraging an API to enhance data releases to PDP sponsors.

Comment: Another commenter requested clarification on the term ''process and ship the data extracts.''

Response: Under the current data fulfillment process, CMS receives the approved request for data. A CMS contractor then extracts the data based on the cohort criteria, validates and performs a quality check on the data extract, and ships the data on an encrypted external hard drive to PBP sponsors.

Comment: A commenter believed that the CMS Health Plan Management System (HPMS) would be an adequate delivery system for the data extracts.

Response: We would clarify that the Medicare claims data extracts will be shipped to PDP sponsors, however, we are exploring the use of the CMS HPMS for submission of the data request by PDP sponsors.

We are finalizing the policies as proposed.

B. Improving Program Quality and Accessibility

1. Medicare Advantage and Part D Prescription Drug Plan Quality Rating System (§§ 422.162(a) and 423.182(a), §§ 422.166(a) and 423.186(a), §§ 422.164 and 423.184, and §§ 422.166(i) and 423.186(i))

a. Introduction

Last year, in the April 2018 final rule, CMS codified at §§ 422.160, 422.162, 422.164, and 422.166 (83 FR 16725 through 83 FR 16731) and §§ 423.180, 423.182, 423.184, and 423.186 (83 FR 16743 through 83 FR 16749) the methodology for the Star Ratings system for the MA and Part D programs, respectively. This was part of the Administration's effort to increase transparency and advance notice regarding enhancements to the Part C and D Star Ratings program. Going forward CMS must propose through rulemaking any changes to the methodology for calculating the ratings, the addition of new measures, and substantive measure changes. The April 2018 final rule included mechanisms for the removal of measures for specific reasons (low statistical reliability and when the clinical guidelines associated with the specifications of measures change such that the specifications are no longer believed to align with positive health outcomes) but, generally, removal of a measure for other reasons would occur through rulemaking.

Commenters to the November 2017 proposed rule (82 FR 56336) expressed overall support for the use of the hierarchical clustering algorithm which is the methodology used for determining the non-Consumer Assessment of Healthcare Providers and Systems (CAHPS) measure-specific cut points. The cut points are used to separate a measure-specific distribution of scores into distinct, non-overlapping groups, or star categories. The cut points are determined using the hierarchical clustering algorithm based on the given year's performance data. Performance data changes from year to year based on industry performance. Therefore, the cut points can also change from year to year. While there was overall support for the use of the hierarchical clustering algorithm, the majority of commenters also recommended some enhancements be made to the proposed clustering methodology to capture the attributes that they consider important. Commenters expressed a strong preference for cut points that are stable, predictable, and free from undue influence of outliers. Further, some commenters expressed a preference for caps to limit the amount of movement in cut points from year to year. CMS did not finalize any changes in last year's rule to the clustering algorithm for the determination of the non-CAHPS cut points for the conversion of measure scores to measure-level Star Ratings, in order to allow the necessary time to simulate and examine the feasibility and impact of the suggestions provided in response to the proposed rule. In addition, CMS evaluated the degree to which the simulations captured the desired attributes identified by the commenters.

In the November 2018 proposed rule, we proposed enhancements to the cut point methodology for non-CAHPS measures. We also proposed substantive updates to the specifications for 2 measures for the 2022 Star Ratings and substantive updates to the specifications for 1 measure for the 2023 Star Ratings. We also proposed rules for calculating Star Ratings in the case of extreme and uncontrollable circumstances. Unless otherwise stated, data would be collected and performance would be measured as described in these proposed rules and regulations for the 2020 measurement period; the associated quality Star Ratings would be released prior to the annual election period held in late 2021 for the 2022 contract year and would be used to assign Quality Bonus Payment ratings for the 2023 payment year. Because of the timing of the release and use in conjunction with the annual coordinated election period, these would be the ''2022 Star Ratings.''

CMS appreciates the feedback we received on our proposals. In the sections that follow, which are arranged by topic area, we summarize the comments we received on each proposal and provide our responses. Below we summarize some comments we received related to the Star Ratings program that are not about any of the proposals outlined in the November 2018 proposed rule.

Comment: A commenter suggested that quality incentive programs should use a small set of outcomes, patient experience, and resource use measures that are not unduly burdensome to

report. Because adjusting measure results for social risk factors can mask disparities in clinical performance, Medicare should account for social risk factors by directly adjusting payment through peer grouping. Another commenter supports CMS efforts to modernize the CMS Quality Rating System by relying more heavily upon measurable improvement in patient clinical outcomes.

Response: We appreciate these comments and have been working towards using more outcome measures and increasing the weight of patient experience of care measures in the Star Ratings system. Currently, to account for social risk factors we do not directly adjust the measure scores (or resulting stars) but add the Categorical Adjustment Index to address the average within-contract disparity in performance among beneficiaries who receive a low income subsidy, are dual eligible individuals, and/or are disabled. CMS is continuing to monitor ongoing work related to socio-economic status of measure developers such as National Committee for Quality Assurance (NCQA) and the Pharmacy Quality Alliance (PQA) and the work of the Office of the Assistant Secretary for Planning and Evaluation (ASPE) as it works to complete its second Report to Congress as required by the Improving Medicare Post-Acute Care Transformation Act of 2014 or the IMPACT Act (Pub. L. 113–185). Changes to how CMS determines Quality Bonus Payments and the methodology for payment to MA organizations generally are out of scope for this rule.

Comment: A commenter urged CMS to develop a strategic plan that includes defined goals for the Quality Star Ratings program and creates a framework for the inclusion and retirement of measures. The commenter stated that CMS should ensure that the Quality Star Ratings are simplified, accurately reflect plan performance, and place the most emphasis on measures plans can influence and that improve beneficiaries' health. The commenter also noted that CMS should focus on data-driven measures with objective clinical relevance, rather than survey-based measures.

Response: We laid out the framework for the Star Ratings in the April 2018 final rule. We will take these comments into consideration as that framework is revised over time. As part of our efforts to put patients first, obtaining direct feedback from beneficiaries is vital in understanding the quality of care provided by plans and is an important component of the Part C and D Star Ratings program.

Comment: A commenter supported CMS's position that all substantive measure changes be proposed through rulemaking. However, this commenter requested more information about what is considered ''substantive''.

Response: The April 2018 final rule provided specific examples of substantive updates to measures. We direct readers to pages 83 FR 16534 through 16535 of the April 2018 final rule.

Comment: Several commenters offered suggestions related to adjusting for socioeconomic status (SES). A commenter suggested CMS adjust for social risk factors. Another commenter requested that Categorical Adjustment Index (CAI) adjustments be made to individual measures instead of to the overall Star Ratings, to increase the measure accuracy. A commenter made suggestions, including that CMS: Enhance the CAI by expanding the range of included measures, letting a 2 percent or greater absolute performance difference between low income subsidy/dual eligible and non-low income subsidy/dual eligible individuals be sufficient for measure inclusion; consider other methods for measuring and rewarding quality for plans with complex members; and engage with both NCQA and PQA to drive the development of adjustments for socioeconomic factors for their respective measures; and accelerate the inclusion of such adjusted measures in the Star Ratings program.

Another commenter recommended that to address D–SNPs, CMS compare D–SNPs to D–SNPs, use appropriate measures for dual eligible individuals, evaluate adjusting individual measures for social risk factors, and make improvements to the CAI to make the adjustment more effective, including additional measures and other adjusters. A commenter suggested HOS-derived measures should be included in the CAI, so that the complexities of each plan's enrollee population would be taken into account. The commenter also requested CMS use HOS samples that are larger when the plan enrollment is larger, to provide a truer representation of the member population. Another commenter expressed support for continued use of the CAI in the Star Ratings program while CMS develops a long-term solution to address disparities in plan performance associated with socio-economic status and other risk factors.

Response: CMS appreciates these comments although changes to how CMS addresses socioeconomic status (SES) are out of scope for this regulation. There continues to be additional work in the research community on both identifying the impact of social risk factors on health outcomes and how to best address the impact on clinical quality measurement such that comparisons across contracts yield accurate representations of true differences in quality as opposed to reflections of changes in the composition of beneficiaries in contracts. CMS is following the related work of the National Quality Forum (NQF) since it will have a widespread impact on quality measurement across multiple settings. The NQF has a longstanding policy prohibiting risk adjustment for SES and other demographic factors. NQF released a final report in July 2017 [29] on the findings of the 2-year trial period that temporarily lifted that prohibition. In the report, NQF recommended a 3-year initiative to further examine and consider social risk adjustment to allow evidence as to whether a change in that longstanding policy should be revised.

In addition, CMS has engaged the NCQA and PQA to review and determine if any measures are sensitive to the composition of the enrollees in a plan and whether any modifications to the specification would be appropriate.

As part of this engagement by the agency, the PQA examined their medication adherence measures, which are currently used in the Star Ratings Program, for potential risk adjustment (that is, adjustment for SES and demographic factors).[30] Based on the results of this analysis, beginning in 2018, the PQA included in the 2018 PQA Measure Manual draft recommendations on risk adjustment of the three medication adherence measures: Medication Adherence for Diabetes Medications, Medication Adherence for Hypertension, and Medication Adherence for Cholesterol. As part of PQA's draft recommendations, they suggest that the three adherence measures be stratified by the beneficiary-level sociodemographic status characteristics listed earlier to allow health plans to identify disparities and understand how their patient population mix is affecting their measure rates.

The PQA indicated that the risk-adjusted adherence measures will be submitted through the NQF consensus

[29] NQF's Final Report can be assessed using the following link: *http://www.qualityforum.org/Publications/2017/07/Social_Risk_Trial_Final_Report.aspx.*

[30] The PQA summary can be accessed at: SDS Risk Adjustment PQA PDC CMS Part D Stars *or http://files.constantcontact.com/e9a15233201/96107f74-f6df-46f9-91e9-4a79d7e1bf0a.pdf?ver=1515729061000.*

development process for maintenance of the measures (NQF Endorsed #0541). If endorsed by NQF, CMS will consider how to implement the PQA recommendations in the future for these Star Ratings measures.

NCQA's 2019 HEDIS Volume 2 includes the additional specifications of 4 measures used in the MA Star Ratings. As discussed in the 2018 Call Letter, the additional specifications for Breast Cancer Screening, Colorectal Cancer Screening, Comprehensive Diabetes Care—Eye Exam Performed, and Plan All-Cause Readmissions [31] break out the rates by SES. While CMS continues to use specifications for the overall measure rates not broken out by SES, which are the same rates as contracts have submitted in past years, CMS is considering if and how to best incorporate the information provided by the stratified reporting in future years of the Star Ratings. In particular, CMS is considering to what extent stratified reporting helps address in a more permanent way the same issues addressed by the Categorical Adjustment Index (CAI).

The Office of the Assistant Secretary for Planning and Evaluation (ASPE), as required in the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act, Pub. L. 113–185), released the first in a two-part series of Reports to Congress (RTC) in December 2016.[32] ASPE's second report is due in the fall of 2019. In the meantime, CMS continues to be in dialogue with ASPE to discuss potential options for future MA Star Ratings.

Based on stakeholders' feedback, the April 2018 final rule expanded the adjusted measure set for the determination of the CAI beginning with the 2021 Star Ratings to all measures identified as a candidate measure. A measure will be adjusted if it remains after applying the following four bases for exclusions as follows: The measure is already case-mix adjusted for SES (for example, CAHPS and HOS outcome measures); the focus of the measurement is not a beneficiary-level issue but rather a plan or provider-level issue (for example, appeals, call center, Part D price accuracy measures); the measure is scheduled to be retired or revised during the Star Rating year in which the CAI is being applied; or the measure is applicable to only Special Needs Plans (SNPs) (for example, SNP Care Management, Care for Older Adults measures). HOS-outcome measures are not included in the measurement set since they are already adjusted for SES. Additionally, since HOS samples are random, increasing their size will not make them more representative.

Comment: A few commenters supported the continued prior adjustments for the lack of low-income subsidy in Puerto Rico which is part of the current CAI calculations with a commenter recommending formalizing the rules for determining the percent LIS for Puerto Rico contracts.

Response: CMS appreciates these comments. The rules for determining the percent LIS for Puerto Rico contracts were codified in the April 2018 final rule at §§ 422.166(f)(2)(vi) and (vii) and §§ 423.186(f)(2)(vi) and (vii).

Comment: A commenter suggested that CMS apply a hold harmless to both the CAI and the Reward Factor going forward. This commenter urged CMS to employ a hold harmless calculation for plan sponsors that are negatively impacted by the CAI value if it lowers a contract's Summary Ratings or Overall Ratings and to remove any negative consequences for high performing contracts related to the Reward Factor since high performing contracts are not able to achieve low variance as easily as low performing contracts.

Response: We note that this comment raises an issue that is outside of the scope of the proposals but we are explaining the current policy and regulations. The CAI values address the average within-contract disparity in performance revealed through the Star Ratings data each year among beneficiaries who receive a low income subsidy, are dual eligible individuals, and/or are disabled. The adjustment factor varies by a contract's categorization into a final adjustment category that is determined by a contract's proportion of low income subsidy/dual eligible individuals and beneficiaries with disability status. By design, the CAI values are monotonic and, thus, contracts with larger percentages of enrollees that are low income subsidy/dual eligible and/or have disability status realize larger positive adjustments. Contracts with few beneficiaries that fall in the low income subsidy/dual eligible and/or disability status categories have small negative adjustments since achieving higher ratings is easier for these contracts relative to ones with more significant percentages of vulnerable beneficiaries. Thus, CMS disagrees that contracts with low percentages of these vulnerable beneficiaries should receive a hold harmless provision. It is not clear how the commenter suggests to remove negative consequences of the Reward Factor since all of the factors are 0 or positive adjustments.

Comment: Another commenter supported both the Star Ratings methodology and past improvements that CMS has made to increase accuracy. The commenter also supported enhancements that aim to signal CMS's willingness to reward MA organizations that demonstrate excellent outcomes and enrollee experiences. Another commenter requested CMS acknowledge that outcome based measures are more challenging for plans serving complex populations.

Response: CMS appreciates these comments. The Star Ratings methodology weights the experience of enrollees and outcome measures heavily, but also includes other metrics of plan performance, as additional dimensions for holding MA and Part D plans accountable for their performance. Outcome measures such as Improving or Maintaining Physical Health and Improving or Maintaining Mental Health are adjusted for the characteristics of the enrollees, including more complex enrollees.

Comment: A commenter expressed support for retiring measures when there are 1 percentage point differences in the same direction year-over-year (for example, for 3 years).

Response: The April 2018 final rule codified rules for the retirement of measures, at §§ 422.164(e)(1) and 423.184(e)(1), which provide for retirement when a measure has low reliability and/or the clinical guidelines change such that the measure specifications are no longer believed to align with positive health outcomes. We appreciate this comment and will take it into consideration as we contemplate future enhancements to these rules.

b. Definitions

We proposed to add the following definitions for the respective subparts in part 422 and part 423, in paragraph (a) of §§ 422.162 and 423.182, respectively.

- *Absolute percentage cap* is a cap applied to non-CAHPS measures that are on a 0 to 100 scale that restricts movement of the current year's measure-threshold-specific cut point to no more than the stated percentage as compared to the prior year's cut point.
- *Cut point cap* is a restriction on the change in the amount of movement a measure-threshold-specific cut point can make as compared to the prior year's measure-threshold-specific cut

[31] A summary of the NCQA analysis and recommendations can be accessed using the link that follows: *http://www.ncqa.org/hedis-quality-measurement/research/hedis-and-the-impact-act.*

[32] ASPE's first Report to Congress: Social Risk Factors and Performance under Medicare's Value-Based Purchasing Programs can be accessed using the link that follows: *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

point. A cut point cap can restrict upward movement, downward movement, or both.

- *Guardrail* is a bidirectional cap that restricts both upward and downward movement of a measure-threshold-specific cut point for the current year's measure-level Star Ratings as compared to the prior year's measure-threshold-specific cut point.
- *Mean resampling* refers to a technique where measure-specific scores for the current year's Star Ratings are randomly separated into 10 equal-sized groups. The hierarchical clustering algorithm is done 10 times, each time leaving one of the 10 groups out. By leaving out one of the 10 groups for each run, 9 of the 10 groups, which is 90 percent of the applicable measure scores, are used for each run of the clustering algorithm. The method results in 10 sets of measure-specific cut points. The mean cut point for each threshold per measure is calculated using the 10 values.
- *Restricted range* is the difference between the maximum and minimum measure score values using the prior year measure scores excluding outer-fence outliers (first quartile − 3*Interquartile Range (IQR) and third quartile + 3*IQR).[33]

We proposed to specify in the definition the criteria used to identify the values that correspond to the outer fences which are used to identify extreme outliers in the data. Outer-fence outliers use established statistical criteria for the determination of the boundary values that correspond to the outer fences. The outer fences are the boundary values for an outer-fence outlier such that any measure score that either exceeds the value of the upper outer fence (third quartile + 3*IQR) or that is less than the lower outer fence (first quartile − 3*IQR) is classified as an outer fence outlier and excluded from the determination of the value of the restricted range cap.

- *Restricted range cap* is a cap applied to non-CAHPS measures that restricts movement of the current year's measure-threshold-specific cut point to no more than the stated percentage of the restricted range of a measure calculated using the prior year's measure score distribution.

We received no comments on these proposed definitions in paragraph (a) of §§ 422.162 and 423.182 and are finalizing them with one non-substantive change to the mean resampling definition; we have finalized the definition with an additional sentence to clarify that by leaving out one of the 10 groups for each run, 90 percent of the measure scores are used for each run of the clustering algorithm.

c. Measure-Level Star Ratings (§§ 422.166(a), 423.186(a))

At §§ 422.166(a) and 423.186(a), we previously codified the methodology for calculating Star Ratings at the measure level in the April 2018 final rule. The methodology for non-CAHPS measures employs a hierarchical clustering algorithm to identify the gaps that exist within the distribution of the measure-specific scores to create groups (clusters) that are then used to identify the cut points. The Star Ratings categories are designed such that the scores in the same Star Ratings category are as similar as possible and the scores in different Star Ratings categories are as different as possible. The current methodology uses only data that correspond to the measurement period of the data used for the current Star Ratings program. The cut points, as implemented now, are responsive to changes in performances from one year to the next. Changes in the measure-level specific cut points across a Star Ratings year reflect lower or higher measure performance than the prior year, as well as shifts in the distribution of the scores.

In the April 2018 final rule, CMS detailed the goals of the Star Ratings program. The overarching goals of the Star Ratings program and the specific sub-goals of setting cut points serve as the rationale for any proposed changes.

The Star Ratings display quality information on Medicare Plan Finder to help beneficiaries, families, and caregivers make informed choices by being able to consider a plan's quality, cost, and coverage; to provide information for public accountability; to incentivize quality improvement; to provide information to oversee and monitor quality; and to accurately measure and calculate scores and stars to reflect true performance. In addition, pursuant to section 1853(o) of the Act and the Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes Final Rule (76 FR 21485 through 21489), the Star Ratings are also used to assign Quality Bonus Payments as provided in § 422.558(d).

To separate a distribution of measure scores into distinct groups or star categories, a set of values must be identified to separate one group from another group. The set of values that break the distribution of the scores into non-overlapping groups is referred to as a set of cut points. The primary goal of any cut point methodology is to disaggregate the distribution of scores into discrete categories such that each grouping accurately reflects true performance.

The current MA Star Ratings methodology converts measure-specific scores to measure-level Star Ratings so as to categorize the most similar scores within the same measure-level Star Rating while maximizing the differences across measure-level Star Ratings. To best serve their purpose, the Star Ratings categories must capture meaningful differences in quality across the Star Ratings scale and minimize the risk of misclassification. For example, it would be considered a misclassification if a ''true'' 4-star contract were scored as a 3-star contract, or vice versa, or if nearly-identical contracts in different measure-level star categories were mistakenly identified. CMS currently employs hierarchical clustering to identify the cut points for non-CAHPS measures to ensure that the measure-level Star Ratings accurately reflect true performance and provide a signal of quality and performance on Medicare Plan Finder to empower beneficiaries, families, and caregivers to make informed choices about plans that would best align with their priorities.

We solicited comments in the 2017 proposed rule regarding the approach to convert non-CAHPS measure scores to measure-level Star Ratings (82 FR 56397 through 56399). We requested stakeholders to provide input on the desirable attributes of cut points and recommendations to achieve the suggested characteristics. In addition, we requested that commenters either suggest alternative cut point methodologies or provide feedback on several options detailed in the proposed rule, such as setting the cut points by using a moving average, using the mean of the 2 or 3 most recent years of data, or restricting the size of the change in the cut points from 1 year to the next.

The commenters identified several desirable attributes for the cut points that included stability, predictability, attenuation of the influence of outliers; restricted movement of the cut points from 1 year to the next; and either pre-announced cut points before the plan preview period or pre-determined cut points before the start of the measurement period. In the April 2018 final rule (83 FR 16567), we expressed appreciation for our stakeholders' feedback and stated our intent to use it to guide the development of an enhanced methodology. So as not to

[33] The first quartile is median of the lower half of the data; in other words, the value in the data once arranged in numerical order that divides the lower half into two equal parts. The third quartile is the median of the upper half of the data.

implement a methodology that may inordinately increase the risk of misclassification, CMS analyzed and simulated alternative options to assess the impact of any enhancements on the Star Ratings program and assess the degree to which a new methodology captures the desirable attributes that were identified by stakeholders. While CMS looked to balance the request of stakeholders to increase predictability and stability of the cut points from year to year in developing its proposal for this rulemaking, the goals of the Star Ratings program, the integrity of the methodology, and the intent of the cut point methodology remain the same. The intent of the cut point methodology is to accurately measure true performance.

A Technical Expert Panel (TEP), comprised of representatives across various stakeholder groups, convened on May 31, 2018 to provide feedback to CMS's Star Ratings contractor (currently RAND Corporation) on the Star Ratings framework, topic areas, methodology, and operational measures, including possible enhancements to the clustering methodology used to convert non-CAHPS measure scores to measure-level Star Ratings. Information about the TEP and their feedback can be found at *http://www.rand.org/star-ratings-analyses.*

In developing the proposal for modifying how cut points are set for non-CAHPS measures, CMS examined numerous alternative methodologies to minimize the influence of outliers, to restrict the upward or downward movement of cut points from one year to the next, and to simulate prediction models to allow either limited advance notice or full advance notice of cut points prior to the measurement period. As part of our analyses, we analyzed trends in performance across the Star Ratings measures. The ability to announce cut points before (full advance notice) or during (partial advance notice) the measurement period requires the use of modeling and older data to project the cut points, as well as the need for an alternative methodology for new measures introduced to the Star Ratings program. We explained in the proposed rule that modeling is challenging given differences in the performance trends over time across the Star Ratings measures; thus, a single approach for predicting all future performance does not accurately reflect performance for all measures.

We also discussed how using prediction models to establish future cut points may have unintended consequences and misalign with the underlying goals of the Star Ratings program and sub-goals of setting cut points. Predicting future cut points using older data can lead to both over or under-estimations of performance which results in a distorted signal of the Star Ratings. Over projections in the cut points will result in higher cut points and lower measure-level Star Ratings. Conversely, under projections can lead to lower cut points and higher measure-level Star Ratings. The risk of misclassification is heightened when the accuracy of the projected cut points is diminished. The use of older data for setting cut points does not allow the Star Ratings to be responsive to changes in performance in the current year. Furthermore, setting cut points in advance of the measurement year may lead to MA organizations and Part D sponsors not focusing on certain areas once they achieve a set threshold, eliminating incentives for improvement.

For example, CMS provided incentives for eligible providers to adopt certified Electronic Health Records (EHRs) and report quality measures under the Meaningful Use (MU) initiative. Consequently, there were large gains in performance for a subset of Star Ratings measures that were enabled through the EHR, which reflected a structural change among health care providers in the delivery of care. Further, an examination of performance over time of EHR-enabled measures indicates a decrease in variability of measure scores with contract performance converging toward greater uniformity. Modeling future performance using past performance from before this leveling out of performance would fail to capture the large gains in performance in the EHR-enabled measures, which would have resulted in cut points that were artificially low and measure-level Star Ratings that were higher than true performance.

We discussed in the proposed rule how pre-announced cut points for other subsets of measures in the Star Ratings would present different challenges as compared to EHR-enabled measures. Performance on new measures typically has more room to improve, and large year to year gains are possible and desirable from a quality improvement perspective. Projecting cut points using older data from periods of rapid improvement would artificially inflate future cut points which would cause artificially low measure-level Star Ratings. Measures that demonstrate very slow, consistent growth over time could have projected cut points that are artificially high. The further the projection is in advance of the measurement period, the larger the potential for unintended consequences. In addition, there exists the possibility of external factors, other than structural, that are unanticipated and unforeseen that could impact the distribution of scores for which modeling would not capture.

We listed in the proposed rule some of the challenges of full or partial advance notice:

- Older data often do not accurately reflect current performance.
- The trend in average performance is not always linear.
- External or structural factors may occur that can lead to substantial changes from period to period rather than steady, slow year-over-year improvement.
- Larger gains in performance year to year exist for relatively new measures, compared to more established measures.
- The rate of change is less likely to be linear at lower threshold levels where contracts have greater opportunities for improvement.
- Decreasing variation in measure scores reflects greater improvements in performance for lower versus higher-performing contracts—contract performance is converging over time toward greater uniformity.

These challenges are critical to consider because if we modify the current methodology to predict (or set) cut points using older data and a single model across all measures, we risk causing unintended consequences such as significantly diminishing incentives for improvement or having the Star Ratings misaligned with changes in performance that may be due to external or structural factors.

Based on stakeholder feedback and analyses of the data, we proposed two enhancements to the current hierarchical clustering methodology that is used to set cut points for non-CAHPS measure stars in §§ 422.166(a)(2)(i) and 423.186(a)(2)(i). The first proposed enhancement was the use of mean resampling. With mean resampling, measure-specific scores for the current year's Star Ratings are randomly separated into 10 equal-sized groups. The hierarchical clustering algorithm is done 10 times, each time leaving one of the 10 groups out. The method results in 10 sets of measure-specific cut points. The mean cut point for each threshold per measure is calculated using the 10 values. We explained in the proposed rule that mean resampling reduces the sensitivity of the clustering algorithm to outliers and reduces the random variation that contributes to fluctuations in cut points and, therefore, improves the stability of the cut points over time. Mean resampling uses the most recent

year's data for the determination of the cut points; thus, it does not require assumptions for predicting cut points over time and it continues to provide incentives for improvement in measure scores. The drawback of mean resampling alone is that it does not restrict the movement of the cut points, so the attribute of predictability is not fully captured with this methodology.

To increase the predictability of the cut points, we also proposed a second enhancement to the clustering algorithm: A guardrail for measures that have been in the Part C and D Star Ratings program for more than 3 years. We proposed a guardrail of 5 percent to be a bi-directional cap that restricts movement both above and below the prior year's cut points. A 5 percent cap restricts the movement of a cut point by imposing a rule for the maximum allowable movement per measure threshold; thus, it allows a degree of predictability. The trade-off for the predictability provided by bi-directional caps is the inability to fully keep pace with changes in performance across the industry. While cut points that change less than the cap would be unbiased and keep pace with changes in the measure score trends, changes in overall performance that are greater than the cap would not be reflected in the new cut points. A cap on upward movement may inflate the measure-level Star Ratings if true gains in performance improvements cannot be fully incorporated in the current year's ratings. Conversely, a cap on downward movement may decrease the measure-level Star Ratings since the ratings would not be adjusted fully for downward shifts in performance.

We discussed in the proposed rule that a measure-threshold-specific cap can be set multiple ways and the methodology may differ based on whether the measure is scored on a 0 to 100 scale or an alternative scale. For measures on a 0 to 100 scale, the cap can restrict the movement of the measure cut points from one year to the next by a fixed percentage, such as an absolute 5 percentage point cap. For measures not on a 0 to 100 scale, the cap can be determined for each measure by using a percentage of the measure's score distribution or a subset of the distribution, such as 5 percent of the range of the prior year scores without outer fence outliers, referred to as a restricted range cap. Alternatively, a restricted range cap can be used for all measures, regardless of scale, using a cap based on the range of the prior year scores without outliers. We proposed an absolute 5 percentage point cap for all measures scored on a 0 to 100 scale and 5 percent of the restricted range for all measures not on a 0 to 100 scale, but we explained that we were also considering alternatives to the 5 percent cap, such as using 3 percent. We noted in the proposed rule our belief that any cap larger than 5 percent would not provide the predictability requested by stakeholders that our proposal was designed to incorporate. While smaller caps provide more predictability, it is more likely that the cut points will not keep pace with changes in measure scores in the industry as the cap size gets smaller, and may require future larger one-time adjustments to reset the measure cut points. Therefore, we explained in the proposed rule that we were not sure that a smaller cap, even at a 3 percent threshold, would meet our programmatic needs and goals of providing accurate pictures of the underlying performance of each contract and its comparison to other contracts. We therefore proposed using a 5 percent cap because the use of the cap allows predictability of the cut points from year to year, but also balances the desire to continue to create incentives for contracts to focus on the quality of care of their enrollees and strive to improve performance. If the cut points are not keeping pace with the changes in the scores over time, CMS may need to propose in the future how to periodically adjust the cut points to account for significant changes in industry performance.

In summary, we proposed to amend §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) to add mean resampling of the current year's data to the current clustering algorithm to attenuate the effect of outliers, and measure-specific caps in both directions to provide guardrails so that the measure-threshold-specific cut points do not increase or decrease more than the cap from one year to the next. We proposed a 5 percentage point absolute cap for measures on a 0 to 100 scale and a 5 percent restricted range cap ((0.05) * (maximum value − minimum value), where the maximum and minimum values are calculated using the prior year's measure score distributions excluding outer fence outliers). For any new measures that have been in the Part C and D Star Rating program for 3 years or less, we proposed to use the hierarchal clustering methodology with mean resampling for the first 3 years in the program in order to not cap the initial increases in performance that are seen for new measures. Under our proposal, existing provisions governing cases where multiple clusters have the same measure score value range (§§ 422.166(a)(2)(ii) and 423.186(a)(2)(ii)) and how the clustering algorithm would apply for setting cut points for the improvement score (§§ 422.166(a)(2)(iii) and 423.186(2)(iii)) remain the same. We solicited comments on this proposal, including comments on the percentage used for the cap, whether the cap should be an absolute percentage difference for measures on a 0 to 100 scale, whether the cap should be a percent of the range of prior year scores without outliers for all measures or for the subset of measures not on a 0 to 100 scale, whether the cap should be in both the upward and downward directions, and alternative methods to account for outliers.

Below we summarize the comments we received and provide our responses and final decisions.

Comment: Commenters overwhelmingly supported increasing the stability and predictability of cut points and attenuating the influence of outliers.

Response: CMS appreciates the support for increasing the stability and predictability of cut points and attenuating the influence of outliers. CMS has examined numerous alternative methodologies for setting cut points and the methodology changes we finalize in this rule are intended to make cut points more stable and predictable.

Comment: Several commenters supported implementing cut point methodology changes for contract year 2020 or as soon as possible and opposed delaying such methodology changes until 2022 Ratings.

Response: CMS appreciates the commenters' requests to implement these changes sooner but, as established in the 2018 final rule, changes to the methodology for Star Ratings go through rulemaking and are finalized prior to the relevant measurement year unless we are applying a standard in the regulation text in making the change. We proposed and are finalizing this change to how cut points for non-CAHPS measures are set for the 2020 measurement year, which is associated with the 2022 Star Ratings.

Comment: Many commenters requested more detail on the resampling methodology, including simulations of the impact of resampling and guardrails, and a couple of commenters requested an additional comment period after CMS provided more detail on the resampling methodology, but before making any changes to the cut point methodology.

Response: The reason for using the resampling approach is to increase

stability and predictability of cut points. The approach is implemented as follows. First, the current year's contract scores for a given measure are randomly divided into 10 groups or subsamples. (The current year's data means the data from the applicable performance year for the given year of Star Ratings being calculated. For example, the 2022 Star Ratings use data from the 2020 performance year.) The process can be replicated when the random number generator is given the same seed prior to each run. Then, for each of the 10 subsamples, the following steps are taken:

- Omit one subsample from the data.
- Calculate thresholds using the clustering approach on the data that combines the remaining 9 subsamples.

After those two steps are completed for each of the 10 subsamples, the resulting 10 sets of cut points are averaged.

There are two advantages of resampling. It contributes to stabilizing the cut points, which is its primary advantage over using clustering without mean resampling, and it partially addresses the sensitivity of the clustering approach to the ordering of the observations in the data set. First, each observation is included in only 90 percent of the cut point estimates that are averaged. This reduces the contribution of each observation, including outliers, to the final cut points. Second, pulling out a random 10 percent of the data prior to cut point calculation alters the order of the data. It partially accounts for the sensitivity of the clustering approach to the ordering of observations, as the tie-breaking approach of the clustering algorithm depends on the ordering of the data. Allowing for altered orders of the data reduces the effect of the tie-breaking on the final cut points. Resampling is computationally more feasible than reordering a large (for example, 1,000) number of times to search for multiple cut point combinations, given the timeline of the Star Ratings calculations. HCAHPS uses an approach that is conceptually similar. HCAHPS cut points are the average of cut points based on four segments of the data, divided by quarters, where each segment contains 25 percent of the data. Whereas this proposal is to average the cut points calculated from each of 10 segments where each segment contains 90 percent of the data.

In response to the commenters' requests, we simulated the impact of the proposed changes to the cut point methodology including mean resampling and a 5 percent guardrail on the 2018 Star Ratings. However, we note that some commenters stated that they simulated the proposed changes themselves prior to commenting on the proposed rule. All commenters could have simulated the proposed changes themselves prior to commenting on the proposed rule based on the measure data from 2018 or 2019 Star Ratings (available at *http://go.cms.gov/partcanddstarratings*). While these data do not contain contracts that terminated from the Medicare program, the available data are sufficient to simulate these methodological changes. Since the guardrail could have an effect not only on the current Star Ratings year but also on subsequent years, we accounted for this by starting our simulation of the combined mean resampling and guardrail approach with the 2016 Star Ratings data. The resulting cut points served as the reference point for applying the guardrail to the cut points obtained through applying both mean resampling and guardrails to the 2017 Star Ratings data. Finally, we simulated the 2018 Star Ratings thresholds with mean resampling and a 5 percent guardrail that referenced the simulated 2017 Star Ratings thresholds from the prior step. Overall the changes in 2018 Star Ratings under this approach were relatively modest. Six percent of MA–PD contracts would have seen their overall rating increase by half a star and five percent would have decreased by half a star. For PDP contracts, 5 percent would have increased by half a star and 7 percent would have decreased by half a star. In our simulations, there was not a disproportionally negative impact on contracts with more LIS/DE enrollees. For MA–PD contracts with LIS/DE beneficiaries of up to 50 percent, 6 percent of contracts moved up a half-star on the overall Star Ratings and 6 percent moved down by half-star. For contracts with greater than 50 percent LIS/DE beneficiaries, 7 percent moved up half-star and 2 percent moved down half-star. With regard to the request for an additional comment period, many other commenters requested CMS implement the changes as soon as possible. Further, as explained previously, some commenters conducted simulations of the proposed methodological changes themselves prior to commenting on the proposed rule. Overall, we received 47 comments on the proposed changes to the cut point methodology from the 60 day comment period. We believe the public understood the proposal and were able to submit comments effectively. Therefore, we are finalizing the proposal to implement mean resampling, because resampling will provide increased stability and predictability of cut points.

Comment: A couple commenters expressed concern that mean resampling can provide varying results depending on the number of samples used and questioned why 10 samples were chosen, and a couple commenters believed mean resampling would make the cut point methodology more complicated.

Response: We proposed and are finalizing the use of 10 samples because, as a common choice in related applications, such as cross-validation, it has proven advantages. Using 10 samples is less computationally intensive than using more samples, which is a significant advantage in light of the limited time between the availability of the measure data and the publication of Star Ratings each year. By using the ''leave-one-out approach,'' we expect improved stability in the cut point thresholds, as each data point (including outliers) will be omitted from 10 percent of the cut points that are estimated and then averaged across the ten 90 percent samples following resampling. We appreciate the commenter's concern about the complexity of mean resampling, however, we find that mean resampling is not overly complex because it is replicable, as long as the contract groupings are pre-specified.

Comment: A commenter suggested CMS provide Statistical Analysis System (SAS) programming code to run the cut points analyses.

Response: CMS provides details about how the cut points are determined, including SAS code, in the Technical Notes CMS provides for each Star Ratings year (see the Attachment regarding Individual Measure Star Assignment Process). The changes to the cut point methodology finalized in this rule will be documented in the Technical Notes for the 2022 Star Ratings. The Technical Notes can be found here: *http://go.cms.gov/partcanddstarratings.*

Comment: Several commenters supported mean resampling to address outliers.

Response: CMS appreciates the support for mean resampling. We are finalizing mean resampling as proposed.

Comment: Some commenters believed resampling would not be sufficient to address outliers or believed resampling does not directly address year to year changes in cut points. A couple commenters supported removing outliers before clustering.

Response: CMS appreciates the commenters concerns and based on these comments evaluated two options to address direct removal of outliers—trimming and Tukey outer fence outlier

deletion. We conducted simulations of the impact of each outlier deletion method combined with a cumulative 5 percent guardrail on the 2018 Star Ratings. In general, there tend to be more outliers on the lower end of measure scores. As a result, the one to two star threshold often increased in the simulations when outliers were removed compared to the thresholds when outliers were not removed, while other thresholds were not as impacted. The simulations of trimming and Tukey outlier deletion also account for the removal of the two Part D appeals measures (Appeals Auto-Forward and Appeals Upheld) and the Part C measure Adult BMI Assessment, because these measures will be removed starting with the 2022 Star Ratings, as announced in the 2020 Call Letter.

Under trimming, all contracts with scores below the 1st percentile or above the 99th percentile are removed prior to clustering. Although trimming is a simple way to remove extreme values, it removes scores below the 1st percentile or above the 99th percentile regardless of whether the scores are true outliers. In some cases, true outliers may be between the 1st and 99th percentile, and trimming will not remove these outliers, and in other cases, trimming will remove scores that are not true outliers, especially when the distribution of scores is skewed. If trimming and a 5 percent cumulative guardrail had been implemented for the 2018 Star Ratings, 2 percent of MA–PD contracts would have seen their overall Star Rating increase by half a star and 17 percent would have had it decreased by half a star. For PDP contracts, 4 percent would have increased their Part D summary Star Rating by half a star and none would have decreased.

Tukey outer fence outlier deletion is a standard statistical method for removing outliers. Under this methodology, outliers are defined as values below a certain point (first quartile − 3.0 × (third quartile − first quartile)) or above a certain point (third quartile + 3.0 × (third quartile − first quartile)). The Tukey outer fence outlier deletion will remove all outliers based on the previous definition and will not remove any cases that are not identified as outliers. As with trimming, the values identified by Tukey outer fence outlier deletion are removed prior to clustering. If Tukey outer fence outlier deletion and a 5 percent cumulative guardrail had been implemented for the 2018 Star Ratings, 2 percent of MA–PD contracts would have seen their Star Rating increase by half a star and 16 percent would have decreased by half a star. For PDP contracts, 2 percent would have increased by half a star and 18 percent would have decreased by half a star.

At this time, CMS is not finalizing a method to directly remove outliers prior to clustering. The methods to directly remove outliers resulted in some shifting of Star Ratings in the simulations, as explained previously. Further, as these methods were not included in the proposed rule, the public has not had an opportunity to comment on them specifically. CMS will continue to evaluate these and possibly other methods to directly address outliers and will consider proposing outlier deletion in future rulemaking.

Comment: A commenter opposed resampling because based on the commenter's simulations it would have little impact on cut points and could lead to cut points being raised more often than lowered.

Response: CMS appreciates the commenter's concerns that the mean resampling will not have a significant impact on cut points. However, we believe that mean resampling in conjunction with the use of the guardrails adequately addresses concerns about outliers and stability from year to year. We are finalizing mean resampling because it will lead to increased stability and predictability of cut points and will address the sensitivity of clustering to the order of the data.

Comment: A couple commenters requested CMS consider whether resampling could increase the influence of outliers on cut points.

Response: Mean resampling decreases the influence of outliers on cut points because each measure score (regardless of whether the score is an outlier) is omitted from 10 percent of the cut point estimates, which are then averaged as part of mean resampling. Based on this, any given outlier is omitted from the cut point estimates in one of the 10 runs of the clustering algorithm. When the 10 sets of cut point estimates are averaged, the influence of an outlier is less than what it would have been if resampling had not been done. Therefore, resampling will not increase the influence of outliers as a function of the methodology.

Comment: A commenter supported resampling but would like individual contract scores to be weighted by enrollment to reduce the impact of small contracts that may experience large changes in scoring from one year to the next due to small numbers.

Response: CMS appreciates the commenter's support for resampling. Giving contracts very different weights would decrease the stability of clustering and increase the role of noise in setting thresholds. The measures used in the Star Ratings program have minimum denominator criteria that must be met for a contract to be scored on a measure. As part of our usual administration of the Star Ratings system, CMS has examined changes in scores from year to year when there have been larger shifts in cut points. However, based on this comment, we again examined the data for large changes in measure scores year-over-year and found that such changes occur even for contracts with moderate or large denominators. We therefore disagree with these commenters and will not change the methodology as recommended.

Comment: A commenter opposed resampling because it does not address social disparity issues faced by some plans and outlier removal would disadvantage plans serving underserved communities by normalizing metrics towards the median. Another commenter requested CMS to consider how methodological changes may necessitate adjustments for socio-economic status (SES) factors.

Response: The purpose of resampling is to create more stability in the cut points over time. Separately, CMS in the April 2018 final rule and the 2020 Call Letter finalized a policy to expand the adjusted measures included in the Categorical Adjustment Index (CAI). Starting with the 2020 Star Ratings the CAI values will be determined using all measures in the candidate measure set for adjustment. A measure will be adjusted if it remains after applying the exclusions as follows: The measure is already case-mix adjusted for SES, the measure is a plan or provider issue, the measure is being retired or revised during the relevant Star Ratings year, or the measure only applies to Special Needs Plans. Further, the CAI for a given ratings year is developed using the same cut point methodology that will be applied in that ratings year. We believe that the CAI adequately addresses the impact of SES on the Part C and D Quality Star Ratings pending the conclusion of ASPE's second report on this issue (scheduled to be released in the fall of 2019) and steps taken by the measure stewards to further address it.

Comment: A commenter supported reordering in place of resampling, because the commenter believes resampling may not result in more stable cut points and reordering would address the sensitivity of the hierarchical clustering algorithm to the order of the data.

Response: We appreciate the commenter's concerns, but we are finalizing mean resampling as proposed. The hierarchical clustering algorithm is sensitive to the order of the data when ties occur in identifying the clusters. This means the cut points generated by the clustering algorithm can sometimes be slightly different depending on the order of the data. Mean resampling helps to address this issue, and we believe mean resampling combined with guardrails adequately addresses concerns about outliers and stability from year to year. Additionally, conducting a full-scale reordering is too computationally intensive given the time constraints of the Star Ratings calculations. Under mean resampling, each time 10 percent of the measure scores are randomly selected and removed prior to clustering the remaining 90 percent, the order of the data will be altered. We will continue to evaluate the impact of resampling on the issue identified by the commenter and consider additional enhancements to the methodology if needed.

Comment: Most commenters supported the implementation of guardrails. While about half of commenters supported setting the guardrails at 5 percent as proposed, other commenters were mixed in supporting various other options for setting guardrails, such as a 2 percent guardrail, a 3 percent guardrail, and a 5 percent restricted range guardrail for all measures.

Response: We thank commenters for their support for implementing guardrails. While we appreciate commenters' suggestions for alternatives to setting guardrails at 5 percent, we are finalizing the guardrails at 5 percent as proposed. Guardrails at 5 percent provide a balance between providing predictability in cut points while also allowing cut points to keep pace with changes in measure scores in the industry. Smaller guardrails may prevent the cut points from keeping pace with changes in measure scores in the industry, and may limit the incentive to improvement. Five percent guardrails will also allow for less frequent or possibly no future adjustments to reset the measure thresholds to keep pace with industry changes in measure scores as compared to smaller guardrails. If cut points are not keeping pace with the changes in scores over time, CMS may propose in the future how to adjust the cut points to account for significant changes in industry performance.

Comment: Some commenters requested additional information about the guardrails including simulations of the impact. Some commenters requested simulation data prior to implementation whereas other commenters requested simulations of the impact but also supported the proposed changes.

Response: We appreciate the commenters request for simulations of the impact of guardrails. We refer readers to the earlier response to comments where we provide the results of the simulations combining mean resampling and a 5 percent guardrail. Commenters could also compare cut points from prior years to see where the guardrail would go into effect to determine which cut points would be affected. Additionally, data are available to conduct a full simulation, as discussed previously.

Comment: A commenter requested CMS delay finalizing the application of a guardrail until a final cut point methodology is finalized, because guardrails should be assessed only after the final cut point methodology is determined.

Response: CMS appreciates the commenter's request but does not believe a delay is necessary or appropriate as the guardrails are a key component of how we intend the cut point methodology to provide stability and predictability from year to year, in balance with reflecting true performance. In addition, many other commenters requested CMS implement the changes as soon as possible. CMS has assessed a number of different approaches for modifying the cut point methodology and simulated the impact of the proposed modifications; therefore, we understand the impact of such changes. We discussed the results of these simulations in response to other comments earlier in this preamble. We are finalizing the guardrails as proposed, because this will lead to increased stability and predictability of cut points.

Comment: A commenter supported guardrails only above the prior year's cut points combined with not allowing cut points to decline from year to year, because the commenter believes cut points should not be allowed to decrease compared to the following year. Another commenter noted a concern for cut points getting lower from year to year since downward movement could discourage plans from making improvements to attain higher ratings.

Response: We thank the commenters for these suggestions and while we share the underlying concern about incentivizing continued improvement in performance, we do not believe restricting downward movement in cut points from year to year is appropriate. There may be instances in which industry performance declines from year to year as a result of factors that are outside of plans' control and cut points should be able to move to account for this. This is in line with our intent for the Quality Star Ratings to provide comparative information about MA and Part D plan performance.

Comment: A couple commenters were concerned about the implementation of guardrails, because it could limit the ability of the Star Ratings to respond to industry changes and make the Star Ratings a less effective comparative tool, and these commenters also suggested that guardrails would diminish incentives for improvement. A commenter was concerned about the need to rebase cut points if they did not keep up with changes in industry performance.

Response: We appreciate the commenters concern and agree the Star Ratings should be able to respond to industry changes and to reflect true performance as accurately as possible. To address this issue, we are finalizing the guardrails at 5 percent as proposed rather than a narrower guardrail. Guardrails at 5 percent provide a balance between providing predictability in cut points while also allowing cut points to keep pace with changes in measure scores in the industry. If cut points are not keeping pace with the changes in scores over time, CMS may propose in the future how to adjust the cut points to account for significant changes in industry performance.

Comment: Some commenters also supported setting guardrails for new measures.

Response: While CMS appreciates the desire for predictability of cut points, we believe setting guardrails on new measures would not allow cut points to keep pace with initial increases in performance that are typically seen for new measures and would diminish incentives for improvement. We have seen that for new measures, plans and their providers work closely to implement processes to improve performance. There is typically more room to improve for new measures and, consequently, we see large year-to-year gains in measure scores in particular for the first three or more years.

Comment: A couple commenters questioned how measures moved to display as a result of specification changes would be treated when they were returned to the Star Ratings.

Response: Measures returning to the Star Ratings after being on display as a result of substantive specification changes would be treated as new

measures. For these measures, we will use the hierarchal clustering methodology with mean resampling for the first 3 years after returning to the Star Ratings and add application of the guardrail only after that point.

Comment: A handful of commenters requested that CMS continue to work with stakeholders and other experts to improve guardrails over time and to identify alternative methodologies to increase the predictability and stability of cut points from year to year, including how to address the impact of outliers.

Response: We appreciate the commenters' suggestions to continue to obtain feedback on ways to improve the methodology over time. We will continue to solicit feedback from stakeholders on this issue, and our Star Ratings contractor will continue to obtain input from the Part C and D Star Ratings Technical Expert Panel. We are committed to continuing to analyze the impact of outliers in the data and may propose additional enhancements to specifically address this issue. We intend to consider all of this information as we develop future policies and regulations for the Part C and Part D Quality Star Ratings program.

Comment: A couple commenters supported guardrails for CAHPS measures, such as a guardrail of 0.5 to 1.00.

Response: Because cut points for CAHPS measures have relatively stable trends over time, CMS did not propose any guardrails for CAHPS measures. We will not finalize any such guardrails in this rule. The proposed narrow guardrails of 0.5 to 1.0 are below typical levels of improvement for CAHPS measures.

Comment: A commenter requested consideration of the base cut points that the guardrails are initially applied to. The commenter stated a recalculation of base cut points using new or improved methodology may be more appropriate prior to application of guardrails.

Response: We agree with the commenter. When guardrails and mean resampling are implemented for the 2022 Star Ratings, CMS will rerun the 2021 Star Ratings thresholds with mean resampling. The 2022 Star Ratings thresholds that include mean resampling will then be compared to the rerun 2021 Star Ratings thresholds in order to apply the 5 percent guardrail. Because our proposal occurred after the start of the 2019 performance period for the 2021 Star Ratings, the use of mean resampling for setting cut points is limited to setting the actual cut points for 2022 and subsequent Star Ratings. We will use the 2021 Star Ratings cut points as the starting point for applying the guardrail aspect of the new methodology, in order to allow for an apples-to-apples comparison when applying the guardrails for the 2022 Star Ratings.

Comment: A commenter believed the proposed methodology changes addressed some of the concerns raised by stakeholders and the TEP and are broadly defensible. However, the commenter believed CMS is moving further away from a standardized, uniform approach to assigning Star Ratings for the various care settings/institutions for which it issues report cards, including the Part C and D Star Ratings program and the multiple fee-for-service (FFS) Star Ratings programs for hospitals, dialysis facilities, and skilled nursing facilities. The commenter also stated the proposed methodology changes make an already complex methodology even more complex and CMS should consider the trade-offs between refining setting- or institution-specific methodologies with the pressing need for simplicity and clarity for health care consumers.

Response: CMS understands the desire to balance customization of the Star Ratings methodology for each of the different CMS programs comparing the quality of care for various types of healthcare providers, while also enhancing stability and predictability of cut points for the MA and Part D Star Ratings programs. While CMS has an overall interest and goal in aligning the various Star Ratings systems across the agency to the extent feasible, our proposal was limited to the Part C and D Star Ratings program and the needs and purposes of that program. Under section 1853(o), the Part C and D Star Ratings are used to identify MA organizations that are eligible for quality bonus payments as well as a means to provide comparative information about plan quality to Medicare beneficiaries. In other programs comparing the quality of care for healthcare providers, such as Hospital Compare for hospitals, Medicare FFS payment is not directly related to the overall Star Rating that is publicly reported. We believe the relationship between the Part C and D Star Ratings system and plan Quality Bonus Payments means that providing a measure of stability and predictability for the rated entities (in this case, MA and Part D contracts and plans), even if it means moving further away from a standardized, uniform approach to assigning Star Ratings across agency programs, is appropriate to ensure predictability and stability. Requiring the various Star Ratings systems to have a uniform methodology for setting cut points would not be consistent with the goals and uses of the separate programs and we decline to make uniformity a goal in and of itself where we see significant policy reasons to modify the cut point methodology for the Part C and D non-CAHPS measures. Simplicity and clarity for healthcare consumers would not be sacrificed by differences between methodologies between various CMS Star Ratings Systems because consumers are less likely than other stakeholders to be interested in understanding the underlying methodologies. For those who want access to more details on the methodology, the Technical Notes can be found here: *http://go.cms.gov/partcanddstarratings.* However, taking into account these differences, CMS works to ensure that the MA and Part D Star Ratings system is as closely aligned with other CMS rating systems as necessary and possible to serve the programmatic needs of each Star Rating system.

Comment: A few commenters supported distributing Quality Bonus Payments on a continuous scale.

Response: We understand the commenters' interest in alternative methods of distributing Quality Bonus Payments, however, the distribution of Quality Bonus Payments is defined in statute to be based on a Five-Star Rating system. Changes to the how Quality Bonus Payments are distributed are out of scope for this regulation.

Comment: Some commenters supported using prospectively set thresholds to create more predictability and stability, while others were opposed to setting thresholds prospectively. A commenter supported setting a predetermined cut point of 95 percent for 5 stars and stated predetermined thresholds have the ability to limit the impact of outliers and reduce the additional steps required by the cut point methodology. Another commenter supported setting fixed 5-star cut-points for measures that have stable performance among the top 25th percentile of plans over time.

Response: We understand the desire of some commenters to have pre-set thresholds. CMS had implemented pre-determined 4-star thresholds for some measures in the 2011 Star Ratings to increase transparency for organizations/sponsors and set *a priori* expectations for high performance. However, we found that pre-set thresholds created more ''noise'' or measurement error in the system and disincentivized contracts from improving once they hit the 4-star threshold. Further, while we agree that operational considerations are

important in selecting and adopting the cut point methodology, particularly as we have a limited amount of time to process the performance data and issue Star Ratings each year, CMS does not believe that those considerations should be the sole driving factor; the ease achieved by using a pre-determined cut point needs to be weighed against the drawbacks with that methodology and our overall policy goals for the Star Ratings program.

Comment: A commenter raised concerns that plans must often set unrealistic targets for physicians in order for the plan to earn incentives from CMS and supported finalizing cut point methodologies that do not impede clinical judgment.

Response: CMS does not set targets that Part C and D plans must achieve to do well in the Star Ratings program; as discussed in the prior response, CMS has moved away from the use of pre-determined cut points for Part C and D Star Ratings. Plans should not be impeding clinical judgment; physicians should be using their clinical expertise to determine how to appropriately deliver care to their patients. Further, the non-interference provision in section 1854(a)(6)(B)(iii) prohibits CMS from requiring MA organizations from having a particular price structure for payments to network providers; the Quality Star Rating system does not itself incentivize plans to compromise the delivery of medically necessary care to enrollees.

Comment: A few commenters suggested CMS use alternative clustering methodologies to address outliers, including K-means clustering with outlier removal (KMOR) and clustering with outlier removal (COR).

Response: CMS appreciates the commenters' suggestions and will consider these comments and alternatives as one of the agency's goals in administering the Quality Star Ratings program is continual improvement. CMS is exploring standard outlier removal techniques, such as Tukey outer fence outlier deletion prior to clustering, that are similar to alternatives that the commenter suggests. These approaches are available in SAS software and thus have the benefit of being accessible and transparent to stakeholders. CMS will continue to evaluate these and possibly other methods to directly address outliers and will consider proposing outlier deletion in future rulemaking.

Comment: A commenter stated cut points need to reflect meaningful differences in plan performance.

Response: CMS agrees that the cut points should provide a meaningful way to distinguish true performance. CMS believes hierarchical clustering combined with mean resampling and guardrails will result in cut points that meaningfully distinguish performance while also creating more stability and predictability. Further, CMS monitors the performance distribution for each measure in the Star Ratings program to determine if scores are tightly compressed and differences are not practically meaningful. Even small differences in scores can be meaningful. For example, Quigley, Elliott et al. (2018) established that even one point differences in CAHPS scores are meaningful. Further, CMS evaluates measures for retirement when scores are compressed and topped out such that the measure has low reliability.

Comment: A commenter supported the proposed changes as an interim step, but offered a number of suggestions for CMS to model, in particular to see the impact on plans with a high proportion of LIS/DE/disabled enrollees. The commenter's suggestions included: Stratifying cohort/peer group quintiles based on percent LIS/DE/disabled prior to applying cut point thresholds, using state as unit of analysis rather than contract, analyzing whether measures are sensitive to provider actions, assessing measures to see whether performance differs across plan benefit packages in a contract, addressing topped out measure performance by assigning thresholds for higher stars based on clinical or public health guidelines, and considering beneficiary characteristics when examining measure results.

Response: CMS appreciates the feedback and will take these suggestions into consideration as CMS makes future changes to the Star Ratings methodology. CMS continually monitors cut points and will evaluate the impact of the changes to the cut point methodology. CMS will propose additional enhancements to the cut point methodology as necessary to further the goals of providing ratings that are a true reflection of plan quality and enrollee experience, minimize the risk of misclassification, treat contracts fairly and equally, and minimize unintended consequences.

Comment: A commenter supported rounding measures scores to the next decimal place (tenths of a percent).

Response: Measure scores are already rounded to the precision indicated next to the label ''Data display'' within the detailed description of each measure in the Part C and D Star Ratings Technical Notes found at *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html.* Most measures are rounded to whole numbers so small differences in performance do not drive the cut points.

Comment: A couple of commenters requested additional data to validate calculations during the second plan preview and to simulate proposed enhancements.

Response: CMS will post example measure data for one Part C and one Part D measure in HPMS at the beginning of the second plan preview for contracts to check the CMS programming. Additionally, all HEDIS data from 1997 on are available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/MA-HEDIS-Public-Use-Files.html.* These data are available in September of each year and can be used to simulate and validate Ratings calculations.

Comment: A commenter questioned whether CMS has considered if measures that have shifts in cut points of 5 points should be included in the Star Ratings due to their volatility.

Response: In general, CMS believes such measures should be included in the Star Ratings. Some measures may have occasional large shifts in the performance distribution, but this does not suggest that the measure is not a reliable measure of performance. Shifts in 5 percentage points can happen occasionally since the clustering algorithm not only looks at changes in the levels of performance, but also takes into account changes in the distribution of scores across the industry. When there are more significant shifts in performance, there may be larger shifts in cut points. As finalized in this rule, the mean resampling and guardrails will prevent any very large cut point shifts.

Comment: A commenter raised concerns that the current clustering methodology is flawed since small plans with more volatility can have an outsized impact on thresholds, resulting in misclassification. Another commenter believed the proposed changes would not adequately address misclassifying nearly identical contracts into different Star Ratings levels.

Response: We appreciate the commenters' concerns about volatility and misclassification. The clustering algorithm is set up to maximize differences across star categories and minimize differences within star categories so to avoid misclassifying nearly identical contracts into different Star Ratings levels. All measures have minimum denominators to ensure that the scores included in the Star Ratings are reliable. Outliers are seen not just for small plans that may have smaller

denominators, but with larger plans with moderate or large denominators. Reducing the impact of outliers on the cut points will help to address any potential volatility. CMS is finalizing mean resampling to help address outliers. Along with guardrails, mean resampling will increase the stability and predictability of cut points. In an earlier response, CMS also presented results from simulations that looked at two ways of directly addressing outliers. CMS will continue to evaluate these and possibly other methods to directly address outliers and will consider proposing outlier deletion in future rulemaking.

Comment: A couple of commenters noted that currently plans may have a score that improves but a star that declines or a score that declines but a star that improves.

Response: Since the hierarchical clustering algorithm not only looks at changes in the levels of performance but also takes into account changes in the distribution of scores across the rated Part C and Part D contracts, scores can decline from the prior year and have a higher Star Rating and similarly scores can increase and have a lower Star Rating. The Star Ratings provide information about comparative performance and how the contracts performed compared to the other contracts. CMS is also looking into methods that directly address outliers and will consider proposing outlier deletion in future rulemaking.

Comment: A commenter requested CMS consider that more beneficiaries are enrolling in the MA program and future enhancements may be warranted to accurately reflect plan performance and not the prior care these beneficiaries received before they joined an MA plan, because quality improvement often takes longer than a year.

Response: CMS appreciates this feedback and will continue to monitor scores across the industry.

Comment: A commenter stated if methodologies are in place to restrict extreme movement of cut points, then contracts should be able to use the prior year's data to set goals and focus on improvement and reaching specific benchmarks.

Response: CMS agrees that by increasing the stability and predictability of the cut points, this methodology will assist Part C and Part D organizations in setting specific goals for improvement on Quality Star Ratings.

Comment: A commenter requested CMS reconsider the model for developing CAHPS thresholds to create meaningful differences in plan quality, because the CAHPS measure scores are clustered tightly.

Response: CMS believes that even one point differences in CAHPS scores are meaningful. See Quigley, Elliott et al. (2018). Further, the methodology for setting cut points for CAHPS measures is outside the scope of the proposal and this rulemaking.

Comment: A commenter supported a three-year rolling average of cut points to increase stability for measures that have not topped out; for topped out measures the commenter supported fixed cut points based on the most recent year when performance is categorized as topped out, and providing advance notice of thresholds for new measures for the first three Star Ratings years then move to the three-year rolling average. Additionally, the commenter stated that topped out measures should not be removed from Star Ratings if high quality is still important to maintain.

Response: Using a three-year rolling average of cut points would increase the lag used to determine cut points, which is problematic because it does not account for real improvement trends in measure performance over time. Providing an accurate reflection of the performance on measures for the applicable measurement year is a key goal of the Quality Star Ratings system. The methodology CMS proposed and is finalizing in this rule will increase stability in cut points without this limitation. As a measure is becoming topped out, the cut points already do not change much from year to year so we disagree that there would be a need to set fixed cut points. If there is no or very little variation across contracts in a measure, the measure would have low reliability and, pursuant to §§ 422.164(e) and 423.184(e), would be removed from the Star Ratings program. We will take these comments into consideration as we consider any changes for our policies regarding measures with low reliability.

Comment: A commenter recommends addressing data reliability by having measure developers review outliers and measure methodology, and set more appropriate specifications, such as increasing the minimum denominator and excluding members for which the measure may not be clinically appropriate. The commenter believes this will stabilize cut points.

Response: CMS agrees that measures used in the Part C and Part D Quality Star Rating System should be based on reliable data and provide useful information about plan performance. As discussed in the April 2018 final rule (83 FR 16521) and November 2017 proposed rule (82 FR 56336), one of the goals of the Star Ratings system is for ratings to be a true reflection of plan performance and enrollee experience and be based on data that are accurate, complete, and reliable. Measure developers have been reviewing their specifications to enhance them and CMS will encourage them to continue to review the specifications to improve their measure specifications. For example, NCQA has increased the denominator for the Plan-All Cause Readmission measure to a minimum of 150. NCQA has also been reviewing the HEDIS measures for the additional exclusion for patients with advanced illness.

Comment: A commenter suggested we consider input from the Pharmacy Quality Alliance (PQA).

Response: CMS welcomes input from all stakeholders, and considered the comments submitted by the PQA when finalizing this rule.

Comment: A commenter suggested setting a minimum number of contracts per cluster in order to address the concern that a single contract could influence a change in cut points even with guardrails.

Response: CMS believes setting a minimum number of contracts per cluster would require making a priori assumptions about the distribution of measure scores. The proposed enhancements to the cut point methodology address the commenter's concerns by moving in the direction of increasing stability and predictability of the ratings without having to make a priori assumptions. Additional outlier deletion methods may be proposed through future rulemaking will further address the commenter's concern. In an earlier response, CMS presented results from simulations that looked at two ways of directly addressing outliers. CMS will continue to evaluate these and possibly other methods to directly address outliers and will consider proposing outlier deletion in future rulemaking.

Comment: A commenter suggested that CMS communicate on Medicare Plan Finder that the decrease in stars for PDPs for the 2019 Star Ratings was due to differing cut points for PDPs versus MA–PDs and the impact of outliers on PDPs.

Response: This comment is outside the scope of our proposal for setting cut points for the 2022 and subsequent Star Ratings. The cut points for MA–PDs and PDPs have historically been set separately since performance across MA organizations that offer Part D and stand-alone PDPs may differ given the

integration of health and drug benefits under an MA–PD is very different than how a stand-alone PDP operates. CMS appreciates the comment, but the notices on Medicare Plan Finder are not designed or intended to address the intricacies of the methodology for the Star Ratings program; however, the Technical Notes for each year's Star Ratings are available publicly for those who are interested in that information and are found at *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html.* CMS is concerned that too much methodological detail can be overwhelming for those who use the Medicare Plan Finder website and believes that most consumers want just to see the Star Ratings, especially the overall ratings. As discussed in this final rule and responses to comments in this section, the proposed resampling and guardrails will help mitigate significant changes in the cut points from year to year.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and our responses to the related comments summarized earlier in this final rule, we are finalizing the methodology to determine cut points as proposed at §§ 422.166(a)(2)(i) and 423.186(a)(2)(i). CMS is committed to incorporating feedback received from commenters about the direct removal of outliers from the calculations and will continue to evaluate the methodologies described earlier for outlier removal and possibly other methodologies. We will consider proposing outlier deletion in future rulemaking to allow all stakeholders the opportunity to comment on potential methodologies.

d. Updating Measures (§§ 422.164, 423.184)

In the April 2018 final rule (83 FR 16537), CMS stated that due to the regular updates and revisions made to measures, CMS would not codify a list of measures and specifications in regulation text; CMS adopted a final list of measures for the contract year 2019 measurement period (83 FR 16537–16546) and indicated how changes to that list—additions, updates, removals—would be done in the future, using the Advance Notice and Rate Announcement under section 1853(b) of the Act or rulemaking. The regulations at §§ 422.164 and 423.184 specify the criteria and procedure for adding, updating, and removing measures for the Star Ratings program. CMS lists the measures used for the Star Ratings each year in the Technical Notes or similar guidance document with publication of the Star Ratings. We proposed measure changes to the Star Ratings program for performance periods beginning on or after January 1, 2020 and performance periods beginning on or after January 1, 2021. For new measures and substantive updates to existing measures, as described at §§ 422.164(c) and (d)(2), and §§ 423.184(c) and (d)(2), CMS will initially announce and solicit comment through the Call Letter attachment to the announcements issued for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act and will subsequently propose these measures to be added to the Star Ratings program through rulemaking. Proposals for substantive updates have been discussed in prior Call Letters (contract years 2018 and 2019). We will continue the process of announcing our intent with regard to measure updates in future Call Letters. Any measures with substantive updates must be on the display page for at least 2 years before use in the Star Ratings program. For new measures and measures with substantive updates, as described at §§ 422.166(e)(2), 423.186(e)(2) and §§ 422.164(d)(2), 423.184(d)(2), the measure will receive a weight of 1 for the first year in the Star Ratings program. In the subsequent years, the measure will be assigned the weight associated with its category.

(1) Proposed Measure Updates

(a) Controlling High Blood Pressure (Part C)

Due to the release of new hypertension treatment guidelines from the American College of Cardiology and American Heart Association,[34] NCQA implemented updates to the Controlling High Blood Pressure measure for HEDIS 2019. NCQA revised the blood pressure target to <140/90 mmHg. NCQA also made some structural changes to the measure that included allowing two outpatient encounters to identify the denominator and removing the medical record confirmation for hypertension, allowing the use of telehealth services for one of the outpatient encounters in the denominator, adding an administrative approach that utilizes CPT category II codes for the numerator, and allowing remote monitoring device readings for the numerator. Given the change to the blood pressure target and our rules for moving measures with substantive changes to the display page, this measure will be moved to the display page for the 2020 and 2021 Star Ratings. We proposed to return this measure as a measure with substantive updates by the measure steward (NCQA) to the 2022 Star Ratings using data from the 2020 measurement year with, as required by §§ 422.164(d)(2) and 422.166 (e)(2), a weight of 1 for the first year and a weight of 3 thereafter.

Below we summarize the comments we received and provide our responses and final decisions.

Comment: The majority of commenters supported our proposal.

Response: CMS appreciates receiving the support for this proposal.

Comment: A few commenters expressed support, but offered additional measure specification change suggestions. These commenters questioned whether the new standards are suitable for all populations (that is, for those with special needs, the aged, and those with multiple co-morbidities and advanced cognitive impairment populations as well as for the generally healthy elderly population). These commenters suggested adding some additional exclusions. A commenter disagreed with the new clinical standards as specified in the updated measure.

Response: NCQA is the measure steward for the Controlling High Blood Pressure measure. As codified at § 422.164(c)(1) CMS tries to include in the Star Ratings, to the extent possible, measures that are nationally endorsed and in alignment with the private sector such as the Plan All-Cause Readmissions measure developed by NCQA. Although a few commenters offered suggestions for additional changes to the measure, CMS is moving ahead to include the revised measure in the 2022 Star Ratings since we believe that this measure has been sufficiently validated by the measure steward and most commenters supported the measure updates to align with the new clinical guidelines for blood pressure control. CMS will share all suggestions, including concerns about additional exclusions and clinical disagreements with the specified updates with NCQA for their consideration as they make future enhancements to the measure.

Comment: A few commenters believe the current measure is too important to remove from the Star Ratings. Rather, they suggested keeping the legacy measure in the Star Ratings while the

[34] See Whelton P.K., Carey R.M., Aronow W.S., et al. (2018). Guideline for the prevention, detection, evaluation, and management of high blood pressure in adults: A report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Journal of the American College of Cardiology. 71(19): e127–e248. Available at *http://www.onlinejacc.org/content/71/19/e127?_ga=2.143510773.1362500146.1536262802-126396490.1536262802.*

updated measure is shown on the display pages.

Response: CMS agrees that the Controlling High Blood Pressure measure is an important measure. However, CMS believes that keeping the legacy measure in the Star Ratings while presenting the updated measure on the display pages, would create significant data collection burden on plans given the data collection complexities of the Controlling High Blood Pressure measure. Although § 422.164(d)(2) permits continued use of legacy measures when there has been a substantive update, the regulation does not require CMS to do so in all cases. Here, CMS believes that it is not appropriate.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and our responses to the related comments summarized earlier, we are finalizing our proposal to return the Controlling High Blood Pressure measure, as updated by the measure steward, to the 2022 Star Ratings using data from the 2020 measurement year with a weight of 1 for the first year and a weight of 3 thereafter, as required by §§ 422.164(d)(2) and 422.166 (e)(2).

(b) MPF Price Accuracy (Part D)

Continued transparency and accuracy of sponsors' pricing data used by beneficiaries is important; therefore, we proposed to make enhancements to the MPF Price Accuracy measure to better measure the reliability of a contract's MPF advertised prices. In accordance with § 423.184(d)(2), the substantively updated measure would be a display measure for 2020 and 2021 and we proposed to use it in the 2022 Star Ratings in place of the existing MPF Price Accuracy measure, which will remain in the Star Ratings until that replacement under § 423.184(d)(2). The proposed update would measure the magnitude of difference, as well as the frequency of price differences. We proposed to implement the following changes for this measure:

• Factor both how much and how often prescription drug event (PDE) prices exceeded the prices reflected on the MPF by calculating a contract's measure score as the mean of the contract's Price Accuracy and Claim Percentage scores, based on the indexes in this rule:

++ The Price Accuracy index compares point-of-sale PDE prices to plan-reported MPF prices and determines the magnitude of differences found. Using each PDE's date of service, the price displayed on MPF is compared to the PDE price. The Price Accuracy index is computed as:

(Total amount that PDE is higher than MPF + Total PDE cost)/(Total PDE cost)

++ The Claim Percentage index measures the percentage of all PDEs that meet the inclusion criteria with a total PDE cost higher than total MPF cost to determine the frequency of differences found. The Claim Percentage index is computed as:

(Total number of claims where PDE is higher than MPF)/(Total number of claims)

++ The best possible Price Accuracy index is 1 and the best possible Claim Percentage index is 0. This indicates that a plan did not have PDE prices greater than MPF prices.

++ A contract's measure score is computed as:

—Price Accuracy Score = 100 − ((Price Accuracy Index − 1) * 100)

—Claim Percentage Score = (1 − Claim Percentage Index) * 100

—Measure Score = (0.5 * Price Accuracy Score) + (0.5 * Claim Percentage Score)

• Increase the claims included in the measure:

++ Expand the days' supply of claims included from 30 days to include claims with fills of 28–34, 60–62, or 90–100 days.

++ Identify additional retail claims using the PDE-reported Pharmacy Service Type code. Claims for pharmacies that are listed as retail in the MPF Pharmacy Cost file and also have a pharmacy service type on the PDE of either Community/Retail or Managed Care Organization (MCO) will be included.

• Round a drug's MPF cost to 2 decimal places for comparison to its PDE cost. Post-rounding, the PDE cost must exceed the MPF cost by at least one cent ($0.01) in order to be counted towards the accuracy score (previously, a PDE cost which exceeded the MPF cost by $0.005 was counted). A contract may submit an MPF unit cost up to 5 digits, but PDE cost is always specified to 2 decimal places.

Under our proposed update, PDEs priced lower than the MPF display pricing will continue to be ignored and will not have an impact on the measure score or rating. Only price increases are counted in the numerator for this measure. We proposed to add this updated measure to the 2022 Star Ratings based on the 2020 measurement year with a weight of 1.

Below we summarize the comments we received and provide our responses and final decisions.

Comment: The majority of commenters supported the measure's proposed changes, citing it is critical to provide enrollees with information they have confidence is reliable and accurate. There was strong support for price transparency, and making sure contract performance is measured in a meaningful and useful manner.

Response: CMS appreciates these commenters' support of this measure and the proposed changes, and more broadly the confirmation that beneficiaries rely on the MPF's accuracy to make critical enrollment choices. We agree that it is essential to continue this measure so that enrollees can remain confident that the data displayed on the MPF are reliable and accurate. Our Star Ratings contractor will also continue to obtain feedback on price transparency and related measure concepts as part of their TEP. CMS always values feedback on display and Star Ratings measures and will continue to identify future ideas in the 2021 Call Letter.

Comment: Several commenters opposed the addition of frequency of price differences to the measure, stating this would not be a concern to beneficiaries, or that the current Star Rating measure already includes this. They also state the frequency of pricing differences between the data available on the MPF and the price reflected in the PDE data is not due to a contract's performance, but due to established CMS timelines for MPF updates.

Response: We disagree with these commenters, and believe both the magnitude and frequency of price inaccuracies are important. A one-time discrepancy illustrates different performance by a Part D plan on this issue than multiple occasions where the price is higher than posted on the Medicare Plan Finder website; we believe both that beneficiaries appreciate such differences in performance and need to be aware of them. With the current methodology (as of the 2019 Star Ratings), a sponsor who frequently submits small inaccuracies may receive a similar score to a sponsor who submits MPF prices with very large price differences only a few times.

Comment: Some commenters criticized the overall measure because MPF files are prepared and submitted by a Part D plan according to the CMS-issued calendar and guidelines, which do not allow submissions outside the specified bi-weekly schedule. Because CMS posts files two weeks after submission which are then displayed on MPF for two weeks, the commenters state the data are typically between 19 to 31 days old.

Response: CMS understands that pricing may change much more frequently than MPF submission

windows. We have instituted a biweekly submission window to allow for a correction period (to avoid suppression of plans on MPF). This submission schedule does not dictate the schedule or frequency by which a sponsor chooses to update their own price files prior to submission to CMS. Sponsors who perform well in this measure typically update their pricing files at least every other week and typically closer to the submission dates.

Comment: A few commenters were opposed to the measure because MPF pricing data are based on a single reference/proxy NDC and are compared to an expanded list of NDCs on the PDEs. They state this is a flaw since drug costs vary by NDC, even those with the same strength or dosage form. This variability leads to unavoidable inconsistencies between a Part D plan's submitted price and the price on the claim or PDE record.

Response: For the Star Rating measure, prices that are higher on MPF as opposed to the PDE do not harm the plans' scores. CMS had expanded the list of NDCs to be compared to the MPF prices beginning with the 2011 Star Ratings in response to sponsors' requests to expand the claims studied. Previously, sponsors were only evaluated with PDEs with the same reference NDC, which limited claims, and sponsors stated, unfairly portrayed their accuracy, especially if they did not support the pricing NDC selected on the FRF. To ensure that the measure is sensitive to the accuracy of claims of NDCs beyond those on the FRF, claims for non-reference NDCs that can be linked to a reference NDC with the same brand name, generic name, strength, and dosage form are included in the measure. The inclusion of these additional claims allows for a more robust method of measuring price accuracy. We remind commenters that the average score in this measure ranged from 98–99 for PDPs and MA–PDs in the 2019 Star Ratings.

Comment: A few commenters stated a meaningful price difference to beneficiaries would be greater, and in the range $0.50–$1.00, and that the de minimis amount of $0.01 also does not account for all rounding errors.

Response: The measure's current price threshold of $0.005 was based on data analyses, and sponsor performance has been high for many years. We are raising to $0.01 to account for rounding, and thus allowing a larger variation in prices that are not counted as price increases for purposes of the measure than previously allowed. Raising the threshold level for counting a price increase to $0.50 or higher would significantly lower the usefulness of the measure as a whole, given that plans' scores have been typically clustered in the high 90s.

Comment: Some commenters were overall against CMS using the MPF Price Accuracy measure in the Star Ratings program. They state that a 100 rating in this measure does not reflect truly accurate pricing, but instead is driven primarily by the timing of the files and subsequent measure auditing of pricing. While they agree it is an important measure to ensure MAOs and PDPs are accurately representing drug pricing to plan members; the cut points require near perfection. They propose the measure instead be moved to the display page for monitoring, and that plans not be penalized by timing issues outside of plan control.

Response: CMS disagrees. The cut points are based on the clustering algorithm and reflects actual performance. CMS does not modify the cut points to require near perfection, it is that Part D sponsors generally do a good job of posting prices that are at least as high as the actual charged prices. CMS sees sponsors' frequent auditing of MPF and price adjudication files to be a beneficial result from the measure. Beneficiaries and other public stakeholders are interested in this measure as well. Knowing that they can expect accurate pricing on the MPF is extremely helpful to beneficiaries using the tool to choose their prescription drug plans.

Comment: A commenter recommended that CMS assess the additional value to beneficiaries of the MPF measure based on usage patterns for price data, etc., and weigh that against the costs to the program (through higher plan bids) that will arise from additional investments that may be required for Part D plans to comply with the revised methodology for this measure.

Response: The regulation at §§ 423.184 (c)(3) and (d)(2) requires new measures and substantively updated measures to be on the display page for at least two years prior to using the updated measure to calculate and assign Star Ratings; for the revised Part D price accuracy measure finalized here, this two year display period will be the 2020 and 2021 display page. During that period, CMS will be using the legacy measure in the Star Ratings. Additional feedback on this revised measure may be submitted during the annual Call Letter process based on experience with the revised measure on the display page. CMS does not agree that the measure's revised methodology imposes additional plan burden. Part D sponsors are required to submit accurate pricing for MPF, and adjudicate claims accurately at the point of sale.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and our responses to related comments, we are finalizing the provisions related to updating the MPF Price Accuracy measure. As proposed, we will first display the updated measure for 2020 and 2021 and then use it to replace the existing measure in the 2022 Star Ratings. Publishing the display measure for at least two years will allow Part D sponsors additional experience with contract-specific results using the new specifications.

(c) Plan All-Cause Readmissions (Part C)

NCQA is modifying the Plan All-Cause Readmissions measure for HEDIS 2020 (measurement year 2019).[35] The measure assesses the percentage of hospital discharges resulting in unplanned readmissions within 30 days of discharge. The changes made by NCQA to the measure are: Adding observation stays as hospital discharges and readmissions in the denominator and the numerator; and removing individuals with high frequency hospitalizations. These changes were implemented by the measure steward (NCQA) based on the rise in observation stays to ensure the measure better reflects patient discharge and readmission volumes. Removing individuals with high frequency hospitalizations from the measure calculation allows the readmissions rates not to be skewed by this population. To date, CMS has only included the 65+ age group in the Plan All-Cause Readmissions measure. In addition to the updates made by the measure steward, CMS proposed to combine the 18–64 and 65+ age groups as the updated measure specifications are adopted and to use NCQA's new recommendation of 150 as the minimum denominator. Given the substantive nature of the proposed updates for this measure, it would be moved to display for the 2021 and 2022 Star Ratings under our proposal and § 422.164(d)(2). We proposed to return this measure as a measure with substantive updates by the measure steward (NCQA) to the 2023 Star Ratings using data from the 2021 measurement year with, as required by §§ 422.164(d)(2) and 422.166(e)(2), a weight of 1 for the first year and a weight of 3 thereafter.

[35] HEDIS 2019, Volume2, Technical Update, Attachment C. *https://www.ncqa.org/wp-content/uploads/2018/10/HEDIS-2019-Volume-2-Technical-Update.pdf.*

Below we summarize the comments we received and provide our responses and final decisions.

Comment: The majority of commenters supported our proposal.

Response: CMS appreciates receiving the support for this proposal.

Comment: Some commenters questioned specific aspects of the measure specification, including the inclusion of observation stays in the measure's numerator and denominator and whether the measure is appropriate for high risk populations. A commenter suggested that by focusing on decreasing readmissions, mortality rates could increase. The commenter cited a 2018 JAMA Cardiology article [36] which presented data showing that the implementation of the Hospital Readmissions Reduction Program (HRRP) was temporally associated with a reduction in 30-day and 1-year readmissions but an increase in 30-day and 1-year mortality for patients discharged after heart failure among fee-for-service Medicare beneficiaries. The authors of this article suggested that this may be just a temporary association and requested additional research to confirm these results.

Response: NCQA is the measure steward for the Plan All-Cause Readmission measure. As codified at § 422.164(c)(1) CMS tries to include in the Star Ratings, to the extent possible, measures that are nationally endorsed and in alignment with the private sector such as the Plan All-Cause Readmissions measure developed by NCQA. Despite some commenters questioning specific aspects of the measures, most commenters provided support for the readmissions measure. CMS believes that this is an important outcome measure for MA contracts since the basis of the MA program is for MA contracts to coordinate the care of their enrollees. MA contracts are responsible for coordinating care following a hospitalization to ensure that their enrollees are receiving appropriate care following a hospitalization, including whether they need to be rehospitalized due to further declines in health. CMS will share all comments concerning appropriate enrollees eligible for the measure, the inclusion of observations stays, and the belief that decreasing readmissions might increase mortality with NCQA for consideration as they make future updates to the measure. Following our rules for moving measures with substantive changes to the display page, this measure will be moved to the display page for the 2021 and 2022 Star Ratings for contracts to acclimate to the new measure specifications.

Comment: A commenter suggested that when the measure is returned to the Star Ratings, the measure should have a weight of 1 for two years, not only for the first year.

Response: Using a weight of 1 for the first year of a new or newly revised MA measure is required by the regulations at §§ 422.164(d)(2) and 422.166(e)(2). Measures with substantive specification changes are treated as new measures. Changes to that policy are out of scope for this regulation. We direct readers to 83 FR 16534 for a discussion of that particular policy.

Comment: A few commenters expressed the belief that the current measure is too important to remove from the Star Ratings. Rather they suggested keeping the legacy measure in the Star Ratings, while the updated measure is on the display page for two years.

Response: CMS considered keeping the legacy measure in the Star Ratings while displaying the updated measure on the display pages, but believes that it would create a significant data collection burden for plans to submit two different sets of data that follow different specifications. This measure is relatively complex and we believe that the value gained by reporting both the legacy and updated measure would not be justified by the additional administrative burden. Although § 422.164(d)(2) permits continued uses of legacy measures when there has been a substantive update, the regulation does not require CMS to do so in all cases. Here, CMS believes that it is not appropriate.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and our responses to the related comments summarized earlier, we are finalizing our proposal to return the Plan All-Cause Readmissions measure, as updated by the measure steward, to the 2023 Star Ratings with a weight of 1 for the first year and a weight of 3 thereafter, as required by §§ 422.164(d)(2) and 422.166(e)(2). Pursuant to § 422.164(d)(2), the revised measure will be collected for display only for the measurement periods of 2020 and 2021.

(d) Improvement Measures (Parts C and D)

The process for identifying eligible measures to be included in the improvement measure scores is specified as a series of steps at §§ 422.164(f)(1) and 423.184(f)(1). As part of the first step, the measures eligible to be included in the Part C and D improvement measures are identified. Only measures that have a numeric score for each of the 2 years examined are included. We proposed to add an additional rule at §§ 422.164(f)(1)(iv) and 423.184(f)(1)(iv) that would exclude any measure that receives a measure-level Star Rating reduction for data integrity concerns for either the current or prior year from the improvement measure(s) used for the applicable contract. The proposed new standard would ensure that the numeric scores for each of the 2 years are unbiased. If a measure's measure-level Star Rating receives a reduction for data integrity concerns in either of the 2 years, the measure would not be eligible to be included in the improvement measure(s) for that contract.

Below we summarize the comments we received and provide our responses and final decisions.

Comment: The vast majority of commenters supported our proposal.

Response: CMS appreciates receiving the support for this proposal.

Comment: A few commenters suggested different ideas for how the improvement measures should be calculated: (1) Use a logarithmic scale rather than a linear scale; (2) calculate improvement measures for the display measures and count them in the Star Ratings improvement measures; (3) modify the hold harmless policy; and (4) weight the improvement change taking into account how well the contract performed in the prior year and the increased difficulty to improve at the higher star levels. A commenter suggested that the improvement measures be entirely dropped from the Star Ratings, stating they are unnecessary.

Response: CMS appreciates the additional feedback related to potential enhancements to the improvement measures. However, these suggestions are outside the scope of the proposed rule. CMS will consider these suggestions as we contemplate future enhancements.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and our responses to the related comments summarized earlier, we are finalizing the amendment to how improvement measures are identified and used as proposed for performance periods beginning on or after January 1, 2020.

[36] Gupta A et al, JAMA Cardiol. 2018; 3(1): 44–53. *https://jamanetwork.com/journals/jamacardiology/fullarticle/2663213.*

Table 2—Additions and Updates to Individual Star Rating Measures

The measure descriptions listed in the tables are high-level summaries. The Star Ratings measure specifications supporting document, *Medicare Part C & D Star Ratings Technical Notes,* provides detailed specifications for each measure. Detailed specifications include, where appropriate, the identification of a measure's: (1) Numerator; (2) denominator; (3) calculation; (4) timeframe; (5) case-mix adjustment; and (6) exclusions. The Technical Notes document is updated annually. In addition, where appropriate, the Data Source descriptions listed in this table reference the technical manuals of the measure stewards. The annual Star Ratings are produced in the fall of the prior year to assist beneficiaries in choosing their health and drug plan during the annual open enrollment. For example, Star Ratings for the year 2022 are produced in the fall of 2021.

1. If a measurement period is listed as 'the calendar year 2 years prior to the Star Ratings year' and the Star Ratings year is 2022, the measurement period is referencing the January 1, 2020 to December 31, 2020 period.

2. For CAHPS, HOS, and HEDIS/HOS measures, the measurement period is listed as 'most recent data submitted for the survey of enrollees.' See measure stewards' technical manuals, as referenced in Data Source column, for the specific measurement periods of the most recent data submitted.

TABLE 2A—UPDATES TO INDIVIDUAL STAR RATING MEASURES FOR PERFORMANCE PERIODS BEGINNING ON OR AFTER JANUARY 1, 2020

Measure	Measure description	Domain	Measure category and weight	Data source	Measurement period	NQF endorsement	Statistical method for assigning star ratings	Reporting requirements (contract type)
Part C Measure								
Controlling Blood Pressure (CBP).	Percent of plan members 18–85 years of age who had a diagnosis of hypertension (HTN) and whose blood pressure was adequately controlled (<140/90).	Managing Chronic (Long Term) Conditions.	Intermediate Outcome Measure Weight of 3.	HEDIS*	The calendar year 2 years prior to the Star Ratings year.	#0018	Clustering	MA-PD and MA-only.
Part D Measure								
MPF Price Accuracy.	A score comparing the prices members actually pay for their drugs to the drug prices the plan provided for the Medicare Plan Finder website.	Drug Safety and Accuracy of Drug Pricing.	Process Measure Weight of 1.	PDE data, MPF Pricing Files.	The calendar year 2 years prior to the Star Ratings year.	Not Applicable	Clustering	MA-PD and PDP.

*NCQA HEDIS Technical Specifications, Volume 2.

TABLE 2B—UPDATES TO INDIVIDUAL STAR RATING MEASURES FOR PERFORMANCE PERIODS BEGINNING ON OR AFTER JANUARY 1, 2021

Measure	Measure description	Domain	Measure category and weight	Data source	Measurement period	NQF endorsement	Statistical method for assigning star ratings	Reporting requirements (contract type)
Part C Measure								
Plan All-Cause Readmissions (PCR).	Percent of acute inpatient stays that were followed by an unplanned acute readmission or an observation stay for any diagnosis within 30 days, for members ages 18 and over. Rates are risk-adjusted.	Managing Chronic (Long Term) Conditions.	Intermediate Outcome Measure Weight of 3.	HEDIS*	The calendar year 2 years prior to the Star Ratings year.	#1768	Clustering	MA-PD and MA-only, except for 1876 Cost Plans.

*NCQA HEDIS Technical Specifications, Volume 2.

Below we summarize additional comments CMS received on measures that were not part of the proposed rule and provide our responses. CMS appreciates the additional feedback related to potential enhancements to measures and will take this feedback into consideration as we make future measure enhancements.

Comment: Commenters requested measure updates for and possible removal of the following measures: Annual Flu Vaccine, Osteoporosis Management in Women who had a Fracture, and Rheumatoid Arthritis Management. CMS also received requests for updates to the following measures: Getting Needed Care, Getting Appointments and Care Quickly, and Members Choosing to Leave the Plan. Some of the comments indicated these measures need additional specifications and exclusions, especially for the Puerto Rican population. Another commenter further suggested the need for measures specifically designed for the advanced illness populations.

Response: These comments are outside of the scope of the proposed and final rules. Where appropriate CMS will share all measure specification suggestions, including concerns about additional measure exclusions and the design of measures specifically for the advanced illness populations, with the appropriate measure stewards.

Comment: A commenter suggested that for the Part D Appeals Auto-Forward measure the minimum enrollment size for a plan to be eligible for this measure be raised or that plans having fewer than two auto-forwards be exempted from reporting. Another commenter suggested that CMS combine the call center sampling for the Part C and Part D Call Center Foreign Language Interpreter and TTY Availability measures.

Response: These suggestions are outside the scope of the proposed and final rules; however, we will take them into consideration as we contemplate future enhancements.

Comment: For the measures Complaints about Health/Drug Plans, a commenter stated these measures should be modified due to complaints arising from restricting beneficiaries' access to opioids.

Response: This suggestion is outside the scope of the proposed and final rules; however, we will take it into consideration as we contemplate future enhancements. In addition, prior to use in the Star Ratings, complaints are reviewed for resolution by plans' and CMS Regional caseworkers. If necessary, a complaint may be labeled as a CMS issue, and thus excluded from the Complaints Star Rating measure. Please note however that not all opioid related complaints should be considered to be ''CMS issues''; for example, a complaint that a plan did not properly implement opioid safety edits, or did not follow Part D requirements for coverage determinations/appeals would remain included in a plan's complaints measure data.

Comment: A few commenters suggested the measure weights for both the CAHPS and HOS measures should be reduced.

Response: In the April 2018 final rule, CMS codified, at §§ 422.166(e)(1) and 423.186(e)(1), the general rules for assigning measures the weight associated with their category. Changes to that policy are out of scope for the proposed and final rules.

Comment: A few commenters suggested electronic survey administration and electronic submission of hybrid measures to reduce provider burden and paperwork.

Response: These comments are outside of the scope of the proposed and final rules. CMS also supports the move to more electronic modes of data collection. CMS will be soliciting comment in an OMB Paperwork Reduction Act (PRA) package as CMS plans to test the web mode of survey administration across various CMS surveys. NCQA has also developed HEDIS Electronic Clinical Data Systems (ECDS) to support obtaining information that is currently available in electronic clinical datasets for HEDIS quality measures.

Comment: A commenter suggested that given the changes with the implementation of section 17006 of the Cures Act, CMS should begin to consider one or more ESRD quality measures specific to ESRD beneficiaries, home dialysis, and/or education about home dialysis.

Response: These comments are outside of the scope of the proposed and final rules. CMS has begun to consider what measures will potentially be relevant for ESRD beneficiaries. We are following the work NCQA will be doing with the National Kidney Foundation to develop a provider-level measure focused on screening for nephropathy in patients with diabetes. This work may inform potential updates/changes for the plan-level measure in HEDIS. We are also following the quality measurement work in the Comprehensive ESRD Care (CEC) Model test to see if any of those measures will be relevant. We are open to suggestions for additional measures.

Comment: A commenter suggested developing measures that reflect care for under-65 populations who are Medicare-eligible due to disability and that, while also being consistent with the Medicare Star Ratings methodology, the measures also reflect complex medical conditions that these individuals have. To bolster the ability of states and others to analyze data across various factors and programs, the commenter also requested CMS provide access to data at levels below the contract and disaggregated.

Response: These comments are outside of the scope of the proposed and final rules. CMS appreciates the importance of measuring plan performance in serving the under-65 population and the comment explaining why. To allow comparisons below the level of the contract and/or disaggregated in other ways may be challenging, since valid and reliable comparisons at those levels could be very burdensome to plans or may not be possible. However, CMS has and will continue to explore ways to address the needs of states and others to assess care for subpopulations.

Comment: A commenter suggested CMS focus more on outcome measures than on process measures.

Response: These comments are outside of the scope of the proposed and final rules. CMS agrees with the importance of focusing on outcome measures and welcomes all suggestions for potential outcome measures as additions to the Star Ratings.

Comment: CMS received a request for additional discussions of how MA and FFS/ACO regulations can be similarly constructed to streamline provider compliance and beneficiary understanding. CMS received a request to publicly post measure guides (for example, Patient Safety Report User Guides) in addition to the Star Ratings Technical Notes. The commenter referenced as an example CMS's use of member months in the Statin Use in Persons with Diabetes (SUPD) measure which differs from the PQA measure specifications, and that additional information would help improve consistency in sponsors' quality improvement efforts. Currently, more detailed information is included in the Patient Safety Report User Guides compared to the Star Ratings Technical Notes.

Response: CMS appreciates suggestions for standardizing measures and regulations across programs. CMS is currently working to ensure consistency of measure specifications across programs where applicable. CMS will consider these suggestions as we contemplate future enhancements.

CMS also agrees about the importance of transparency in CMS's calculation of Star Ratings. Sponsors and their authorized users may access the Patient Safety User Guides through the Patient Safety Analysis website set up by CMS for Part D sponsors to have access to monthly Patient Safety Reports to compare their performance to overall averages and monitor their progress in improving the prescription drug patient safety measures. We will consider options to either publicly post the Patient Safety Report User Guides or incorporate additional details in the Star Ratings Technical Notes. The commenter's reference of CMS using member months in the SUPD measure is an example of a modification necessary to fairly evaluate performance of Part D sponsors. The member-years of enrollment adjustment is used to account for beneficiaries who are enrolled for only part of the contract year. The measure is weighted based on enrollment since beneficiaries with longer enrollment episodes account for more member-years and therefore have a larger impact on a contract's rates. Each episode of enrollment is considered separately.

Comment: A commenter suggested CMS use the Net Promoter Score (NPS) rather than CAHPS measures.

Response: These comments are outside of the scope of the proposed and final rules. CMS disagrees that the NPS

should replace the CAHPS measures. NPS was developed to measure customer loyalty and does not provide information about why a customer may recommend a brand or product. Unless an organization is collecting supplemental information, NPS scores will not help drive quality improvement. Among proponents of the NPS score, there is agreement that additional feedback needs to be collected from customers.[37] This score alone is not sufficient. MA and Part D contracts can collect for their own purposes a limited number of supplemental survey items on the CAHPS surveys if they add them to the end of the survey. Some contracts do add similar questions to the NPS item to the current CAHPS surveys for their own internal purposes. There are multiple concerns about using the NPS score instead of CAHPS, including that the score may mask important differences in performance between organizations and the score is more volatile and less reliable than a composite measure that includes multiple survey questions.

Summary of Regulatory Changes

No changes are being finalized based on these comments that are out of scope of the proposed rule.

(5) Data Integrity (§§ 422.164(g), 423.184(g))

In the April 2018 final rule (83 FR 16562), CMS codified, at §§ 422.164(g)(1)(iii) and 423.184(g)(1)(ii), a policy to make scaled reductions to the Star Ratings for a contract's Part C or Part D appeals measures because the relevant Independent Review Entity (IRE) data are not complete based on the Timeliness Monitoring Project (TMP) or audit information. The reduction is applied to the measure-level Star Ratings for the applicable appeals measures. We proposed to add a provision at §§ 422.164(g)(1)(iii)(O) and 423.184(g)(1)(ii)(M) that would assign a 1-star rating to the applicable appeals measure(s) if a contract fails to submit TMP data for CMS's review to ensure the completeness of their IRE data. We explained in the proposed rule that we believe it is appropriate to assume that there is an issue related to performance when the MA organization or Part D plan sponsor has refused to provide information for the purposes of our oversight of the compliance with the appeals requirements. We also explained how our proposal to modify measure-specific ratings due to data integrity issues is separate from any CMS compliance or enforcement actions related to a sponsor's deficiencies; these rating reductions are necessary to avoid falsely assigning a high star to a contract, especially when the MA organization or Part D sponsor has refused to submit data for us to evaluate performance in this area and to ensure that the data submitted to the IRE are complete.

Below we summarize the comments we received and provide our responses and final decisions.

Comment: Most commenters supported the downgrade to one star if a contract fails to submit TMP data for CMS's review to ensure the completeness of the IRE data. A commenter suggested that a reduction should only occur when there is a complete failure to submit TMP data for CMS review.

Response: CMS appreciates the support of the data integrity policies. To fully assess the completeness of the appeals data, the TMP data need to be complete and submitted in a timely manner. The data integrity policies align with our commitment to data quality and preserve the integrity of the Star Ratings. CMS designed the data integrity policies to distinguish between occasional errors and systematic issues. This policy and these rating reductions are necessary to avoid falsely assigning a high Star Rating to a contract, especially when deficiencies have been identified that show CMS cannot objectively evaluate a sponsoring organization's performance in an area.

Comment: A commenter questioned whether the proposal is only referring to the Appeals Auto-Forward measure as the Part D appeals measure.

Response: The data assignment of one star is for both the appeals timeliness and upheld measures for Part C and Part D. If a contract does not submit the TMP data for the Part C measures, Plan Makes Timely Decision about Appeals (Part C) and the Reviewing Appeals Decisions (Part C), both will receive reductions. The same policy applies to the two Part D appeals measures, Appeals Auto-Forward (Part D) and Appeals Upheld (Part D).

Comment: Many commenters generally opposed scaled reductions, characterizing them as ''data integrity penalties'' using TMP and audit data, and a commenter supported use of audits and TMP data for scaled reductions. The commenters that were opposed stated these data integrity findings are not a reflection of the plan's quality. Others stated that the TMP is burdensome due to an additional requirement that they need to budget for and manage. A commenter opposed use of audits because they believe there could be auditor subjectivity (varying interpretation of the same issue) and changes in the audit process. Many commenters gave recommendations for the TMP or requested clarifications on the process of scaled reductions. A couple of commenters recommend consolidating auditing and/or TMP efforts with other requirements and offered suggestions such as eliminating the TMP and modifying the Part D reporting requirements and Technical Specifications for Coverage Determinations and Redeterminations reports to collect the same or similar data to confirm the accuracy of IRE data. A commenter recommended applying the requirements of Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs to fulfill the Star Ratings integrity goal, be operationally less burdensome for plan sponsors, and also save CMS and the Part D program the amount it paid for the TMP audit in 2017 and 2018. A commenter requested that CMS provide its methodology for determining which cases are in scope for scaled reductions. Another commenter requested CMS wait a minimum of 2 calendar years to use the findings in a ''punitive'' manner to allow the plans to adapt to the process. And a commenter suggested CMS examine methods to simplify appeals administration language and address areas of subjectivity identified within the guidelines that result in differing interpretations.

Response: As explained in the proposed rule, the use of the data downgrade is not a penalty or punitive but a necessary measure to reflect how the data underlying the measure are not reliable and to avoid false high ratings on these measures where the sponsoring organization has failed to provide the data necessary to ensure that performance is accurately reflected on these measures. As we explained in the April 2018 final rule at 83 FR 16562, all measures and the associated data for the Star Ratings have multiple levels of quality assurance checks. Our longstanding policy has been to reduce a contract's measure rating if we determine that a contract's data are incomplete, inaccurate, or biased. If there are data issues, we cannot accurately measure quality and performance. The data downgrade policy was adopted not as a penalty but to address instances when the data that will be used for specific measures are not reliable for measuring performance

[37] *https://aishealth.com/medicare-and-medicaid/nps-is-viewed-as-useful-but-not-best-as-sole-satisfaction-measure-for-ma-plans/.*

due to their incompleteness or biased/erroneous nature. For instances where the integrity of the data is compromised because of the action or inaction of the sponsoring organization (or its subcontractors or agents), this policy reflects the underlying fault of the sponsor and without it sponsoring organizations could ''game'' the Star Ratings and merely fail to submit data that illustrate poor performance. Not only is accepting biased data from a sponsor not fair to other organizations that follow rules and have procedures in place to properly handle appeals, but it is also not fair to beneficiaries, as they would receive inaccurate information on the plan's performance regarding its handling of appeals. The use of TMP data for scaled reductions of the appeals measures was finalized in the April 2018 final rule. In this CY2020 rulemaking, CMS only proposed a reduction to one star for the applicable appeals measures for the contracts that do not submit any TMP data but did not reopen for comment the entire provision regarding use of TMP data or scaled reductions as a whole. Therefore, while CMS appreciates this feedback related to the TMP and scaled reductions in general, these comments are outside the scope of the proposed rule; CMS will consider these suggestions as we make future enhancements.

Comment: A commenter stated the additional change modifies the appeals measures from a timeliness measure to a timeliness and data integrity measure.

Response: CMS disagrees with this assertion. The proposed addition to the scaled reductions for not submitting TMP data is not a modification to the appeals measures but a mechanism to ensure that the data used for evaluating performance on a measure are accurate, complete, and unbiased. If a contract does not submit TMP data, CMS does not have information to assess the completeness of the data used for these measures. The data used for CMS's Star Ratings must be reliable, meaning that they are accurate, complete, and without bias. CMS has historically identified issues with some contracts' data and has taken steps to protect the integrity of the data and the Star Ratings; publishing Star Ratings that are not an accurate reflection of plan performance would not be consistent with CMS's statutory obligation to provide comparative information to beneficiaries under section 1851(d) of the Act or with the goals of the Quality Payment Bonus under section 1853(o) of the Act. Our longstanding policy has been to reduce a contract's measure rating if we determine that a contract's measure data are incomplete, inaccurate, or biased. Determinations that data are inaccurate or biased may result from the mishandling of data, inappropriate processing, or implementation of incorrect practices.

Comment: A few commenters noted that there is a short window for the plans to submit TMP data and that results are not shared until 9 months later. A few commenters requested that plans be provided with TMP results in advance of the first plan preview period. A commenter requested that if CMS chooses to continue the TMP process, CMS should hold the auditor accountable for providing at least a draft audit report within 30 days.

Response: CMS appreciates this feedback. As described in the December 21, 2018 HPMS memo entitled 2019 Timeliness Monitoring Project (TMP), the data collection is done in three waves beginning in January 2019. CMS receives initial TMP results at the end of Spring 2019, and then analyzes each contract's data to apply the scale reductions as required by §§ 422.164(g)(1)(iii) and 423.184(g)(1)(ii); where the applicable regulation does not require a reduction, no reduction is taken. There are no draft TMP reports. CMS will again provide TMP results and scaled reduction information in the first plan preview and sponsoring organizations may submit any questions or comments if they believe they should not have received a reduction. CMS will consider if it is operationally feasible to make these data available any earlier in future years. CMS strongly recommends sponsoring organizations being proactive in adopting policies to ensure that data are accurate, complete, and unbiased, and that the data integrity downgrades are not applicable to them.

Comment: A commenter did not support the proposal to reduce to one star for not producing the TMP data citing that CMS should ensure that the Star Ratings system is focused on improving quality of care received by beneficiaries instead of incorporating ''penalties'' on plans for compliance purposes. Another commenter supported the proposal to reduce to one star if a contract fails to submit TMP data but stated that reducing the Star Ratings for data integrity errors confuses quality measurement with compliance and audit activities. The commenter stated that a plan that is ''penalized'' through compliance audits should not be ''penalized'' a second time through the Star Ratings, which should be focused on clinical quality and beneficiary satisfaction.

Response: CMS agrees that the Star Ratings should be focused on improving the quality of care provided by health and drug plans, but in order to ensure that the Star Ratings can focus on that, the data used to measure performance in CMS's Star Ratings program must be accurate, complete, and unbiased. We reiterate that (1) the reductions required by §§ 422.164(g) and 423.184(g) are not a penalty but a means to reflect how the sponsoring organization has not produced accurate, complete, and unbiased data for purposes of performance measurement and (2) that our proposal was on the narrow issue of addressing the failure of a sponsoring organization to submit TMP data so that CMS could evaluate if the data integrity provision would require a scaled reduction in certain appeals measures. Our longstanding policy has been to reduce a contract's measure rating if we determine that a contract's data are inaccurate, incomplete, or biased. If there are data issues, we cannot accurately measure quality and performance. Public postings of the Star Ratings data use a notice that CMS has identified issues with a plan's data in lieu of the actual rating for a measure; this notice is used when CMS has determined that inaccurate, incomplete, or biased data (such as resulting from the mishandling of data, inappropriate processing, or implementation of incorrect practices) has had an impact on the measure score. The number of stars applied to the measure will be governed by §§ 422.164(g) and 423.184(g), which address scaled reductions to appeals measures based on an analysis of TMP or audit data and to one star for HEDIS measures and other measures based on NCQA audits, lack of compliance with CMS data validation policies, and other means to identify data integrity issues. The data integrity policies align with our commitment to data quality and preserve the integrity of the Star Ratings. CMS designed and finalized these data integrity policies in the April 2018 final rule to distinguish between occasional errors and systematic issues.

Comment: A commenter suggested that if the TMP is used to measure completeness of data, it should be limited to the data for just one measure, the Part D Appeals Auto-Forward measure.

Response: The TMP assess the completeness of the IRE data for all applicable appeals measures which include two Part C and two Part D appeals measures. The assignment to one star when no TMP data are submitted is also applied to the applicable appeals measures since data completeness issues impact the data used for both the timeliness and upheld

measures for Part C and Part D. If cases are missing for the timeliness measure for either Part C or Part D, it would also result in missing cases for the applicable upheld measure.

Comment: A commenter requested that CMS provide more information on the impact of cut points if a plan fails to submit their TMP audit results and the proposal to reduce the plan's rating on the appeals measures is implemented.

Response: If a contract fails to submit TMP data for CMS's review to ensure the completeness of their IRE data, the contract receives one star for the applicable appeals measure(s) under the new regulation provision we proposed and are finalizing at §§ 422.164(g)(1)(iii)(O) and 423.184(g)(1)(ii)(M). Because CMS would have determined that the data reported as performance under the applicable appeals measure(s) was inaccurate, incomplete or biased, that data are not included in the creation of cut points. We base cut points on an analysis of performance data believed to be accurate, complete, and unbiased.

Comment: A commenter questioned what happens if a sponsor submits TMP data late. Their understanding is that currently, because there is no late submission deadline for submitting TMP data, the result is a reduction to one star. They sought to understand the impact of submitting data late under this new provision, and how this provision differs from the existing one.

Response: Failure to submit data by the deadline or an extension granted by CMS is failure to submit the TMP data. Under the new regulation provision we proposed and are finalizing here at §§ 422.164(g)(1)(iii)(O) and 423.184(g)(1)(ii)(M), the assignment of one star for the applicable appeals measures will happen if a contract fails to submit any TMP data. The December 21, 2018 HPMS memo entitled 2019 Timeliness Monitoring Project (TMP) provides details about data submission, including the deadlines. Under the current practice, a sponsor can let CMS know if there is an issue meeting the submission deadline for the TMP data and CMS can work with the sponsor to determine if an alternative deadline is feasible. CMS needs adequate time to analyze the TMP data once submitted to be able to determine the completeness of the appeals data. If the data are submitted beyond the deadline or an extension granted by CMS, it is treated as a failure to submit the TMP data.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and our responses to the related comments summarized earlier, we are finalizing at §§ 422.164(g)(1)(iii)(O) and 423.184(g)(1)(ii)(M) the assignment of a 1-star rating to the applicable appeals measure(s) if a contract fails to submit TMP data for CMS's review to ensure the completeness of the contract's IRE data.

(6) Review of Sponsors' Data (§§ 422.166(h), 423.186(h))

At §§ 422.164(h)(1) and 423.184(h)(1), CMS proposed to codify a policy regarding the deadlines for an MA organization or Part D plan sponsor to request the IRE or CMS to review a contract's appeals data or CMS to review a contract's Complaints Tracking Module (CTM) data. For example, information regarding the Part C and Part D appeals process is available to MA organizations and is updated daily on the IRE website. Additionally, sponsors can access the Part D Appeals Reports under the Performance Metrics pages in HPMS. To allow enough time for the IRE to make any necessary changes to ensure the accuracy of a contract's measure score, we proposed that requests for CMS or the IRE to review contract data must be received no later than June 30 of the following year in order to have time to use accurate information in the Star Ratings calculations (for example, changes to contract year 2018 appeals data must be made by June 30, 2019 for the 2020 Star Ratings). Reopenings are not taken into account under this proposed deadline for corrections to the IRE data. For purposes of the appeals measures, if a reopening occurs and is decided prior to May 1, the revised determination is used in place of the original reconsidered determination. If the revised determination occurs on or after May 1, the original reconsidered determination is used.

Similarly, we proposed that any requests for adjustments following CMS's CTM Standard Operating Procedures for the complaints measures be made by June 30 of the following year in order for the changes to be reflected in a contract's Star Ratings data (for example, changes to contract year 2018 complaints data must be made by June 30, 2019 for the 2020 Star Ratings).

Below we summarize the comments we received and provide our responses and final decisions.

Comment: Many of the commenters supported a deadline for an MA organization or Part D plan sponsor to request the IRE or CMS to review a contract's appeals or CMS to review a contract's CTM data, but they did not support the proposal of the June 30th date. They all recommended that the date should be following the first plan preview stating that the later date would allow plans to fully respond to all appeals and complaints.

Response: CMS appreciates the feedback and is finalizing our proposal with a modification that will permit CMS to set the date annually to allow flexibility each year to determine the date based on the availability of data for plans to review.

Comment: A commenter noted that the timeframes/deadlines CMS is proposing do not appear to align with the allotted timeframes CMS allows for plans and the IRE to re-open decisions. The commenter proposed CMS review the IRE reopening process and timeframes to ensure all cases submitted to the IRE, in the measurement plan year, are fully resolved by the first plan preview period. Additionally, the commenter recommended that if the IRE does not meet the IRE reconsideration timeframes, which are outlined in the MAXIMUS Federal Medicare Health Plan Reconsideration Process Manual, then plans would still be held accountable for the outcome of the reconsideration but those cases should not be included in the plan's performance scores since they were not fully resolved.

Response: Because CMS does not want to implement policies that promote reopenings, CMS will not adopt the policy the commenter recommends. Excluding cases that were reopened but do not yet have a decision would encourage organizations to reopen more cases and possibly manipulate their ratings. Therefore, if the reopening is not decided by May 1st, the original reconsideration decision is used in the measure. Reopenings are supposed to be rare. CMS appreciates the feedback about the data timeframe for reopenings and will consider this comment in the future.

Comment: A commenter did not support the data review deadline, because CMS (and its contractor, MAXIMUS) does not provide full visibility into the fields that are required to calculate compliance on an ongoing basis. For example, the commenter pointed out that there is no timeliness indicator on MAXIMUS' website and as a result, some of the data cannot be monitored on an ongoing basis for accuracy. Instead, MA plans must develop a workaround, such as monitoring case dates for accuracy. Something as simple—and predictable—as a national holiday where mail is not delivered can result in an incorrect timeliness measure.

Response: Although there are enough data provided on the MAXIMUS website for contracts to determine if a case is late, CMS has worked with MAXIMUS, the IRE, to add a late indicator on the website for Part C Appeals data to make it easier for plans to monitor the timeliness of their cases. This update will further allow plans to request adjustments to their Part C appeals, if necessary, in a timely manner before Star Ratings calculations.

Comment: A commenter supported the proposal, but requested a clarification of the application of the deadline related to CTM data, because CMS often changes the CTM case status so that cases are no longer visible and cannot be monitored for accuracy.

Response: We appreciate the support and the opportunity to clarify which CTM data are used for Star Ratings purposes. For CTM, the quarterly reports only contain CTM complaints that are used to calculate the Star Rating CTM measure. If a CTM is not in the report, the complaint is not considered a plan issue and it would not be included in the Star Ratings measure. Therefore, sponsoring organizations may wish to focus their requests for CMS review of CTM data on the data that are part of the quarterly reports.

Comment: A few commenters supported the proposal but noted that CMS should publish a schedule of the timing of all related reports, while a commenter did not support the proposal and requested similarly a schedule of reports. Additionally, a commenter stated the Part C MAXIMUS IRE reports are not published and are only made available upon request to the CMS account manager each quarter.

Response: We appreciate the support and the opportunity to clarify the timing and availability of the reports which contain data used for the Star Ratings. Part D appeals and CTM reports are posted in HPMS quarterly; approximately 2 months following the close of the quarter. Information regarding the Part C reconsideration process is available to Medicare Advantage (MA) organizations on the *www.medicareappeal.com* website. The data available on this website are updated daily; therefore, MA organizations that notice discrepancies or have questions about the data should bring these issues to the attention of the IRE as they arise. On the website, MA organizations are able to see all the cases related to a particular plan for the date range they chose and they are also able to search by case number. MAXIMUS has added a late indicator to their website to help in the review; therefore, plans should be able to fully monitor their data throughout the year.

Comment: A commenter supported the codification of deadlines for requests by an MA organization or Part D plan sponsor to review contract appeals or Complaints Tracking Module data.

Response: CMS appreciates the support.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and our responses to related comments summarized earlier, we are finalizing the provisions at §§ 422.164(h)(1) and 423.184(h)(1) related to the policy regarding the deadlines for an MA organization or Part D plan sponsor to request CMS or the IRE to review its' appeals data or CMS to review its' Complaints Tracking Module (CTM) data with a substantive modification. We are not finalizing the June 30th deadline in regulation. To provide more flexibility to set the deadline contingent on the timing of the availability of data for plans to review, we are finalizing in this regulation that an MA organization or Part D plan sponsor may request that CMS or the IRE review its' data, provided that the request is received by the annual deadline set forth by CMS for the applicable Star Ratings year. We intend to use the annual Call Letter or an HPMS memo to set the annual deadline.

e. Extreme and Uncontrollable Circumstances (§§ 422.166(i), 423.186(i))

We proposed a policy to address how extreme and uncontrollable circumstances may have a negative impact on the Quality Star Ratings of an MA or Part D plan. Extreme and uncontrollable circumstances such as natural disasters can directly affect Medicare beneficiaries and providers, as well as the Parts C and D organizations that provide them with important medical care and prescription drug coverage. These circumstances may negatively affect the underlying operational and clinical systems that CMS relies on for accurate performance measurement in the Star Ratings program, all without fault on the part of the MA organization or Part D plan sponsor. We proposed to adjust the Star Ratings to take into account the effects of extreme and uncontrollable circumstances that occurred during the performance or measurement period in a manner that would generally hold the affected contract harmless from reductions in Star Ratings. We proposed to codify a series of special rules for calculation of the Star Ratings of certain contracts in certain extreme and uncontrollable circumstances in paragraph (i) of §§ 422.166 and 423.186.

We proposed that the adjustments be tailored to the specific areas experiencing the extreme and uncontrollable circumstance in order to avoid over-adjustment or adjustments that are unnecessary. Health and drug plans can serve enrollees across large geographic areas, and thus they may not be impacted in the same manner as healthcare providers such as hospitals or medical centers in specific physical locations. To ensure that the Star Ratings adjustments focus on the specific geographic areas that experienced the greatest adverse effects from the extreme and uncontrollable circumstance and are not applied to areas sustaining little or no adverse effects, our proposal targeted the adjustments to specific contracts and further specified and limited the adjustments.

Below we summarize the comments we received on the disaster adjustments in general.

Comment: Most commenters supported our proposals to adjust Star Ratings in the event of an extreme and uncontrollable circumstance.

Response: We thank the commenters for their support of the proposal, which we are finalizing with some substantive modifications in this final rule as described below.

Comment: A few commenters requested that CMS delay codifying the extreme and uncontrollable circumstances policy and continue to assess and develop the methodology in case additional modifications are needed. A commenter requested that CMS implement the policy for measurement year 2018 in order to avoid a temporary lapse in the application of the proposed policy.

Response: The policy being adopted in this final rule will apply to the 2022 Star Ratings and beyond, for extreme and uncontrollable circumstances that begin on or after January 1, 2020. If adjustments are needed to the policy, CMS will propose them through a future rulemaking or sub regulatory guidance. The 2020 Call Letter includes CMS's policy for the 2020 Star Ratings for extreme and uncontrollable circumstances that occurred in 2018. We decline to delay adoption of this policy for a future period, because similar procedures were successfully applied to the 2019 Star Ratings as a result of the multiple 2017 disasters.

(1) Identification of Affected Contracts

In paragraph (i)(1) of §§ 422.166 and 423.186, we proposed to identify MA

and Part D contracts affected by extreme and uncontrollable circumstances during the performance or measurement period that may have affected their performance on Star Ratings measures or their ability to collect the necessary measure-level data. Under our proposal, these ''affected contracts'' are the contracts eligible for the specified adjustments that take into account the effects of the extreme and uncontrollable circumstances. For an MA or Part D contract to be considered an affected contract under our proposal, the contract would need to meet all of the following criteria:

- The contract's service area is within an ''emergency area'' during an ''emergency period'' as defined in section 1135(g) of the Act.
- The contract's service area is within a county, parish, U.S. territory or tribal area designated in a major disaster declaration under the Stafford Act and the Secretary exercised authority under section 1135 of the Act based on the same triggering event(s).
- A certain minimum percentage (25 percent for measure star adjustments or 60 percent for exclusion from cut point and Reward Factor calculations) of the enrollees under the contract must reside in a Federal Emergency Management Agency (FEMA)-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance.

We proposed to identify an area as having experienced extreme and uncontrollable circumstances if it is within an ''emergency area'' and ''emergency period'' as defined in section 1135(g) of the Act, and also is within a county, parish, U.S. territory or tribal government designated in a major disaster declaration under the Stafford Act, and the Secretary exercised authority under section 1135 of the Act based on the same triggering event(s) (*https://www.phe.gov/emergency/news/healthactions/section1135/Pages/default.aspx*). Major disaster areas are identified and can be located on FEMA's website at *https://www.fema.gov/disasters.* To ensure the policy is applied to those contracts most likely to have experienced the greatest adverse effects, we proposed to narrow it to apply to contracts with a certain minimum percentage of enrollees residing in an area declared as an Individual Assistance area because of the disaster declaration. Individual Assistance includes assistance to individuals and households, crisis counseling, disaster case management, disaster unemployment assistance, disaster legal services, and the disaster Supplemental Nutrition Assistance Program. We explained that our focus on enrollees residing in counties eligible for Individual Assistance because of a major disaster was because most Star Ratings measures are based on services provided directly to beneficiaries in their local area. Health and drug plans can serve enrollees across large geographic areas, and thus they may not be impacted in the same manner as healthcare providers such as hospitals or medical centers in specific physical locations. Therefore, we proposed to target the adjustments based on extreme and uncontrollable circumstances to contracts serving beneficiaries who were eligible for individual and household assistance because of the disaster declaration.

We further proposed that at least 25 percent or 60 percent of the enrollees under the contract must reside in Individual Assistance areas identified because of the extreme and uncontrollable circumstances in order for the contract to be an affected contract eligible for adjustments. We explained that this limitation would ensure that the adjustments are limited to contracts that we believe may have experienced a real impact from the extreme and uncontrollable circumstance in terms of operations or ability to serve enrollees. In calculations for the 2019 Star Ratings, we observed that contracts tend to have either very few enrollees impacted or most of their enrollees impacted due to the nature of contracts either covering a broad region or a localized area; if 1 out of 4 enrollees were impacted during the period of the year when the disaster hit, we stated our belief that there would be a small chance that scores may have been impacted. We proposed to exclude the numeric measure scores from contracts with 60 percent or more enrollees impacted by the extreme and uncontrollable circumstances from the determination of the cut points and explained it as a conservative rule that would apply only in cases where a clear majority or all of the enrollees are impacted. We also explained that using the Individual Assistance major disaster declaration as a requirement to identify contracts that would be eligible for adjustments ensures that the policy applies only when the event is extreme, meriting the use of special adjustments to the Star Ratings.

We proposed that contracts that do not meet the definition of an ''affected contract'' would not be eligible for any adjustments based on the occurrence of the extreme and uncontrollable circumstances but also noted that the criteria to be an affected contract would not be sufficient to receive all the adjustments we proposed.

Below we summarize the comments we received on the identification of affected contracts and provide our responses and final decisions.

Comment: Several commenters suggested that CMS commit to being transparent in how it has applied the regulations, such as which contracts received adjustments and the impact on the Star Ratings program. A few stated this would allow sponsors a better understanding of marketplace performance and reduce inquiries to CMS. A commenter recommended that CMS announce areas designated as disasters for the purposes of Star Ratings on a quarterly basis, and another requested greater specificity on how a plan within a given county would qualify for the exemption rules. Another commenter requested that data and analysis on affected contracts be shared with state Medicaid agencies as this information is relevant to the states, and data sharing reduces burden on the plans.

Response: Information about which areas are designated in a major disaster declaration under the Stafford Act and when the Secretary exercised authority under section 1135 of the Act based on the same triggering event(s) are all public information we are extracting from the relevant websites. CMS published the list of relevant 2017 disasters and affected counties in the 2019 Call Letter, and state, county, and contract enrollment data are publicly available, so information about affected contracts is already available. We agree that providing additional information when the adjustments authorized under §§ 422.166(i) and 423.186(i) may be possible. To that end, CMS plans to provide information identifying contracts that meet the definition of affected contracts in §§ 422.166(i)(1) and 423.186(i)(1). We note that the definition of ''affected contract'' in these regulations is substantially similar to the definition and standards CMS used to make similar adjustments in the 2019 Star Ratings based on disasters that occurred in 2017. For the 2019 Star Ratings, which were adjusted for the disasters (Hurricanes Harvey, Irma, and Maria, and the wildfires in California) that occurred during the 2017 performance period, 77 contracts met the 25 percent threshold of beneficiaries in FEMA-designated Individual Assistance areas at the time of the disaster. Based on a similar policy to that we are now codifying in §§ 422.166(i) and 423.186(i), affected contracts reverted to the prior year's rating an average of five times for Part

C measures and three times for Part D measures. For the 2019 Star Ratings, 57 contracts met the 60 percent threshold of beneficiaries in FEMA-designated Individual Assistance areas and had their numeric values excluded from the clustering algorithm so they did not influence cut points. CMS will continue to release the list of relevant disasters and FEMA-designated Individual Assistance counties in the Call Letter each year after the performance period so contracts know in advance of the Star Ratings preview periods whether they might be considered an affected contract based on their service area.[38]

Comment: A commenter questioned whether requiring affected contracts to meet all three criteria in §§ 422.166(i)(1) and 423.186(i)(1) was too restrictive if it requires a state-level declaration of emergency and suggested that the third criteria (that is, §§ 422.166(i)(1)(iii) and 423.186(i)(1)(iii)) was most applicable.

Response: Stafford Act disaster declarations are made by state but designate specific counties that are affected. Our policy addresses contracts with service areas in FEMA-designated Individual Assistance counties. We proposed that for a contract to be considered an affected contract it would need to meet all three criteria in §§ 422.166(i)(1) and 423.186(i)(1). This ensures the extreme and uncontrollable circumstances policy is limited to contracts that may have experienced a real impact from the disaster in terms of operations or ability to serve enrollees. It also ensures that it applies only when the event is extreme, meriting the use of special adjustments to the Star Ratings.

Comment: A commenter was concerned that contracts may deliberately combine contracts with enrollment from a non-disaster area with enrollment in a disaster area in order to meet the 25 percent threshold for Star Ratings adjustments and encouraged CMS to implement safeguards to prevent abuse of the extreme and uncontrollable circumstances policy.

Response: CMS appreciates this comment and notes that the April 2018 final rule addresses contract consolidations. In particular, for consolidations approved on or after January 1, 2019 we assign Star Ratings based on the enrollment-weighted mean of the measure scores of the surviving and consumed contract(s) so that the ratings reflect the performance of all contracts (surviving and consumed) involved in the consolidation. Further, the scenario described by the commenter is unlikely to occur as contract consolidations are generally approved in advance; a sponsoring organization would not be able to take advantage of an extreme and uncontrollable circumstance by subsequently consolidating contracts.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and our responses to the related comments summarized earlier, we are finalizing the definition of an affected contract in paragraph (i)(1) of §§ 422.166 and 423.186. We are also finalizing the introductory sentence in paragraph (i) substantially as proposed to establish a rule that in the event of certain extreme and uncontrollable circumstances, CMS calculates Star Ratings for affected contracts using the rules specified in paragraphs (i)(2) through (i)(10). Those specific rules and the text in paragraphs (i)(2) through (i)(10) are addressed in sections II.B.1.e.(2) through (10). In finalizing the first sentence of paragraph (i), we are making a grammatical change to use ''calculates'' in place of ''will calculate.'' We address additional text we are also finalizing as a new last sentence in the introductory text of paragraph (i) in section II.B.1.e.(6).

(2) CAHPS Adjustments

For CAHPS, we proposed two different types of special rules for affected contracts: Exemption from having to administer the CAHPS survey or adjustments to the Star Ratings on the CAHPS measures if the affected contract must administer the CAHPS survey. CAHPS measures are based on a survey conducted early in the year in which the Star Ratings are released, that is, the year before the year to which the Star Ratings are applicable. For example, the CAHPS survey in early 2019 will be used for the 2020 Star Ratings, which are released in late 2019, before the annual coordinated election period for 2020.

We proposed at §§ 422.166(i)(2)(i) and 423.186(i)(2)(i), that an MA and Prescription Drug Plan contract, even if it is an affected contract, must administer the CAHPS survey unless the contract demonstrates to CMS that the required sample for the CAHPS survey cannot be contacted because a substantial number of the contract's enrollees are displaced due to a FEMA-designated disaster in the prior calendar year and requests and receives a CMS approved exemption. We explained in the proposed rule our belief that displacement of a substantial number of the contract's enrollees would make it practically impossible to contact the required sample for the CAHPS survey. For an affected contract that receives the exemption from administering the CAHPS survey, we proposed at §§ 422.166(i)(2)(iii) and 423.186(i)(2)(iii) that the affected contract would receive the prior year's CAHPS measure stars (and corresponding measure scores).

We proposed that affected contracts with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance would receive the higher of the previous year's Star Rating or the current year's Star Rating (and corresponding measure score) for each CAHPS measure (including the annual flu vaccine measure). For example, for the 2022 Star Ratings for affected contracts, we would take the higher of the 2021 Star Ratings or the 2022 Star Ratings for each CAHPS measure. The affected contract would receive the CAHPS measure score for the corresponding Star Rating year chosen. We proposed the 25 percent threshold to avoid including contracts with very few enrollees impacted and explained our belief that the measure-level scores should not be adjusted for contracts with very few enrollees impacted by the extreme and uncontrollable circumstances. We stated that if a small percentage of enrollees were impacted by an extreme and uncontrollable circumstance, there should not be a significant impact on measure scores. Comments received on this specific proposal in §§ 422.166(i)(2) and 423.186(i)(2) are discussed in section II.B.1.e.(6) of this final rule.

(3) HOS Adjustments

For the HOS survey, we proposed to follow similar procedures as CAHPS but due to the follow-up component of HOS, we proposed that the adjustment be to the Star Ratings for the year after the completion of the follow-up HOS survey (that is administered 2 years after the baseline HOS survey). For example, the 2022 Star Ratings are based on data collected from April through June 2020 and reflect experiences over the past 12 months. The data collected in 2021 will be used for the 2023 Star Ratings, so responses may reflect the impact of 2020 extreme and uncontrollable circumstances and thus, those circumstances may have an impact on the 2023 Star Ratings.

We proposed at § 422.166(i)(3)(i) that an MA contract, even if it is an affected contract, must administer the HOS surveys the year after the extreme and

[38] Tables 14 and 15 in the 2020 Call Letter contain a list of the section 1135 waivers that could affect the 2020 Star Ratings and Individual Assistance counties from all of the 2018 FEMA major disaster declarations. *https://www.cms.gov/medicare/health-plans/medicareadvtgspecratestats/announcements-and-documents.html.*

uncontrollable circumstance unless the contract demonstrates to CMS that the required sample cannot be contacted because a substantial number of the contract's enrollees are displaced due to a FEMA-designated disaster during the measurement period and requests and receives a CMS approved exemption. For an affected contract that receives the exemption from administering the HOS survey, we proposed at paragraph (i)(3)(iii) that the affected contract would receive the prior year's HOS and HEDIS–HOS measure stars (and corresponding measure scores).

We proposed at § 422.166(i)(3)(iv) that affected contracts with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance would receive the higher of the previous year's Star Rating or current year's Star Rating for each HOS and HEDIS–HOS measure (and corresponding measure score) for the Star Ratings 3 years after the eligible extreme and uncontrollable circumstance. As an example, we explained that for the 2023 Star Ratings for contracts affected by an extreme and uncontrollable circumstance in 2020, we would take the higher of the 2022 or 2023 Star Rating (and corresponding measure score) for each HOS and HEDIS–HOS measure in applying the proposal. Comments received on this specific proposal in § 422.166(i)(3) are discussed in section II.B.1.e.(6).

(4) HEDIS Adjustments

For HEDIS, we proposed that an MA contract, even if an affected contract, would be required to report HEDIS data to CMS unless the contract demonstrates to CMS an inability to obtain both administrative and medical record data required for HEDIS measures due to a FEMA-designated disaster in the prior calendar year and requests and receives a CMS approved exemption. We stated in the preamble of the proposed rule that all contracts in FEMA-designated disaster areas can work with NCQA to request modifications to the samples for measures that require medical record review; however, in our proposed regulation text codifying this ability, we proposed only that ''affected contracts'' without an exemption from reporting HEDIS data would be able to seek that kind of modification from NCQA. For affected contracts that have service areas with at least 25 percent of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance, we proposed to take the higher of the previous year's Star Rating or current year's Star Rating (and corresponding measure score) for each HEDIS measure. For example, for the 2022 Star Ratings for affected contracts we would take the higher of the 2021 or 2022 Star Ratings for each HEDIS measure. Comments received on this specific proposal in § 422.166(i)(4) are discussed in section II.B.1.e.(6). of this final rule.

(5) New Measure Adjustments

At proposed §§ 422.166(i)(5) and 423.186(i)(3), we proposed to implement a hold harmless provision for *new* Star Ratings measures if the inclusion of all applicable new measure(s) brings down the summary and/or overall rating. That is, for affected contracts with at least 25 percent of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance, all the new measures would be excluded from the calculation of the summary and/or overall rating if their inclusion brings a contract's summary (or in the case of MA–PD contracts, the overall) rating down. Comments received on this specific proposal in §§ 422.166(i)(5) and 423.186(i)(3) are discussed in section II.B.1.e.(6). of this final rule.

(6) Other Star Ratings Measure Adjustments

For all other measures for affected contracts with at least 25 percent of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance (that occurs during the measurement or performance period), we proposed to take the higher of the previous or current year's measure Star Rating (and then use the corresponding measure score), as described at proposed §§ 422.166(i)(6)(i) and 423.186(i)(4)(i). For example, for the 2022 Star Ratings for affected contracts, we would take the higher of the 2021 or 2022 Star Ratings. We also proposed to exclude from this adjustment policy the Part C Call Center—Foreign Language Interpreter and TTY Availability and Part D Call Center—Foreign Language Interpreter and TTY Availability measures, except for extreme and uncontrollable circumstances where there are continuing communications issues related to loss of electricity and damage to infrastructure during the call center study. We explained the proposed exclusion by noting that these measures and the underlying performance are completely in the plan's control and we believed therefore that there should generally be no impact from the declaration of an extreme and uncontrollable circumstance on plan performance in these areas.

Below we summarize the comments we received on the proposed rules at §§ 422.166(i)(2) through (6) and 423.186(i)(2) through (4) for adjustments to CAHPS, HOS, HEDIS, new, and other measures and provide our responses and final decisions.

Comment: A few commenters requested that we clarify whether our extreme and uncontrollable circumstances policy is ''best of'' the Star Rating or measure score. A commenter proposed that we take the higher of the previous and current year's measure score if the Star Rating is the same in both years to ensure the higher score is used in the improvement calculation.

Response: We proposed, for affected contracts as described specifically in the applicable regulation text, to select the higher of the current or previous year's measure-level Star Rating and then use the measure score that corresponds with the year selected with the higher rating. We proposed this use of the ''higher Star Rating'' rule for CAHPS, new, and other measures for MA and Part D ratings, and for HOS and HEDIS measures for MA ratings. We use the Star Rating for the measure-level comparison because the measure stars are used to calculate the overall Star Rating and the measure-level cut points can change each year. We use the corresponding measure scores for improvement calculations in order to maintain consistency in the years being compared. Where the higher score does not correspond to the higher rating, we use the score from the year with the higher Star Rating for the measure nonetheless. If the Star Rating for a measure is the same in both years we use the current year's data (that is, Star Rating and score). We only revert to the previous year's measure Star Rating if it is higher. The regulation text reflects this rule by referring to the higher of the previous or current year's Star Rating (and corresponding measure score) in §§ 422.166(i)(2)(iv), 422.166(i)(3)(iv), 422.166(i)(4)(v), 422.166(i)(6)(i), 423.186(i)(2)(iv), and 423.186(i)(4)(i).

Comment: A few commenters were concerned that the 25 percent cutoff for measure-level adjustments may be inadequate, or that the policy is biased against larger contracts serving populations spread across multiple regions.

Response: CMS chose the 25 percent cutoff for measure-level adjustments because this cutoff avoids including contracts with very few enrollees impacted by extreme and uncontrollable circumstances. As explained in the

proposed rule, we do not believe it would be appropriate to provide an adjustment to the ratings when fewer than a quarter of the enrollees covered under the contract are affected by the extreme and uncontrollable circumstance. If only a small percentage of enrollees is impacted by a disaster, there should not be a significant impact on measure scores (and therefore not on Ratings). We disagree that the policy is biased against larger contracts, since it is applied the same to all contracts. Further, for contracts with smaller service areas, the declaration of an emergency and designation of a FEMA-designated Individual Assistance area in one county might be sufficient to result in 25 percent or more of the contract's enrollees being in the FEMA-designated Individual Assistance area whereas a larger contract covering the same county might only have a small portion of its overall enrollment in the FEMA-designated Individual Assistance area.

Comment: A few commenters suggested that we instead remove beneficiaries who live within impacted geographic areas from measurement calculations. Commenters stated this would ensure that all affected contracts receive an adjustment that is proportionate with the level of impact to plan performance, be consistent with other exclusion criteria used in Star Ratings measures, and ensure that Star Ratings performance is representative of performance during the measurement period.

Response: We decline to revise our policy to include this type of adjustment, either instead or in addition to the adjustments we proposed and are finalizing in §§ 422.166(i)(2) through (6) and 423.186(i)(2) through (4). For many measures, this is not operationally feasible. For example, this would require modifications to CAHPS and HOS sampling, as well as to HEDIS reporting requirements. Other measures do not have beneficiary-level data that could be adjusted.

Comment: Several commenters questioned how CMS will apply the policy for contracts impacted by disasters in consecutive years. A few suggested that CMS use the ''higher of'' the current year's Star Rating and prior year's adjusted Star Rating, or link back to the most recent year's data not affected by disasters. Another suggested using best of ratings from periods or sources: Current measurement year performance, prior year performance, parent organization average performance, or industry average performance. Other commenters were concerned about old data being pulled forward each year. A commenter stated a ''higher of'' policy would be inappropriate for consecutive disasters, and that CMS should treat multiple year-disaster contracts as new contracts, rate them on a very small set of measures, or base their rating on a small portion of their service area. A commenter suggested that that CMS drop the threshold for relief below 25 percent and 60 percent for contracts that have had two consecutive years of disaster impact. Several commenters requested that CMS extend the disaster adjustment multiple years for select regions continuing to recover from a disaster (for example, Puerto Rico that is still recovering from 2017 hurricanes).

Response: CMS appreciates these comments and acknowledges that our proposal did not address year-over-year disasters. Given the number of comments on this topic, we believe it is appropriate to address by adopting additional provisions specific to this topic. We agree with commenters that are concerned about looking back too many years for contracts affected by disasters multiple years in a row, as well as about including too many measurement periods in 1 year of Star Ratings. We also must consider operational feasibility, and using different thresholds for contracts affected by disasters in different ways would be very complicated for administration and for providing the necessary transparency to MA organizations, Part D plan sponsors, and beneficiaries who use and rely on the Star Ratings.

We must balance these concerns about using older data with concerns about using data based on performance that has been impacted by consecutive disasters. In striking a balance of these concerns, we are finalizing a policy for setting the Star Ratings for contracts with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas that were affected by disasters that began in one year that were also affected by disasters that began in the previous year. Under the regulations we are adopting in this final rule, such multiple year-affected contracts receive the higher of the current year's Star Rating or what the previous year's Star Rating would have been in the absence of any adjustments that took into account the effects of the previous year's disaster for each measure. For example, if a multiple year-affected contract reverted back to the 2021 Star Rating on a given measure in the 2022 Star Ratings, the 2021 Star Rating is *not* used in determining the 2023 Star Rating; rather, the 2023 Star Rating is compared to what the 2022 Star Rating would have been absent any disaster adjustments. The rule for treatment of multiple year-affected contracts then does not carry very old data forward into the Star Ratings for many years. Under this final rule, we will use the measure score associated with the year with the higher measure Star Rating regardless of whether the score is higher or lower that year. We are finalizing this policy to address when contracts are affected by separate extreme and uncontrollable circumstances that occur in successive years for the adjustments to CAHPS, HOS, HEDIS, and other measures. This rule would apply for CAHPS, HOS, HEDIS, new, and other measures. Therefore, we are adopting new provisions at §§ 422.166(i)(2)(v), 422.166(i)(3)(v), 422.166(i)(4)(vi), 422.166(i)(6)(iv), 423.186(i)(2)(v), and 423.186(i)(4)(iv) to include this rule for how ratings for these measures will be adjusted in these circumstances.

The issue about whether and how to take into account extreme and uncontrollable circumstances that occur in successive years also raises the question of how to address a specific extreme and uncontrollable circumstance that spans two years. For example, we note that while Hurricane Maria happened in 2017 and the associated declarations of emergency under section 1135 of the Act initially happened in 2017, those declarations extended for some areas into 2018. We did not propose a specific policy for addressing such situations. We are finalizing new text at the end of the introductory language of paragraph (i) of both §§ 422.166 and 423.186 to clarify that the incident start date will be used to determine which year of Star Ratings could be affected. We believe this clarification is necessary because, in some cases, the incident period end date may change, which would make it difficult operationally to determine which Star Ratings year is impacted. For example, the major disaster declaration (DR–4353) for the California wildfires was declared January 2, 2018. The incident period was originally only in December 2017, but it was subsequently extended by FEMA through January 2018. Limiting adjustments for a single extreme and uncontrollable circumstance to one year is appropriate to avoid adversely impacting operational timelines, to limit impacts on contracts not impacted by disasters, and to preserve transparency of the Star Ratings for consumers by not using data from many different measurement years. Further, as we finalized several years ago, at §§ 422.504(o) and 423.505(p), MA organizations and Part D sponsors must develop, maintain, and implement

a business continuity plan containing policies and procedures to ensure the restoration of business operations following disruptions to business operations which would include natural or man-made disasters, system failures, emergencies, and other similar circumstances and the threat of such occurrences. We expect that these business continuity plans will address many of the issues that would result in an impact on the performance of an affected contract where there are extreme and uncontrollable circumstances that occur in successive years or over more than one performance period.

We note that the proposed rule establishing the exemption for administering CAHPS (§§ 422.166(i)(2)(ii) and 423.186(i)(2)(ii)), administering HOS (§ 422.166(i)(3)(ii)), and reporting HEDIS (§ 422.166(i)(4)(ii)) did not specify which type of affected contract could apply for the exemption. This lack of clarity also affected the proposed rules in §§ 422.166(i)(2)(iii), 422.166(i)(3)(iii), 422.166(i)(4)(iii), and 423.186(i)(2)(iii) that address how a contract with the exemption would receive the prior year's CAHPS, HOS, or HEDIS measure Star Rating (and corresponding measure scores). We clarify here that we intended these specific rules to apply to affected contracts with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance. In finalizing this policy, we are using the lowest threshold identified in the definition of affected contract in paragraph (i)(1)(iii). As a result, the most generous interpretation of the potential ambiguity of our proposal is being finalized.

Finally, comments about disasters that began in 2017 are out of scope of this rule as our proposal and final regulations apply to adjustments to Star Ratings to take into account extreme and uncontrollable circumstances that begin on or after January 1, 2020.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and our responses to the related comments summarized earlier, we are finalizing the methodology for adjustments to CAHPS measures (§§ 422.166(i)(2) and 423.186(i)(2)), HOS and HEDIS measures (§§ 422.166(i)(3) and (i)(4)), new measures (§§ 422.166(i)(5) and 423.186(i)(3)), and other Star Ratings measures (§§ 422.166(i)(6) and 423.186(i)(4)) with substantive and non-substantive revisions. The final regulation text includes the following substantive changes on measure adjustments:

- In §§ 422.166(i)(2)(ii) and 423.186(i)(2)(ii) for CAHPS measures, 422.166(i)(3)(ii) for HOS measures, and 422.166(i)(4)(ii) for HEDIS measures, we are finalizing additional text to clarify the section applies to affected contracts with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance.
- In § 422.166(i)(4)(iv), the final regulation text clarifies that all contracts required to report HEDIS data can work with NCQA to request modifications to the samples for measures that require medical record review. While we did not receive comments on this, CMS realized that the preamble and proposed regulation inadvertently limited which contracts are eligible to request modifications to samples from NCQA. We are finalizing corrected regulation text to eliminate this inadvertent limitation.
- In §§ 422.166(i)(2)(v) and 423.186(i)(2)(v) for CAHPS measures, 422.166(i)(3)(v) for HOS measures, 422.166(i)(4)(vi) for HEDIS measures, and 422.166(i)(6)(iv) and 423.186(4)(iv) for other Star Ratings measures, we are finalizing regulation text to identify multiple year-affected contracts as contracts that have at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance with regard to separate extreme and uncontrollable circumstances that begin in successive years. We are finalizing regulation text that a multiple year-affected contract receives the higher of the current year's Star Rating or what the previous year's Star Rating would have been in the absence of any adjustments that took into account the effects of the previous year's disaster for each measure (using the corresponding measure score for the Star Ratings year selected).
- We noted that the regulation text did not address how this policy would be applied in the event an extreme and uncontrollable circumstance occurred during two performance periods. Because in some cases the incident period end date may change, which would make it difficult operationally to determine which Star Ratings year is impacted, we are finalizing regulation text in the introductory paragraph of (i) of §§ 422.166 and 423.186 to clarify that the start date of the incident period will be used to determine which year of Star Ratings could be affected, regardless of whether the incident period lasts until another calendar year.

In addition to these substantive changes, we are finalizing non-substantive changes in paragraphs (ii)(B) and (iii) of §§ 422.166(i)(2), 422.166(i)(3), 422.166(i)(4), and 423.186(i)(2) to replace ''exception'' with ''exemption'' and refer to the exemption ''described'' elsewhere instead of ''defined'' elsewhere. We are also making technical revisions to verb tense, and in §§ 422.166(6)(i) and 423.186(4)(i) we changed ''then use the corresponding measure score'' to ''(and corresponding measure score).'' In § 422.166(i)(3)(ii)(A) we added the word ''paragraph,'' and we simplified the description of §§ 422.166(5) and 423.186(3) for clarity.

(7) Exclusion From Improvement Measures

Contracts must have data for at least half of the measures [39] used to calculate the Part C or Part D improvement measures to be eligible to receive a rating in each improvement measure. For affected contracts that revert back to the data underlying the previous year's Star Rating for a particular measure, we proposed that measure would be excluded from both the count of measures (for the determination of whether the contract has at least half of the measures needed to calculate the relevant improvement measure) and the applicable improvement measures for the current and next year's Star Ratings as stated at proposed §§ 422.166(i)(7) and 423.186(i)(5). That is, we proposed to codify the application of our usual rule in these special circumstances: To receive a Star Rating in the improvement measures, a contract must have measure scores for both years in at least half of the required measures used to calculate the Part C improvement or Part D improvement measures; our proposal to use the data from the previous year's Star Ratings means that there is no measure score from the current year's Star Ratings, so the usual rule would eliminate the measure from consideration. As an example, for affected contracts that revert back to the 2021 Star Ratings data for a particular measure for the 2022 Star Ratings, we would exclude that measure from the count of measures and applicable improvement measures for the 2022 and 2023 Star Ratings.

Below we summarize the comments we received on the exclusion from improvement measures and provide our responses and final decisions.

[39] See §§ 422.164(f) and 423.184(f) for more information on Part C and Part D improvement measures.

Comment: A commenter was concerned that CMS's policy would permit quality improvement measures to be excluded continually when there are repeated disasters, which they stated would undermine the goals of the Star Ratings program. A couple of commenters noted that CMS's proposed policy of using prior year's measure stars (and corresponding measure scores) could influence its use in the improvement calculation.

Response: We proposed in §§ 422.166(i)(7) and 423.186(i)(5) that any measure that reverts back to the data underlying the previous year's Star Rating under the rules in paragraph (i) of §§ 422.166 or 423.186 is excluded from the improvement calculation. This would apply to multiple year-affected contracts as well. Most affected contracts should still receive improvement measure scores since contracts only need data in half of the measures used to calculate improvement to receive an improvement measure score. We also clarify in the final regulations at §§ 422.166(i)(7) and 423.186(i)(5) that contracts affected by extreme and uncontrollable circumstances do not have the option of reverting to the prior year's improvement rating. This clarification is necessary because of the new multiple year-affected contract policy. The improvement rating is based on other measure data included in the Star Ratings program, so taking the higher of the two improvement ratings would nullify the calculations and the application of the disaster policy for the other measures. The improvement measure calculates how much of the plan's performance improved or declined from the previous year to the current year. Allowing affected contracts to revert to the prior year's improvement measure rating could result in different years of data being used for the improvement scores and for the measure scores, or different time periods used for improvement calculations for different contracts. This would be difficult to operationalize and confusing to consumers. Therefore, we decline to adopt such an adjustment in this final rule.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and our responses to the related comments summarized earlier, we are finalizing the rule for calculating the improvement score for affected contracts at §§ 422.166(i)(7) and 423.186(i)(5) as proposed with substantive and non-substantive revisions. We are finalizing a substantive change to clarify that contracts affected by extreme and uncontrollable circumstances do not have the option of reverting to the prior year's improvement rating. We are also making a technical revision to verb tense.

(8) Missing Data

Except in cases where an exemption was granted as described earlier, we proposed that for all measures eligible for the extreme and uncontrollable circumstance adjustment, if an affected contract has missing data in either the current or previous year (for example, because of a biased rate or the contract is too new or too small), the final measure rating would come from the current year. We proposed to codify this rule at §§ 422.166(i)(8) and 423.186(i)(6). For example, if a contract affected by an eligible 2020 extreme and uncontrollable circumstance was not granted an exemption for data collection and does not have sufficient data to receive a measure-level 2022 Star Rating, it would not receive a numeric rating for that measure for the 2022 Star Ratings regardless of whether it received a numeric rating in the previous year. Similarly, if an affected contract has missing measure data in the previous year but received a numeric rating in the current year, it would receive the current year's rating for its final measure rating. In both cases, the measure would be excluded from the contract's improvement score(s) following our usual rules.

Below we summarize the comments we received on missing data and provide our responses and final decisions.

Comment: A commenter questioned how CMS will rate contracts affected by disasters that are too new to be measured.

Response: The missing data policy proposed and codified in this final rule at §§ 422.166(i)(8) and 423.186(i)(6) applies to contracts that are too new to be measured. As proposed and finalized, the regulation does not exclude new contracts from its application. We proposed that except in cases where an exemption was granted as described earlier, for all measures eligible for the extreme and uncontrollable circumstance adjustment, if an affected contract has missing data in either the current or previous year (for example, because of a biased rate or the contract is too new or too small), the final measure rating would come from the current year.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and our responses to the related comments summarized earlier, we are finalizing the methodology for missing data as proposed at §§ 422.166(i)(8) and 423.186(i)(6) as proposed with non-substantive revisions to replace ''will come'' with ''comes'' and ''exceptions'' with ''exemptions.''

(9) Cut Points for Non-CAHPS Measures

Currently, the Star Rating for each non-CAHPS measure is determined by applying a clustering algorithm to the measures' numeric value scores from all contracts required to submit the measure. The cut points are derived from this clustering algorithm. At proposed §§ 422.166(i)(9) and 423.186(i)(7), we proposed to exclude from this clustering algorithm the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance. We explained that the exclusion would ensure that any impact of the extreme and uncontrollable circumstance on an affected contract's measure-level scores would not have an impact on the cut points for other contracts. We also explained that, under our proposal, these cut points calculated for all other non-affected contracts would be used to assess these affected contracts' measure Star Ratings. We would compare the affected contract's previous year's measure Star Ratings to the current year's measure Star Ratings to determine which is higher, and therefore used for the affected contract's Star Ratings calculations, as previously discussed. For example, for the 2022 Star Ratings we would compare the 2021 and 2022 measure Star Ratings for affected contracts.

Below we summarize the comments we received on cut points for non-CAHPS measures and provide our responses and final decisions.

Comment: Several commenters were concerned that removing affected contracts from cut point calculations may skew the clustering methodology or adversely impact plans not affected by disasters, or that contracts in disaster areas may make less of an effort to improve on measures. A commenter requested a simulation of what the Star Ratings would be using this methodology and 2019 data. A commenter encouraged ongoing evaluation of cut points to ensure they are not unduly impacted by adjustments for disaster-stricken areas year-over-year.

Response: We proposed to exclude the performance data of affected contracts that meet the 60 percent

threshold (that is, 60 percent or more of the contract's enrollees reside in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance) from the data used to set cut points for non-CAHPS measures. We proposed to limit this rule to non-CAHPS measures because CAHPS measures use relative distribution and significance testing rather than clustering to determine Star Ratings cut points. This rule, codified at §§ 422.166(i)(9) and 423.186(i)(7), ensures that any impact of the disaster on their measure-level scores does not impact the cut points for other contracts. In our analysis, when affected contracts were removed from the distribution of measure-level scores, the distribution of the remaining contracts looked very similar, suggesting that the affected contracts are randomly distributed among the rating levels. CMS will continue to review the impact of the extreme and uncontrollable circumstances policy on the Star Ratings of affected and unaffected contracts to determine whether any enhancements need to be proposed to these regulations in the future. Finally, the extreme and uncontrollable circumstances policy applied in the 2019 Star Ratings was very similar so existing contracts have access to data on how their contracts were affected.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and our responses to the related comments summarized earlier, we are finalizing the methodology for cut points for non-CAHPS measures as proposed at §§ 422.166(i)(9) and 423.186(i)(7) with technical revisions to the verb tense.

(10) Reward Factor

Similarly, at §§ 422.166(i)(10) and 423.186(i)(8), we proposed that affected contracts with 60 percent or more of their enrollees impacted would also be excluded from the determination of the performance summary and variance thresholds for the Reward Factor. However, these contracts would still be eligible for the Reward Factor based on the mean and variance calculations of other contracts.

Below we summarize the comments we received on the Reward Factor and provide our responses and final decisions.

Comment: A commenter supported the 60 percent cutoff for Reward Factor calculations but was concerned that the number of contracts excluded from Reward Factor calculations could become significant if disasters become more frequent.

Response: CMS appreciates the concern about frequency of extreme and uncontrollable circumstances and will continue to monitor application of the policy to determine if enhancements are needed.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and our responses to the related comments summarized earlier, we are finalizing the methodology for the Reward Factor as proposed at §§ 422.166(i)(10) and 423.186(i)(8) with technical revisions to the verb tense.

2. Improving Clarity of the Exceptions Timeframes for Part D Drugs (§§ 423.568, 423.570, and 423.572)

In the proposed rule we proposed a change to Part D adjudication timeframes related to exceptions requests in cases where a prescribing physician's or other prescriber's supporting statement has not been received by the plan sponsor. We proposed to limit the amount of time an exceptions request can be held open in a pending status while the Part D plan sponsor attempts to obtain the prescribing physician's or other prescriber's supporting statement. Due to the importance of the prescriber's supporting statement in the exceptions process, the adjudication timeframes for a coverage determination that involves an exceptions request do not begin until the prescribing physician's or other prescriber's supporting statement is received by the Part D plan. As we noted in the preamble to the proposed rule, we are seeking to balance the importance of the plan receiving the prescriber's supporting statement so that a thorough decision may be made on the request and having a standard maximum time for notifying an enrollee of an exceptions request decision. We believe greater certainty in the exceptions process will be beneficial to enrollees and plans.

We proposed to amend §§ 423.568(b), 423.570(d)(1) and 423.572(a) to state that, for an exceptions request, the plan must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its decision no later than 72 hours (or 24 hours in the case of an expedited decision) after receipt of the prescriber's supporting statement or 14 calendar days after receipt of the request, whichever occurs first. We invited comments on this proposal and received the following comments discussed below.

Comment: Several commenters expressed support for the proposed changes to the Part D exceptions timeframes, citing increased clarity in the exceptions process, and questioned that CMS finalize the rule as proposed.

Response: We thank the commenters for their support of our proposal to add clarity to the exceptions process. We believe the timeframes we are finalizing in this rule establish clear timeframes for exceptions requests and strike a balance between timely notification of decisions to enrollees and affording plan sponsors sufficient time to obtain and review prescriber supporting statements. As explained more fully below, we are modifying the proposal based on comments we received requesting that the process clearly account for circumstances where a prescriber's supporting statement is received late in the 14 calendar day timeframe. Under this final rule, if a supporting statement is received by the end of 14 calendar days from receipt of the exceptions request, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours (24 hours for an expedited request) from the date the supporting statement was received. If a supporting statement is not received by the end of 14 calendar days from receipt of the exceptions request, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours (24 hours for an expedited request) from the end of 14 calendar days from receipt of the exceptions request. In addition to achieving the goal of greater certainty in the exceptions process, we believe this modified approach balances protection for beneficiaries with affording plan sponsors sufficient time to obtain and review prescriber supporting statements.

Comment: Several commenters supported the enhanced clarity of the proposed rule in establishing a maximum timeframe of 14 days for a plan sponsor to notify an enrollee of a decision on an exceptions request, but also believe there is some ambiguity on how to handle cases where a prescriber's supporting statement is received late in the 14 day period and questioned whether the plan sponsor would have 72 hours (24 hours for expedited) from the end of the 14 days period in which to notify an enrollee of a decision.

Response: We thank commenters for their support for more certainty in the process and for requesting additional

clarity on how to handle situations where a prescriber's supporting statement is received late in the proposed 14 calendar day period. We agree that if a prescriber's supporting statement is received late in this 14 calendar day period, the plan sponsor should have adequate time to review the clinical documentation to determine whether it is appropriate to approve the exceptions request. After consideration of these comments, we are establishing the 14 calendar day time period as the outer limit for receipt of a prescriber's supporting statement. In all cases, the plan sponsor must notify the enrollee (and prescriber, as appropriate) of its decision no later than 72 hours (24 hours for expedited cases) of the date of receipt of the supporting statement. If the supporting statement is not received by the end of the 14 calendar days, then the plan sponsor must notify the enrollee (and prescriber, as appropriate) of its decision no later than 72 hours (24 for expedited cases) from the end of the 14 calendar days from receipt of the exception request. Plan sponsors are responsible for making reasonable and diligent efforts to promptly obtain a prescriber's supporting statement if the supporting statement is not included with the request for an exception, so as to avoid the need for an exceptions request to remain in a pending status for any longer than necessary. We are finalizing this rule to reflect the policy stated previously.

Comment: A few commenters stated that they believe the proposed rule is inconsistent with recently released draft manual guidance, which recommends a 14-day timeframe to receive a supporting statement. Commenters expressed support for this approach and suggested that the final rule clearly align with the manual guidance. Commenters also requested that CMS phase-in the effective dates of the manual guidance and final rule to allow plans time to implement new procedures. Three commenters requested a January 1, 2020 compliance effective date.

Response: We agree that plan sponsors should have up to 14 calendar days in which to attempt to obtain a prescriber's supporting statement. The prescriber's supporting statement is a key component of the exceptions process. We believe that allowing up to 14 calendar days for a plan sponsor to attempt to obtain a supporting statement appropriately balances the interests of enrollees receiving a timely decision based on a thorough clinical review of the request and of plan sponsors having adequate time to review the exceptions request. In all cases, the enrollee must be notified of the decision as expeditiously as his or her health condition requires. We emphasize that it is not our expectation that plan sponsors routinely have exceptions requests in a pending status for 14 calendar days. When an exceptions request is received, the plan sponsor is responsible for promptly requesting any documentation needed to support the request. When a prescriber's supporting statement is received, the plan must notify the enrollee of its decision within 72 hours (24 hours for expedited cases) of receipt of the supporting statement.

In response to the commenters' request that there be alignment between the approach to Part D exceptions request timeframes taken in this final rule and the combined Part C & Part D appeals manual guidance, we agree and believe the modified approach taken in this final rule aligns with the guidance; however, if additional clarity is necessary, revisions will be made to the manual guidance. We also agree with commenters who requested an effective date of January 1, 2020. The requirements of the final rule are applicable January 1, 2020, and we believe this applicability date provides plan sponsors adequate time to implement this regulatory requirement. We expect plans are already making and notifying enrollees of decisions on exceptions requests under a similar reasonable timeframe and that changes to plan sponsor operations will be minimal.

Comment: A commenter recommended CMS work with prescribers to emphasize the need to submit supporting statements as expeditiously as possible.

Response: We thank the commenter for the suggestion. We do not have a direct contractual relationship with prescribers by which we could influence timely submission of supporting statements, but we will review our provider tip sheets and other provider communications to ensure relevant CMS publications convey the importance of a prescriber's supporting statement in the Part D exceptions process. We also encourage MA–PDs to communicate the importance of timely submission of supporting statements in their provider communication materials.

Comment: We received one comment suggesting we specify that in addition to notifying enrollees of appeal rights, the MA plan be required to notify enrollees that they are also entitled to submit a new exceptions request. The commenter states it would not be appropriate for an enrollee to be denied a medically necessary and appropriate exception because an arbitrary deadline has been missed.

Response: Under existing regulations, if a plan sponsor denies the request because it does not receive timely supporting clinical documentation, the enrollee (or the prescriber on the enrollee's behalf) has the opportunity to address the exceptions request on appeal by submitting documentation that demonstrates the medical necessity of an exception. The right of an enrollee to request a coverage determination (which includes an exceptions request) is not extinguished by a plan sponsor issuing a denial; however, if an exceptions request is denied, then the appropriate next step is an appeal, and the plan can review and approve the request for a formulary or tiering exception on appeal.

Comment: A commenter requested confirmation that this requirement does not impose an obligation on the plan to do outreach and obtain the prescriber's supporting documentation within the 14-day timeframe. The commenter noted that compliance with such a requirement within that timeframe would be operationally difficult.

Response: We thank the commenter for feedback on the operational challenges of outreach for the purposes of obtaining the prescriber's supporting statement within the 14 calendar day timeframe. Under existing regulatory requirements at § 423.566(a), Part D plans must have a procedure in place for making coverage decisions. This includes soliciting necessary clinical documentation. This rule does not change plan sponsors' obligation for doing outreach for necessary clinical documentation but, instead, establishes a time limit for a plan sponsor's attempts to obtain the information. When a Part D sponsor does not have all of the information it needs to make a coverage decision, the plan must make reasonable and diligent efforts to obtain all necessary information, including medical records and other pertinent documentation, from the enrollee's prescriber within the applicable adjudication timeframe. For guidance on best practices related to outreach, please see the February 22, 2017 HPMS memorandum titled ''Updated Guidance on Outreach for Information to Support Coverage.'' The memorandum can be found under ''Downloads'' at: *https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/index.html?redirect=/MedPrescriptDrugApplGriev/.*

We believe that plans will have ample time to modify, as needed, their operations related to adjudication timeframes for exceptions in order to comply with this final rule. We expect plans are already making and notifying

enrollees of decisions on exceptions requests under a similar reasonable timeframe and that changes to plan sponsor operations will be minimal.

Comment: A commenter suggested that CMS standardize the policy for 14-day tolling followed by the 72 and 24 hour(s) adjudication timelines across all exceptions requests; including exceptions related to formulary, tiering, quantity limits, and utilization management. The commenter also suggested that CMS apply tolling to other types of coverage determinations.

Response: Based on the comment, there may be some confusion regarding what types of decisions are covered by this rule. This rule covers all types of exceptions requests, including tiering and formulary exceptions (that is, requests for off-formulary drugs and exceptions to utilization management requirements applicable to formulary drugs). We appreciate the suggestion, but this rule does not apply to other types of coverage determinations that do not involve an exceptions request; for example, a coverage determination where the enrollee is seeking to satisfy a utilization management requirement, such as prior authorization.

Comment: A commenter expressed support for our efforts to expedite the decision making process for beneficiaries, but noted concern about the potential for denials because providers missed a deadline, or because the plan lacked the time to review the documentation, causing beneficiaries to rely on the appeals process. The commenter suggested CMS require plans read and incorporate documentation as long as it comes within the deadline.

Response: We appreciate the commenter's concerns about the potential for denials due to an adjudication deadline. However, we believe it is important for there to be certainty in the timeframe in which a plan has to notify an enrollee of its decision. We acknowledge that there may be circumstances where the plan has to issue a denial because supporting documentation has not been received in a timely manner, but we believe this is offset by enhancing certainty in the process by having clear adjudication timeframes. With respect to the commenter's suggestion, § 423.566(a) requires Part D plan sponsors to have procedures for making timely coverage decisions. This includes soliciting necessary clinical documentation. If a Part D plan sponsor does not have all of the information it needs to make a coverage decision, the plan must make reasonable and diligent efforts to obtain all necessary information, including medical records and other pertinent documentation, from the enrollee's provider.

Comment: A few commenters stated they support CMS providing additional clarity, stating the previous ''reasonableness'' standard may have resulted in longer wait times. However, these commenters encourage a shorter timeframe, citing a risk of significant delays in enrollees getting access to needed medication.

Response: We thank the commenters for expressing support for the proposal to provide additional clarity. While we understand the commenters' concern about the length of the timeframe for adjudicating exceptions requests, we are attempting to balance the need to provide a timely decision with affording plan sponsors sufficient time to attempt to obtain the prescriber supporting statement and perform the clinical review necessary to determine if an exception should be granted. Plans are responsible for attempting to obtain any necessary supporting documentation and for notifying an enrollee of its decision no later than 72 hours of receipt of the prescriber's supporting statement (24 hours for an expedited request). Again, it is not our intent in establishing this timeframe that all exceptions requests be in a pending status for 14 calendar days but, instead, to establish an outer limit on the time a case can be pending for receipt of the prescriber's supporting statement. We agree with the commenters who urged us to account for circumstances where the supporting statement is not received promptly following a plan's request for such information from the prescriber and to allow sufficient time for review of the supporting clinical documentation. Accordingly, we are modifying our proposal to account for circumstances where the prescriber's supporting statement is received late in the 14 calendar day period.

Comment: A commenter suggested CMS consider replacing tolling altogether in favor of fixed processing timeframes.

Response: Under this final rule, we are retaining the current regulatory requirement of the plan sponsor notifying the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours (24 hours for an expedited request) after receipt of the physician's or other prescriber's supporting statement. As explained earlier, the prescriber's supporting statement is a critical aspect of the exceptions process. Therefore, we are retaining the existing standard of tying the start of the adjudication timeframe to receipt of the supporting statement. A plan sponsor cannot adequately assess the merits of an exceptions request in the absence of the prescriber's supporting statement. However, we are establishing a maximum timeframe under which an exceptions request can be held open pending receipt of the prescriber's supporting statement. If a supporting statement is not received by the end of 14 calendar days from receipt of the exceptions request, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours (24 hours for an expedited request) from the end of 14 calendar days from receipt of the exceptions request. We believe this approach achieves the goals of allowing adequate time to obtain the prescriber statement that supports the exceptions request and establishing greater certainty in the process by establishing a maximum period of time a request can be held open.

Based on several comments received, we are finalizing this provision with modification to account for circumstances where the prescriber's supporting statement is received late in the 14 calendar day period. Under this final rule, a Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination on an exceptions request as expeditiously as the enrollee's health condition requires, but no later than 72 hours (24 hours for an expedited request) after receipt of the physician's or other prescriber's supporting statement. If a supporting statement is not received by the end of 14 calendar days from receipt of the exceptions request, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours (24 hours for an expedited request) from the end of 14 calendar days from receipt of the exceptions request. We believe this approach achieves the goal of balancing the importance of the plan receiving the prescriber's supporting statement so that a thorough review of the request can be performed and having a maximum time for notifying an enrollee of a decision so that exceptions requests are not held in a pending status for an indefinite or unreasonable period of time.

C. Clarifying Program Integrity Policies

1. Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in MA, Cost Plans, and PACE

a. Background

In the April 2018 final rule, we removed several provider enrollment requirements pertaining to the MA and Part D programs. One requirement, outlined in § 423.120(c)(6), stated that for a prescription to be eligible for coverage under the Part D program, the prescriber must have: (1) An approved enrollment record in the Medicare fee-for-service program; or (2) a valid opt-out affidavit on file with a Part A/Part B Medicare Administrative Contractor (A/B MAC). A second requirement, outlined in § 422.222, stated that providers furnishing health care items or services to a Medicare enrollee who receives his or her Medicare benefit through an MA organization must be enrolled in Medicare and be in an approved status no later than January 1, 2019. (The removal of these requirements had been proposed in a proposed rule published in the **Federal Register** on November 28, 2017, titled ''Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program'' (82 FR 56336) (hereafter referred to as the November 2017 proposed rule).

The overall purpose of Medicare provider enrollment is to prevent fraud, waste, and abuse, and to protect Medicare beneficiaries, by allowing CMS to carefully screen all providers and suppliers (especially those that potentially pose an elevated risk to Medicare) to confirm that they are qualified to furnish, order, certify, refer, or prescribe Medicare items, services, or drugs.

During our preparations to implement the Part D and MA enrollment provisions by the January 1, 2019 effective date, several provider organizations expressed concerns about our forthcoming requirements. The principal concern was that the burden of the enrollment process on the provider community would outweigh the program integrity benefits to the MA and Part D programs.

Given this, we stated in the April 2018 final rule our belief that the best means of reducing the burden of the Part D and MA enrollment requirements without compromising our payment safeguard objectives would be to focus on prescribers and providers that pose an elevated risk to Medicare beneficiaries and the Trust Funds. We accordingly established in the April 2018 final rule an overall policy under which: (1) Such problematic parties would be placed on a ''preclusion list''; and (2) payment for Part D drugs and MA services and items prescribed or furnished by these individuals and entities would be rejected or denied, as applicable. Among the policies we finalized in the April 2018 final rule were the following:

• In § 423.100 (for Part D) and § 422.2 (for MA), we stated that the term ''preclusion list'' means a CMS-compiled list of, as applicable, prescribers and providers that:

++ Meet all of the following requirements:

++ The individual or entity is currently revoked from the Medicare program under § 424.535.

++ The individual or entity is currently under a reenrollment bar under § 424.535(c).

++ CMS determines that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program. In making this determination under this paragraph, CMS considers the following factors:

—The seriousness of the conduct underlying the individual's or entity's revocation.

—The degree to which the individual's or entity's conduct could affect the integrity of the Part D or MA program.

—Any other evidence that CMS deems relevant to its determination; or

++ Meet both of the following requirements:

++ The individual or entity has engaged in behavior for which CMS could have revoked the individual or entity to the extent applicable if they had been enrolled in Medicare.

++ CMS determines that the underlying conduct that would have led to the revocation is detrimental to the best interests of the Medicare program. In making this determination under this paragraph, CMS considers the following factors:

—The seriousness of the conduct underlying the individual's or entity's revocation.

—The degree to which the individual's or entity's conduct could affect the integrity of the Part D or MA program.

—Any other evidence that CMS deems relevant to its determination.

• We revised and added various provisions in 42 CFR part 498, subpart A that permitted individuals and entities to appeal their inclusion on the preclusion list. Specifically:

++ We added a new paragraph (20) to § 498.3(b) stating that a CMS determination to include an individual or entity on the preclusion list constitutes an initial determination.

++ In § 498.5, we added a new paragraph (n) containing the following provisions:

—In paragraph (n)(1), we stated that any individual or entity dissatisfied with an initial determination or revised initial determination that they are to be included on the preclusion list may request a reconsideration in accordance with § 498.22(a).

—In paragraph (n)(2), we stated that if CMS or the individual or entity under paragraph (n)(1) is dissatisfied with a reconsidered determination under paragraph (n)(1), or a revised reconsidered determination under § 498.30, CMS or the individual or entity is entitled to a hearing before an administrative law judge (ALJ).

—In paragraph (n)(3), we stated that if CMS or the individual or entity under paragraph (n)(2) is dissatisfied with a hearing decision as described in paragraph (n)(2), CMS or the individual or entity may request review by the Departmental Appeals Board (DAB) and the individual or entity may seek judicial review of the DAB's decision.

• In § 423.120(c)(6)(v) (for Part D) and § 422.222(a)(2) (for MA), we stated that CMS would send written notice to the individual or entity via letter of their inclusion on the preclusion list. The notice would contain the reason for this inclusion and would inform the individual or entity of their appeal rights. We further stated that the affected party could appeal their inclusion on the preclusion list in accordance with Part 498.

• We stated in § 423.120(c)(6)(iv)(A) that a Part D sponsor or its Pharmacy Benefit Manager (PBM) must not reject a pharmacy claim or request for reimbursement for a Part D drug unless the sponsor has provided the written notice to the beneficiary described in § 423.120(c)(6)(iv)(B). Under paragraph (iv)(B), the Part D sponsor or its PBM must:

++ Provide an advance written notice to any beneficiary who has received a prescription from a prescriber on the preclusion list as soon as possible but to ensure that the beneficiary receives the notice no later than 30 days after the posting of the most recent preclusion list; and

++ Ensure that reasonable efforts are made to notify the prescriber of a beneficiary who was sent a notice under paragraph (iv)(B).

• We stated in the preamble to the April 2018 final rule that individuals and entities would only be placed on the preclusion list upon exhausting their first level of appeal.

• In the preamble to the November 2017 proposed rule (82 FR 56446), we stated that if a beneficiary's access to a service, item, or drug is denied because of the application of the preclusion list to his or her prescriber or provider, the beneficiary would be permitted to appeal alleged errors in applying the preclusion list. In the preamble to the April 2018 final rule (83 FR 16660), however, we stated that if payment is denied because the prescriber or provider is on the preclusion list, the beneficiary would not have the right to appeal as denials due to preclusion are not coverage determinations accompanied by appeal rights.

• We stated in the preamble to the April 2018 final rule (83 FR 16642) that an unenrolled individual or entity would remain on the preclusion list for the same length of time as the reenrollment bar that we could have imposed on the individual or entity had they been enrolled in Medicare and then revoked.

We also stated in that preamble that the preclusion list provisions in the April 2018 final rule (83 FR 16440) were to become effective on January 1, 2019.

b. Proposed Changes

In CMS–4185–P, we proposed several changes to our existing preclusion list policies. These changes, for the most part, stemmed from further CMS consideration of, and stakeholder feedback on, some of the provisions we finalized in the April 2018 final rule and the need for modifications thereto. These proposed provisions, and brief explanations of the rationale for them, are summarized in this section of this final rule.

(1) Appeals Process for Individuals and Entities on the Preclusion List

As already mentioned, we stated in the preamble to the April 2018 final rule (83 FR 16662) that individuals and entities would only be placed on the preclusion list upon exhausting their first level of appeal. Upon further analysis, we became concerned that there could be a very lengthy delay before the individual or entity is actually placed on the list. This is because the individual or entity, under existing regulations, would be able to first appeal their Medicare revocation and, if unsuccessful, could then appeal their placement on the preclusion list (due to the revocation). This is inconsistent with the principal goal of the preclusion list, which is to prevent payment for Part D drugs or MA services or items prescribed or furnished, as applicable, by problematic parties. So as to shorten the timeframe before a provider is placed on the preclusion list, we proposed the following regulatory revisions:

• In § 423.120(c)(6)(v), we proposed to:

++ Consolidate the existing version of paragraph (v) into a revised § 423.120(c)(6)(v)(A).

++ Establish a new § 423.120(c)(6)(v)(B) stating that in situations where the prescriber's inclusion on the preclusion list is based on a contemporaneous Medicare revocation under § 424.535:

—The notice described in paragraph (c)(6)(v)(A) must also include notice of the revocation, the reason(s) for the revocation, and a description of the prescriber's appeal rights concerning the revocation.

—The appeals of the prescriber's inclusion on the preclusion list and the prescriber's revocation shall be filed jointly by the prescriber and, as applicable, considered jointly by CMS under 42 CFR part 498.

• In § 422.222(a)(2), we proposed to do the following:

++ Move the existing version of this paragraph into a new § 422.222(a)(2)(i).

++ Establish a new § 422.222(a)(2)(ii) stating that in situations where the individual's or entity's inclusion on the preclusion list is based on a contemporaneous Medicare revocation under § 424.535:

—The notice described in paragraph (a)(2)(i) must also include notice of the revocation, the reason(s) for the revocation, and a description of the individual's or entity's appeal rights concerning the revocation.

—The appeals of the individual's or entity's inclusion on the preclusion list and the individual's or entity's revocation shall be filed jointly by the individual or entity and, as applicable, considered jointly by CMS under 42 CFR part 498.

• In § 498.5(n)(1), we proposed to:

++ Move the existing version of this paragraph to a new § 498.5(n)(1)(i).

++ Establish a new § 498.5(n)(1)(ii)(A) stating that in situations where the individual's or entity's inclusion on the preclusion list is based on a Medicare revocation under § 424.535 and the individual or entity receives contemporaneous notice of both actions, the individual or entity may request a joint reconsideration of both the preclusion list inclusion and the revocation in accordance with § 498.22(a).

++ Establish a new § 498.5(n)(1)(ii)(B) stating that the individual or entity may not submit separate reconsideration requests under paragraph (ii)(A) for inclusion on the preclusion list or a revocation if the individual or entity received contemporaneous notice of both actions.

We believed that these changes would clarify our expectations and the program procedures concerning the filing of appeals when a party's placement on the preclusion list is based on a Medicare revocation. We also stressed that our proposed appeals consolidation would not affect appeals of OIG exclusions, which are handled through a separate process outlined in the applicable OIG regulations.

(2) Timing of Addition to the Preclusion List

While, again, we stated in the preamble to the April 2018 final rule (83 FR 16662) that prescribers and providers would only be placed on the preclusion list upon exhausting their first level of appeal, we did not include this language in the regulatory text. We therefore proposed to do so in CMS–4185–P. Specifically, we proposed in new § 423.120(c)(6)(v)(C)(*1*) (for Part D) and new § 422.222(a)(3)(i) (for MA) that, respectively, a prescriber or provider would only be included on the preclusion list after the expiration of either of the following:

• If the prescriber or provider does not file a reconsideration request under § 498.5(n)(1), the prescriber or provider will be added to the preclusion list upon the expiration of the 60-day period in which the prescriber or provider may request a reconsideration.

• If the prescriber or provider files a reconsideration request under § 498.5(n)(1), the prescriber or provider will be added to the preclusion list effective on the date on which CMS, if applicable, denies the prescriber's or provider's reconsideration.[40]

Notwithstanding the above, we noted that section 1862(e) of the Act (42 U.S.C. 1395y(e)) states that no federal health care program payment may be made for any items or services furnished by an excluded individual or entity, or directed or prescribed by an excluded physician. We believed that a failure to add an excluded provider or prescriber

[40] In the April 2018 final rule, we adopted cross-references in 42 CFR parts 417 and 460 to part 422 so that our MA preclusion list provisions in that rule would also apply to, respectively, cost plans (Part 417) and PACE organizations (Part 460). Consistent with said cross-references, we proposed that our MA preclusion list provisions in the proposed rule would similarly apply to cost plans and PACE organizations.

to the preclusion list until the expiration of the applicable time periods in § 423.120(c)(6)(v)(C)(*1*) (for Part D) and § 422.222(a)(3)(i) (for MA) would be inconsistent with section 1862(e) of the Act. Accordingly, we proposed in new § 423.120(c)(6)(v)(C)(*2*) (for Part D) and § 422.222(a)(3)(ii) (for MA) that an excluded prescriber or provider would be added to the preclusion list effective on the date of the exclusion.

(3) Effective Date

We generally proposed that the preclusion list regulatory revisions and additions addressed in CMS–4185–P would become applicable to MA organizations (and cost plans and PACE organizations by virtue of cross-references in parts 417 and 460 to the MA part 422 regulation) and Part D plans on January 1, 2020, which we believed would give stakeholders adequate time to prepare for our proposed changes. We did, however, propose one exception to this, in that the effective date of our previously mentioned consolidated appeals provisions in §§ 423.120(c)(6)(v), 422.222(a)(2), and § 498.5(n)(1) would be 60 days after their publication in a final rule. This was to ensure that problematic providers and prescribers were placed on the preclusion list as soon as possible. We also solicited public comments on whether some or all of our other proposed preclusion list provisions discussed in section III.C. of the proposed rule should become effective and applicable beginning 60 days after the publication date of a final rule.

We noted that the January 1, 2019 preclusion list effective date identified in the April 2018 final rule for the provisions finalized in that rule would remain in place.

(4) Claim Denials and Beneficiary Notification

We stated in the preamble to the April 2018 final rule (83 FR 16440) that, upon CMS' publication of the first preclusion list, once a prescriber or provider is added to such initial list after the completion of their first level of appeal, claims would not be impacted for up to a 90-day period thereafter (82 FR 16667). We explained that this 90-day period would include—(1) a 30-day period for the plans and MA organizations to intake the preclusion list data; and (2) a 60-day period in which the plan or MA organization would—(a) notify the beneficiary of the prescriber's or provider's preclusion; and (b) allow time for the beneficiary to transition to a new prescriber or provider. Once this 90-day period expires, claim denials and rejections would commence. Yet for all subsequent updates (that is, all updates after the release of the initial preclusion list), we would not require the expiration of a 90-day period before claims were denied.

After additional review, we became concerned that beneficiaries whose prescribers and providers were added to subsequent updates to the preclusion list would not receive any notice of those additions nor of the consequences of placement of such providers and prescribers on the preclusion list. Consequently, we proposed in CMS–4185–P that claim denials for preclusion list updates, beginning in 2020, would occur consistent with the following timeframes:

- Upon the posting of the updated preclusion list, the Part D sponsor or MA organization would be required to send notice to the beneficiary that his or her prescriber or provider has been added to preclusion list within 30 days of the posting of the updated preclusion list.
- Beginning 60 days after sending the beneficiary notice(s) described in the previous paragraph, the plan sponsor or MA organization would deny the prescriber's or provider's prescriptions or claims. This 60-day period would give beneficiaries time to locate another prescriber or provider from whom they can receive Part D prescriptions or MA services and items.

We recognized in the proposed rule that applying this 60 to 90-day period to subsequent updates (rather than exclusively to the initially published list) could result in a precluded prescriber or provider being permitted to continue treating Part D and MA beneficiaries for up to 3 months without their Part D prescriptions or MA claims being denied. However, we believed that the prevention of potentially serious dangers to the health and safety of Medicare beneficiaries that could ensue if they are without crucial medications for an extended period must take precedence.

Although we discussed the delayed claim denial period in the preamble to the April 2018 final rule, we did not incorporate this policy into the regulatory text. In addition, while § 423.120(c)(6) contained certain provisions regarding beneficiary notification about the preclusion list, there were no such concomitant provisions for MA in § 422.222. Thus, we proposed to make the following revisions and additions, as applicable, to § 423.120(c)(6) and § 422.222 in the April 2018 final rule:

- Section 422.222 would be revised as follows:

++ Existing paragraph (a)(1) would be moved to a new paragraph (a)(1)(i) that would state: ''Except as provided in paragraph (a)(1)(ii) of this section, an MA organization must not make payment for a health care item or service furnished by an individual or entity that is included on the preclusion list, defined in § 422.2.''

++ New paragraph (a)(1)(ii) would state: ''With respect to MA providers that have been added to an updated preclusion list, the MA organization must do all of the following:''

++ New paragraph (a)(1)(ii)(A) would state: ''No later than 30 days after the posting of this updated preclusion list, must provide an advance written notice to any beneficiary who has received an MA service or item from the individual or entity added to the preclusion list in this update.''

++ New paragraph (a)(1)(ii)(B) would state: ''Must ensure that reasonable efforts are made to notify the individual or entity described in paragraph (a)(1)(ii) of this section of a beneficiary who was sent a notice under paragraph (a)(1)(ii)(A) of this section; and''

++ New paragraph (a)(1)(ii)(C) would state: ''Must not deny payment for a service or item furnished by the newly added individual or entity, solely on the ground that they have been included in the updated preclusion list, in the 60-day period after the date it sent the notice described in paragraph (a)(1)(ii)(A) of this section.''

We noted that, consistent with § 422.224, the prohibition against paying precluded individuals and entities would include contracted and non-contracted parties for purposes of the provisions in § 422.222(a)(1).

Consistent with our proposed changes to § 422.222(a)(1), we proposed to delete the existing structure of § 423.120(c)(6)(iv), which we cited previously, and replace it with the following:

++ A new opening paragraph of (c)(6)(iv) would state: ''With respect to Part D prescribers that have been added to an updated preclusion list, the Part D plan sponsor must do all of the following:''

++ Revised paragraph (c)(6)(iv)(A) would state: ''Subject to all other Part D rules and plan coverage requirements, and no later than 30 days after the posting of this updated preclusion list, must provide an advance written notice to any beneficiary who has received a Part D drug prescribed by a prescriber added to the preclusion list in this update.''

++ Revised paragraph (c)(6)(iv)(B) would state: ''Must ensure that reasonable efforts are made to notify the prescriber described in paragraph (c)(6)(iv) of this section of a beneficiary who was sent a notice under paragraph (c)(6)(iv)(A) of this section; and''

++ New paragraph (c)(6)(iv)(C) would state: ''Must not reject a pharmacy claim or deny beneficiary request for reimbursement for a Part D drug prescribed by the prescriber, solely on the ground that they have been included in the updated preclusion list, in the 60-day period after the date it sent the notice described in paragraph (c)(6)(iv)(A) of this section.''

We mentioned that for providers and prescribers that are both on the preclusion list and excluded by the OIG, the aforementioned beneficiary notification process would not be intended to replace or supplant any existing OIG processes for notifying beneficiaries of excluded providers or prescribers.

(5) Beneficiary Appeals

We noted earlier that in the preamble to the April 2018 final rule, we stated that if payment is denied because the prescriber or provider is on the preclusion list, the affected beneficiary would not have the right to appeal that denial as denials due to preclusion are not coverage determinations accompanied by appeal rights. As we did not include accompanying regulatory text in the April 2018 final rule, we proposed in CMS–4185–P to add new § 423.120(c)(6)(viii) and § 422.222(a)(4) stating that payment denials based upon, respectively, a prescriber's or provider's inclusion on the preclusion list are not appealable by beneficiaries.

(6) Felony Convictions

We proposed in the November 2017 proposed rule to keep unenrolled prescribers and providers on the preclusion list for the same length of time as the reenrollment bar that we could have imposed on the prescriber or provider had they been enrolled and then revoked. While this policy was finalized in the April 2018 final rule, it was not included in the regulatory text. Given this, we proposed several regulatory revisions.

First, we proposed to revise the definitions of ''preclusion list'' in §§ 423.100 and 422.2. The current definitions contain two general categories of parties that could be included on the preclusion list—(1) prescribers and providers that are currently revoked from Medicare and are under a reenrollment bar; and (2) prescribers and providers that have engaged in behavior for which CMS could have revoked the prescriber or provider to the extent applicable had they been enrolled in Medicare. While these two categories encompass felony convictions, we stated in CMS–4185–P that the severity of felonious behavior warranted the establishment of a third category that is specific to felony convictions. We therefore proposed to remove felony convictions from the scope of the first two categories, with the new third category covering prescribers and providers—regardless of whether they are or were enrolled in Medicare—that have been convicted of a felony under federal or state law within the previous 10 years that CMS deems detrimental to the best interests of the Medicare program. Recognizing that the facts of each case are different and must be judged on their own merits, we proposed that CMS would first consider the following factors before determining whether a prescriber's or provider's inclusion on the preclusion list is warranted under our new proposed third category for felony convictions: (1) The severity of the offense; (2) when the offense occurred; and (3) any other information that CMS deems relevant to its determination. In conformity with this change, we also proposed to add an ''or'' to the regulatory text immediately after the second category in the preclusion list definitions; this would clarify that a prescriber or provider need only come within the purview of one of the three categories to be included on the preclusion list.

Second, we proposed to establish new §§ 423.120(c)(6)(vii) and 422.222(a)(5) that would codify, clarify, and expand upon the previously mentioned policy concerning the length of a prescriber's or provider's inclusion on the preclusion list:

- In §§ 423.120(c)(6)(vii)(A) and 422.222(a)(5)(i), we proposed that, except as provided in §§ 423.120(c)(6)(vii)(C) and (D) and 422.222(a)(5)(iii) and (iv), revoked prescribers and providers, respectively, would be included on the preclusion list for the same length of time as the prescriber's or provider's reenrollment bar.
- In §§ 423.120(c)(6)(vii)(B) and 422.222(a)(5)(ii), we proposed that, except as provided in §§ 423.120(c)(6)(vii)(C) and (D) and 422.222(a)(5)(iii) and (iv), unenrolled prescribers and providers, respectively, would be included on the preclusion list for the same length of time as the reenrollment bar that we could have imposed on the prescriber or provider had they been enrolled and then revoked.
- In §§ 423.120(c)(6)(vii)(C) and 422.222(a)(5)(iii), we proposed that, except as provided in §§ 423.120(c)(6)(vii)(D) and 422.222(a)(5)(iv), prescribers and providers—regardless of whether they are or were enrolled in Medicare—that are included on the preclusion list because of a felony conviction would remain on the preclusion list for a 10-year period, beginning on the date of the felony conviction, unless CMS determines that a shorter time length of time is warranted. Factors that we would consider in making such a determination would be: (1) The severity of the offense; (2) when the offense occurred; and (3) any other information that CMS deems relevant to its determination.

We mentioned in CMS–4185–P that because our proposed preclusion list period for felonious prescribers and providers would begin on the date of the conviction, such parties may actually be included on the preclusion list for less than 10 years even if CMS imposes the full 10-year period.

We also explained in CMS–4185–P that the OIG in many cases excludes providers and prescribers for a period that is longer than the period permitted for a reenrollment bar under § 424.535(c). We believed that CMS should keep an excluded provider or prescriber on the preclusion list at least until the provider or prescriber has been reinstated by the OIG in order to be consistent with section 1862(e) of the Act. We thus proposed in new § 423.120(c)(6)(vii)(D) and 422.222(a)(5)(iv) that in cases where a prescriber or provider is excluded by the OIG, the prescriber or provider remains on the preclusion list until the expiration of the CMS-imposed preclusion list period or reinstatement by the OIG, whichever occurs later.

(7) Beneficiary Liability

Consistent with our existing authority under section 1857(e)(1) of the Act, we proposed to add a new paragraph (g)(1)(iv) to § 422.504 under which the MA organization is required to agree that the enrollee must not have any financial liability for services or items furnished to the enrollee by an MA contracted individual or entity on the preclusion list, as defined in § 422.2 and as described in § 422.222. This provision would be limited to providers under contract with the MA organization, for we believed this is consistent with the general applicability and scope of § 422.504 and the ability of the MA organization to control or

impose requirements on the health care providers that furnish covered services and items to enrollees. We stated our belief that proposed paragraph (g)(1)(iv) would help financially protect beneficiaries from problematic providers. It would also formally codify this position, which we expressed in the preamble to the April 2018 final rule but did not address in the regulatory text.

(8) Technical Correction Concerning the Term ''Individual'' in § 423.120(c)(6)

We also proposed to make technical changes to § 423.120(c)(6)(i), (ii), (iii), and (vi). These paragraphs stated as follows, respectively:

- Except as provided in paragraph (c)(6)(iv) of this section, a Part D sponsor must reject, or must require its PBM to reject, a pharmacy claim for a Part D drug if the individual who prescribed the drug is included on the preclusion list, defined in § 423.100.
- Except as provided in paragraph (c)(6)(iv) of this section, a Part D sponsor must deny, or must require its PBM to deny, a request for reimbursement from a Medicare beneficiary if the request pertains to a Part D drug that was prescribed by an individual who is identified by name in the request and who is included on the preclusion list, defined in § 423.100.
- A Part D plan sponsor may not submit a prescription drug event (PDE) record to CMS unless it includes on the PDE record the active and valid individual NPI of the prescriber of the drug, and the prescriber is not included on the preclusion list, defined in § 423.100, for the date of service.
- CMS has the discretion not to include a particular individual on (or if warranted, remove the individual from) the preclusion list should it determine that exceptional circumstances exist regarding beneficiary access to prescriptions.

Because some states permit pharmacies to prescribe medications under very specific circumstances, we believed that the use of the term ''individual'' in paragraphs (i), (ii), (iii), and (vi) was too restrictive. We therefore proposed in paragraphs (i), (ii), and (vi) to change this term to ''prescriber'' so as to clarify that the prescriber need not be an individual when these specific circumstances are met. In a similar vein, we proposed:

- In § 423.120(c)(6)(iii) to change the phrase ''individual NPI of the prescriber'' to ''NPI of the prescriber'', and
- In paragraph (2)(i) of the definition of ''Preclusion list'' in § 423.100 (and as reflected in our previously discussed proposal to revise this paragraph (see section (C)(1)(b)(6) above)) to change the phrase ''he or she'' to ''prescriber.''

c. Comments Received

We received comments concerning our proposed changes from approximately 25 commenters. The comments are summarized below, followed respectively by our responses thereto. They are organized into general categories, though we note that some comments and responses involve multiple policy areas.

(1) Claim Denials

Comment: With respect to claim denials, a commenter questioned: (1) Whether plans should deny all claim types (regardless of origin) when the claim date of service is equal to or greater than the ''claim reject date'' (for example, point of service claims; batch claims; paper claims); and (2) whether the ''claim reject date'' is the date that CMS will use to edit the PDE. In a similar vein, another comment questioned whether: (1) Part D plan sponsors should utilize the ''claim reject date'' (rather than the ''effective date'' field) as the relevant field for the date when claim rejections begin; and (2) the ''claim reject date'' is the relevant date for when CMS validates the PDE.

Response: We will be addressing operational issues in guidance as necessary and appropriate. We note, though, that PDE editing will use the ''claim reject date.'' (See HPMS memorandum, ''February 2019 Updates to the Drug Data Processing System (''DDPS''),'' dated January 8, 2019 and released January 9, 2019.)

Comment: A commenter stated that if CMS intends for each Part D plan to separately track a 60-day period after beneficiary notices have been sent before claim denials can occur, this could create non-standardized effective dates for claim denials across the industry. The commenter cited the example of one plan sponsor sending the beneficiary notice on day 10 and another sending the notice on day 20. The commenter recommended that CMS standardize the timing of the effective claim denial date so as to ensure (1) consistency within the industry and (2) that claim rejects start on the same day for precluded prescribers.

Response: We respectfully decline to adopt the commenter's suggestion as a regulatory requirement. Given that Part D plans may have different internal procedures, different numbers of beneficiaries to contact, and different operational mechanisms, we believe it is best to afford them the maximum feasible flexibility in sending out beneficiary notices. We believe this ensures that all beneficiaries are provided equal notice and time to find a new provider or prescriber. However, we do understand the commenter's concerns, and have indicated a claims denial/reject date on the preclusion file shared with both Part C and D plans. This date indicates the close of the 90-day period and the latest point at which claims must deny or reject. We will diligently monitor the preclusion list's implementation; should we determine that more uniformity may be necessary, we will consider addressing the matter in future rulemaking as appropriate.

Comment: Once a provider or prescriber has been added to the preclusion list and claims from the precluded provider or prescriber start to be denied, a commenter questioned how CMS expects a Part C organization determination or Part D coverage determination (submitted by either a provider on the preclusion list or an enrollee whose provider or prescriber is on the preclusion list) to be reviewed.

Response: We respectfully believe that this comment may reflect a misunderstanding of how a point-of-sale rejection is treated in the Part D program. A rejection of a pharmacy claim at point-of-sale does not constitute a coverage determination. If a claim is rejected because the prescriber is on the preclusion list, the appropriate action is for the enrollee to find another prescriber to prescribe the drug. Further, as finalized in § 422.222(a)(4), a beneficiary enrolled in an MA plan (or a cost plan or PACE organization under the incorporation of the MA regulation into those programs at §§ 417.478 and 460.86) will not be able to appeal a payment denial that is based on an individual or entity's placement on the preclusion list. The appeal rights available to an enrollee under 42 CFR part 422, subpart M are tied to whether a decision by the MA plan is an organization determination; because there will be no appeal rights for these denials, we do not believe it is appropriate to characterize denials that occur solely because of the preclusion list requirements as organization determinations. We believe that this policy appropriately balances the need to provide an appeal process to ensure protection of Medicare beneficiaries and their ability to challenge denials issued by an MA plan; an MA plan will not have any discretion to pay a precluded provider where this final rule prohibits payment and an appeal by an enrollee of a denial of payment to the precluded provider could never be resolved in the enrollee's favor. Therefore, this is not an issue that can be resolved through the benefit appeals process set forth at part

422, subpart M, under the regulation we are finalizing.

(2) Provider Reinstatement

Comment: Several commenters stated that CMS should explain the process and timing that will be used when a provider is no longer on the preclusion list. A commenter sought clarification as to what a provider record looks like when the provider is reinstated on the file and how this compares to the original provider record.

Response: The preclusion list file will include a reinstatement date indicating when a provider or prescriber is no longer precluded. The reinstatement date will be published upon the provider or prescriber being reinstated. Records of a provider's or prescriber's preclusion will not be removed from the file. We will clarify additional operational details pertaining to these issues in sub-regulatory guidance.

Comment: A commenter requested confirmation as to whether reinstated providers will: (1) Be removed from the preclusion list; or (2) remain in the preclusion list database with a date indicating the end of their preclusion period.

Response: As already mentioned, records of a provider's or prescriber's preclusion will not be removed from the preclusion list file. In such instances, the reinstated provider or prescriber will remain in the preclusion list database. Upon the prescriber or provider being reinstated, the reinstatement date will be indicated.

Comment: A commenter questioned whether reinstatement dates will be provided for each preclusion effective date and, if so, how far in advance of a provider being reinstated will the date be provided in the file.

Response: CMS will not provide advance notice regarding a reinstatement. However, once the provider is reinstated, CMS will populate a reinstatement date on the file.

Comment: A commenter recommended that CMS clarify: (1) That the removal of a provider who successfully appeals his or her addition to the preclusion list would not be retroactive to the date of the provider's original preclusion; (2) that the MA plan would not be required to retroactively pay claims for such a provider; and (3) how MA plans should implement such a provider's removal from the preclusion list. These suggestions stemmed from several concerns the commenter raised. First, requiring plans to pay such claims retroactively could create confusion among members, who may be urged by their precluded providers to continue to see the precluded provider during the appeals. Second, members may be liable for cost sharing associated with the re-submitted claims. Third, plans would face uncertainty in determining how to pay such claims (for example, at what payment rate), for the provider contract will likely have been terminated.

Response: We respectfully disagree with the commenter's apparent request that CMS not reinstate a provider or prescriber back to the original preclusion date. Providers or prescribers who are successful upon appeal will be reinstated back to the preclusion effective date. Once reinstated, the provider would have the option of resubmitting claims that had been denied during the preclusion period, which would be eligible for payment by an MA plan under this final rule, using the plan's rules for claims processing; we are not finalizing a requirement that an MA plan must waive any claims filing deadlines that may have elapsed in the time between the date of service and the decision to reinstate the provider. If a provider is reinstated retroactively, plans should pay claims that were rejected or denied due to the preclusion using, again, the MA plan's usual claims processing procedures; it is, however, the provider's responsibility to resubmit any rejected or denied claims. If a beneficiary paid out of pocket for a Part D drug that was rejected based on the prescriber's preclusion, the beneficiary would have to submit a request for reimbursement. We will clarify the process for reinstated providers and prescribers to resubmit claims in sub-regulatory guidance.

Comment: A commenter sought clarification as to how a beneficiary would know to resubmit a previously rejected claim for reimbursement if a precluded provider is reinstated retroactively.

Response: We intend to address this issue in sub-regulatory guidance. While this final rule does not require the Part D or MA plan to issue additional notices to enrollees about individuals or entities that have been reinstated after a successful appeal of placement on the preclusion list, we encourage plans to do so, especially in cases where placement on the preclusion list was in error.

(3) ''Reasonable Efforts''/Notification

Comment: Several commenters requested clarification as to what the term ''reasonable efforts'' means in the context of furnishing the notification to the prescriber as described in § 423.120(c)(6)(iv)(B). A commenter added that various parts of CMS' sub-regulatory guidance indicate that the ''reasonable efforts'' notification is required but elsewhere state that it is optional; the commenter recommended that CMS explain the circumstances under which it is, or may be, required.

Response: The term ''reasonable efforts'' in both § 423.120(c)(6)(iv)(B) and § 422.222(a)(1)(ii)(B) involves the plan using available contact information it has for a prescriber or provider to copy them on the notice mailed to the beneficiary. We expect that MA organizations would always have contact information for their MA-contracted providers. We acknowledge, however, that they may not have this data for non-contracted providers (unless the non-contracted provider submits a claim) and that Part D plan sponsors may not have this information concerning prescribers of drugs. Given this dilemma, and to ensure that a proper balance is attained between the importance of notification and the fact that contact data may be unavailable in certain circumstances, we are changing the timing and scope of this notification requirement. We are finalizing § 422.222(a)(1)(ii)(B) and § 423.120(c)(6)(iv)(B) with the following modifications:

++ The existing versions of these paragraphs will be incorporated into, respectively, new paragraphs §§ 422.222(a)(1)(ii)(B)(*1)* and 423.120(c)(6)(iv)(B)(*1*). The beginning of these respective new paragraphs, moreover, will state, ''Subject to paragraph (a)(1)(ii)(B)(*2*) of this section'' and ''Subject to paragraph (c)(6)(iv)(B)(*2*) of this section''.

++ In new paragraphs §§ 422.222(a)(1)(ii)(B)(*2*) and 423.120(c)(6)(iv)(B)(*2*), we will state that paragraph (B)(*1*) only applies upon receipt of a claim from, respectively, a precluded MA provider (contracted or non-contracted) or upon a prescriber writing a Part D prescription when: (i) Sufficient contact information is available; and (ii) the claim is received after the claim denial or reject date in the preclusion file.

Paragraph (B)(*2*), in effect, means that the ''reasonable efforts'' requirement in paragraph (B)(*1*) will apply only if both of the following conditions are met: (1) The MA organization or plan sponsor has enough information on file to either copy the provider or prescriber on the notification previously sent to the beneficiary or send a new notice informing the provider or prescriber that they may not see plan beneficiaries due to their preclusion status; and (2) the claim is received after the claim denial or reject date in the preclusion file. We believe this second criterion is

necessary to help clarify the timing of the notification requirement; it will also help to mitigate instances where a beneficiary mistakenly receives care from a precluded prescriber.

Comment: A number of commenters opposed the requirement under § 422.222(a)(1)(ii)(B) or § 423.120(c)(6)(iv)(B) that MA organizations and Part D sponsors ensure that ''reasonable efforts'' are made regarding provider and prescriber notification. Some stated that this activity should not be the responsibility of MA plans or Part D plan sponsors; this is because CMS already adequately notifies providers and prescribers of their placement on the preclusion list and remains, in the commenters' view, in the best position to continue doing so. The commenters believed that imposing the requirements of § 422.222(a)(1)(ii)(B) or § 423.120(c)(6)(iv)(B) on MA plans and Part D sponsors would thus: (1) Be both duplicative and a further administrative burden on MA plans and Part D sponsors, involving thousands of additional letters and unnecessary costs; (2) be inconsistent with the Patients over Paperwork initiative; and (3) lead to provider frustration and confusion because the provider would be receiving multiple notices regarding the same matter. A commenter added that precluded providers and prescribers are able to identify their impacted patients and need not receive this information from MA plans and Part D sponsors; the latter should not bear additional cost and burden in order to assist problematic providers and prescribers with managing impacted patients within their practices. Another commenter stated that with respect to MA non-contracted providers, it is possible that the services they provided were on an emergency/urgent basis, rather than for ongoing, routine care; there is, consequently, little value in MA plans furnishing additional notification under § 422.222(a)(1)(ii)(B) given the limited impact on a ''go-forward'' basis. An additional commenter stated that these notification requirements have not been imposed with respect to OIG-excluded providers.

Response: We appreciate the concerns these commenters expressed regarding the aforementioned requirement. Considering, however, the plans' role in the daily operational and logistical facilitation of the Medicare Part C and D programs and their close administrative relationship with prescribers and providers, we believe that the plans are best-positioned to communicate with prescribers and providers regarding their relationships with specific beneficiaries. We mention also that we have attempted to reduce to burden of this requirement with our aforementioned revisions to § 422.222(a)(1)(ii)(B) or § 423.120(c)(6)(iv)(B).

With respect to the final comment, we note that the OIG exclusion list and the administrative requirements pertaining thereto are separate from and non-binding on those regarding the preclusion list. Merely because the OIG regulations lack a requirement concomitant with § 422.222(a)(1)(ii)(B) or § 423.120(c)(6)(iv)(B) does not mandate that CMS eliminate these two provisions.

(4) Notification to Provider of Preclusion

Comment: A commenter recommended that CMS notify the prescriber of their inclusion on the preclusion list because having individual plan sponsors perform simultaneous outreach to providers would be inefficient and confusing.

Response: We believe that the commenter is referring to the CMS requirement that was finalized in the April 2018 final rule and codified in § 423.120(c)(6)(v). Assuming this is so, we agree with the commenter and stress that we did not propose to change this requirement in the November 1, 2018 proposed rule.

Comment: A commenter urged that the written notice to the individual or entity via letter of their inclusion on the preclusion list be sent via certified mail and that the letter be standardized across the MA and Part D programs. This, the commenter explained, would prevent instances where an individual or entity is not properly notified, the letter is lost in transit, or the letter goes to an incorrect office or staff member; it will also help ensure a proper chain of custody. The commenter also stated that standard language and uniformity in the letter's format will assist individuals and entities in distinguishing the notice and its purposes from other communications.

Response: We appreciate this comment and wish to clarify that CMS is indeed mailing these notices via certified mail. Additionally, the same letter template, including similar format and language, is used for notification to both Part C and D providers and prescribers.

(5) Relation to OIG Exclusion List

Comment: Several commenters urged CMS to treat the OIG exclusion list and the preclusion list consistently to avoid provider, beneficiary, and plan confusion. A commenter requested clarification regarding CMS' rationale for treating precluded providers differently than those on the OIG exclusion list, particularly with respect to the timing for the denial of claims. The commenter noted that, in contrast to the OIG exclusion process, claims denials will be delayed for the initial preclusion list and subsequent lists.

Response: We appreciate these comments. As explained in sub-regulatory guidance we have issued (*https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/PreclusionList.html*), we have attempted to conform the preclusion list policies to those concerning the OIG exclusion list as much as possible. We emphasize, however, that complete uniformity and/or full integration of the two lists is impracticable at this time for several reasons. First, the OIG exclusion list is governed by statute, consistent with the provisions of section 1128 of the Act. The OIG exclusion list (and the policies and procedures associated therewith) is operated under an entirely different set of laws and regulations. Second, the requirements for inclusion on the preclusion list and for inclusion on the OIG exclusion list are very different. For instance, revocation of Medicare enrollment (which can be based on any of the reasons identified in § 424.535(a)) and a non-health care related felony can serve as bases for adding a provider to the preclusion list, whereas these grounds are not, in and of themselves, bases for inclusion on the OIG exclusion list. The revocation reasons in § 424.535(a), moreover, are quite distinct from the reasons for imposing an OIG exclusion under section 1128 of the Act. The Medicare enrollment/revocation and OIG exclusion processes, in short, are operated by different agencies under different rules with different requirements, which prevents these lists from being uniform.

We also believe that the preclusion list will apply to a much larger provider population than that included on the OIG exclusion list. We remind commenters that the intent of the preclusion list was to create an effective alternative to enrollment. We thus concluded that it was necessary to establish criteria for a provider to be precluded that were broader than those for exclusion, such as being revoked from Medicare; otherwise, it was possible that certain problematic providers and prescribers could continue to furnish MA services and items or prescribe Part D drugs. By the same token, we have certain safeguards for the preclusion list, such as the claim denial timing, to prevent access to care

issues. We believe this properly balances the need for strong program integrity measures (as evidenced by our above-referenced, broader preclusion list criteria) and the importance of ensuring that beneficiaries receive needed health care.

Notwithstanding the above, we emphasize that the OIG list should take precedence over the preclusion list; consequently, no OIG-excluded provider shall receive payment or the 60-day period addressed in this rule. Once a provider is no longer excluded and a plan must review the preclusion list, there will be instances (based on Medicare reenrollment bars) where a provider is precluded after their reinstatement from an exclusion.

Comment: A commenter stated that administering the preclusion list differently than the OIG exclusion list increases administrative burden for plans while adding little value. The commenter instead supported terminating providers and denying claims in a timeframe consistent with the OIG exclusion process, rather than waiting for at least 60 days after release of the preclusion list, as CMS proposed. The commenter stated that there should not be a 60-day period before claim denials, for a provider would know that they are precluded and should thus not be seeing Medicare beneficiaries or prescribing drugs. The commenter added that having separate notices to the beneficiary and different claims denial timeframes could lead to beneficiary confusion. Accordingly, the commenter recommended that CMS: (1) Use one list that combines exclusions and preclusions; or (2) revise the preclusion list requirements to apply in the same manner as the OIG list, allowing plans to deny claims upon release of the preclusion list.

Response: As already explained, the differing requirements for inclusion on each list, the different legal and statutory requirements, and the different operational aspects involved do not permit us to establish any greater uniformity than that already described in the above-mentioned sub-regulatory guidance. With respect to claim denials, we recognize the validity of the commenter's concern. Considering, however, that (1) the preclusion list is a new concept, (2) plans need time to accustom themselves to the preclusion list process, and (3) some beneficiaries will need time to find new prescribers or providers, we are not in a position at this stage to require immediate claim denials upon release of the preclusion list. In time, should stakeholders (including the plan and beneficiary communities) become fully acclimated to the preclusion list process such that a period as long as 90 days is not realistically needed, CMS may revisit this issue in future rulemaking.

Regarding the commenter's concerns about plan and beneficiary burden and confusion, we will continue our educational and outreach efforts to stakeholders so as to minimize these effects.

Comment: A commenter recommended that CMS only include non-OIG excluded prescribers on the preclusion list in order to keep the preclusion and OIG exclusion lists separate. The commenter was concerned that with both programs releasing a monthly file at different times during the month, the potential exists for timing problems and confusion.

Response: We appreciate this suggestion. However, because (1) an OIG exclusion constitutes grounds for revocation under § 424.535(a) and (2) the revocation policies in § 424.535 (for example, application of a reenrollment bar) would apply in such cases, we believe it is important to include all revocation grounds and policies within the scope of the preclusion list. We will continue to work with stakeholders to minimize confusion regarding the interaction between the two lists. We are confident that, with time, affected parties will become acclimated to the different processes.

Comment: A commenter contended that including preclusion list standards on top of the existing OIG exclusion statutory requirements is unnecessary, creates numerous inconsistencies, and imposes operational complexities. For example, the commenter stated, once a provider is added to the OIG exclusion list, there is no grace period during which plans can continue to make payment. The proposed rule, however, contains such a period for the preclusion list under §§ 422.222(a)(1) and 423.120(c)(6)(iv). The commenter stated that: (1) Simultaneous compliance with both of these standards is impossible; and (2) CMS cannot create a rule that directly conflicts with the OIG exclusion provisions in the Social Security Act. The commenter added that while CMS could create exceptions to the preclusion list requirements for excluded providers or revise the preclusion list requirements to be consistent with those applicable to excluded providers, it would be administratively cleaner to simply extract excluded providers from the preclusion list.

Response: For reasons already stated, we are not in a position to separate the two lists or to make the preclusion list processes entirely consistent with those of the OIG exclusion list. We are also unable to remove OIG excluded prescribers and providers from the preclusion list, for CMS takes revocation action that is separate and apart from whatever exclusion action the OIG might take. A revocation action warrants the addition of the prescriber or provider to the preclusion list and is accompanied by a reenrollment bar, which determines the length of the preclusion. The reenrollment bar length may exceed the period for which the prescriber or provider is OIG excluded, which further prohibits the affected prescriber or provider from furnishing items and services to Medicare beneficiaries.

Notwithstanding the above, however, we have already clarified via sub-regulatory guidance that the OIG exclusion list takes precedence over the preclusion list. Thus, if a plan locates a provider on the OIG exclusion list, it need not consult the preclusion list with respect to that provider. The plan would simply follow its processes for OIG excluded providers as described at 42 CFR 422.204(b)(4), 422.224(a), and 422.752(a)(8). We mention further that providers and prescribers who are precluded due to an exclusion are not afforded the 60-day grace period, for the plan would reject the claim or deny the provider's requests for reimbursement based on the exclusion prior to determining if the provider or prescriber is precluded.

To codify the above policy in regulation, we will clarify the opening paragraphs of §§ 423.120(c)(6)(iv) and 422.222(a)(1)(ii) to state that §§ 423.120(c)(6)(iv) and 422.222(a)(1)(ii) do not apply if the prescriber or provider is currently excluded by the OIG. This means, in effect, that if a provider or prescriber is on both the OIG exclusion list and the preclusion list, the MA organization or Part D plan sponsor need not (with respect to that prescriber or provider) carry out the requirements of §§ 423.120(c)(6)(iv) and 422.222(a)(1)(ii) (for example, provide advance written notice to the beneficiary; delay payment denials). We believe this will help reduce duplicative administrative functions (such as letters to beneficiaries) and ensure compliance with the statutory payment prohibitions concerning OIG exclusions (that is, no grace period).

Comment: A commenter recommended that CMS limit the preclusion list to providers who are not on the OIG exclusion list so as to avoid conflicts between the exclusion and preclusion requirements. If CMS declines this suggestion, the commenter stated that giving plans up to 90 days to

begin denying payment would allow them to meet their obligation (under both OIG and CMS regulations) to deny claims for items and services provided by an excluded provider, while also allowing time—where permitted—for members to be notified and transition to a new provider. The commenter contended that this would be more consistent with MAOs' current obligations to provide members with 30 days' advance notice of a provider's contract termination; the commenter questioned why a provider placed on the preclusion list should continue to be paid for a longer period of time than a provider whose contract terminates for another reason.

Response: We previously outlined our rationale for declining to extract OIG-excluded parties from the preclusion list and the reasons for the 90-day delay in claim denials. As we indicated regarding the latter, though, we may in the future consider shortening this time period via rulemaking should circumstances warrant and operational considerations permit. We note that currently, pursuant to § 422.202(d)(4), if an MA plan terminates a contracted provider from the provider network for ''no cause'', the plan is required to furnish the provider with 60 days' advance notice; if an MA plan terminates a provider for cause, the provider is entitled to appeal rights under § 422.202(d)(1) through (3). Based on this, we believe that the timeframe of 60–90 days before an MA plan can deny payment to a precluded provider is similar to what is required when a provider is terminated by the plan under § 422.202(d)(4) without cause.

(6) Relationship to Medicaid

Comment: In cases where Medicaid is the primary payer for a drug for a dual-eligible individual, a commenter questioned whether the pharmacy must fill a prescription for a drug prescribed by a precluded prescriber. The commenter stated that CMS must address how the preclusion list applies to Medicaid-Medicare Plans (MMPs) with a three-way contract. Specifically, in an MMP the enrollee has one insurance card; he or she may thus be confused if the MMP rejects his or her Part D drugs (because the prescriber is precluded) but then pays for the Medicaid drug from the same prescriber.

Response: A Part D drug that is not covered because the prescriber is on the preclusion list—but is otherwise coverable by Part D—is not coverable under Medicaid, including under an MMP as the claim would not cross over once rejected by the Part D plan. In the rare circumstance that Medicaid is the primary payer for a prescription drug furnished to a Part D eligible individual, the preclusion list does not apply as the drug would be adjudicated through the Medicaid claims system.

Comment: A commenter requested that CMS collaborate with states if future consideration is given to the preclusion list's potential application to (and implementation by) state Medicaid agencies in unison with private sector health plan partners.

Response: We appreciate this comment and will make certain to collaborate with the states should the contingency the commenter mentions arises.

(7) Timeframe for Denying Claims

Comment: Noting the proposed commencement of claim denials 61–90 days following preclusion list publication, a commenter recommended a hard timeline of 90 days from file release to claim denial. The commenter believed that this would foster industry-wide consistency. Another commenter stated that if CMS intends to require plans to terminate precluded providers from their networks, CMS should: (1) Promulgate this requirement through rulemaking, not via sub-regulatory guidance; and (2) permit plans to terminate providers at any time prior to when plans must begin denying payments.

Response: We appreciate these comments. However, we do not wish to delay claim denials any longer than absolutely necessary, which is why we respectfully decline to mandate the expiration of a full 90-day period. Under § 422.222(a)(1), as amended in this final rule, an MA organization is prohibited from paying a provider who is on the preclusion list; this prohibition applies to claims with dates of service that fall 60 days or more after the MA organization has notified the enrollee that the provider has been placed on the preclusion list and that claims for services furnished by that provider will be denied. Section 422.222 does not itself require termination of any contract between the MA organization and the precluded provider. We anticipate, though, that many MA plans will take steps to terminate their contracts with precluded providers, at least for purposes of the MA plan, because of the prohibition on payments to precluded providers in connection with items and services provided to Medicare beneficiaries. Further, we do not believe that rulemaking is required regarding language in CMS' sub-regulatory guidance, which only suggests and does not require the removal of precluded providers from plan networks.

We believe that compliance with § 422.222(a)(1) by an MA plan will take slightly different forms depending on whether the precluded individual or entity has a contract with the MA plan to participate in its network. In managing their contracted networks, MA plans: (1) Must provide advance written notice to any beneficiary who received an item or service from an individual or entity added to the preclusion list no later than 30 days after the posting of the updated preclusion list; and (2) may pay the precluded provider for 60–90 days, depending on when the enrollee was notified. When an enrollee has received services from a non-network precluded provider, MA plans should notify the enrollee that the non-contract provider is precluded and the plan will not pay any claims from the precluded provider with a date of service after the expiration of the allowable payment period for that precluded provider.

Comment: A commenter agreed that the previously mentioned 60–90 day claim denial period will assist beneficiaries in transitioning to new providers.

Response: We appreciate the commenter's support.

Comment: Several commenters expressed support for the proposed application of the 90-day period before a claim is denied to all releases of the preclusion list (not merely the initial preclusion list).

Response: We appreciate the commenters' support.

Comment: A commenter stated that payment denials should be allowed to begin at any point up to 90 days after the provider is placed on the preclusion list. Any member notice requirement, the commenter contended, should be independent of the time frame for denying payments.

Response: Under § 422.222(a)(1)(ii)(C), the prohibition on payment to a precluded individual or entity is tied to expiration of a period of 60 days from issuance of the advance written notice to the enrollee. However, the MA plan may terminate a network provider under its contract, thereby removing the provider from its network of providers available to its enrollees in accordance with other procedures and requirements. The MA regulation at § 422.202(d) permits for-cause and without-cause terminations of provider participation agreements; § 422.111(e) specifies that an MA organization terminating a provider must make a good-faith effort to notify enrollees at least 30 calendar days before the provider termination date. If an enrollee is left without a primary care provider

and one is necessary in order to access coverage and benefits under the MA plan, § 422.112(a)(2) permits the MA organization to assign a primary care provider to the enrollee; further, § 422.122(b) imposes coordination of care responsibilities on MA organizations, which CMS generally believes means that an MA organization should offer to assist enrollees in locating a suitable provider and in ensuring that ongoing treatment is properly transitioned to a new health care provider. Section 422.222(a)(1)(ii)(A) requires that MA organizations notify enrollees within 30 days from when the MA plan receives notification from CMS that a provider has been placed on the preclusion list, which will start the 60-day period for when denials of payment based solely on the provider's inclusion on the preclusion must occur.

The enrollee notification of a terminated provider should inform the enrollee that the terminated precluded provider is no longer available to furnish plan services and offer to assist the enrollees in transitioning to a new network provider. For services received from a non-contracting precluded provider, the MA plan must also notify the enrollee that the non-network provider is precluded and include in that notification the date on which the plan will not pay any further claims from that precluded provider. This gives the enrollee time to transition to an alternative non-network provider if he or she chooses to do so.

While we believe it is clear that § 422.222 is equally applicable to network and non-network precluded providers, we wish to eliminate any confusion on this matter. As such, we are changing the title of § 422.222 from ''Preclusion list'' to ''Preclusion list for contracted and non-contracted individuals and entities.'' We believe this will help clarify the applicability of § 422.222,

Comment: A commenter urged CMS to allow plans up to 90 days to commence denying payments, meaning that plans would be permitted to: (1) Immediately stop paying claims (as required with OIG excluded providers); and (2) begin denials at any point within 90 days if there is no other legal requirement to act immediately. The commenter stated that requiring plans to pay claims for a period of time after the provider is placed on the preclusion list conflicts with other requirements that plans must follow and introduces multiple challenges. The commenter added that because the applicable statute prohibits plans from making payment for items and services furnished or prescribed by an excluded provider, CMS cannot impose a separate requirement that plans continue to pay claims for precluded providers (some of whom will also be on the exclusion list) for a particular period of time.

Response: As previously explained, we believe that beneficiaries should be afforded a sufficient opportunity to locate a new prescriber or provider should their current prescriber or provider be included on the preclusion list. We note also that nothing in the provisions we finalized in the April 2018 final rule or are finalizing in the present rule prohibit plans from immediately denying claims based on an OIG exclusion pursuant to the long-standing requirement to do so under the Social Security Act. Indeed, we refer the commenter to our previously mentioned changes to §§ 423.120(c)(6)(iv) and 422.222(a)(1)(ii), under which these provisions would not apply if the prescriber or provider is currently excluded by the OIG.

Comment: A commenter stated that the April 2018 final rule prohibits MAOs from paying claims from precluded providers and contains no requirement that the MAO notify the member or otherwise delay the denial of payment. The commenter also pointed out, however, that the previously mentioned HPMS Memo ''recommends'' that MAOs wait 90 days before denying payment. The commenter stated it will be impossible for MAOs to comply with both the immediate payment prohibition and the 90-day recommendation for claim denials.

Response: CMS acknowledges, in the previously mentioned HPMS memo, the failure to include in the regulatory text of the April 2018 final rule certain policies outlined in our responses to the comments therein. Due to the language in the April 2018 final rule preamble summarized above and our guidance in the HPMS memo, we believe that the 90-day approach is permissible for plans pending the applicability date of this final rule and our amendments to § 422.222(a). We clarify here that the HPMS memo simply requests that plans follow the 90-day approach and that this approach is being codified in the regulatory text of this final rule. We mention, however, with the finalization of this rule, that the above-referenced 60-day period and beneficiary notification will be required upon the final rule's effective date.

(8) Beneficiary Notification

Comment: A commenter sought clarification on how a plan should proceed (assuming a January 1, 2019 release of the initial preclusion list) if, on day 89 following the publication of the preclusion list, a beneficiary receives a service from a precluded provider for which no pharmacy claims history exists. The commenter questioned whether: (1) This beneficiary would receive notification from the plan about the provider's preclusion; (2) the 90-day clock will begin to run again for this beneficiary; and (3) a provider or prescriber identified on January 1, 2019 as meeting the requirements for preclusion could provide services to a Medicare beneficiary for close to 6 months following its preclusion. The commenter believed that if CMS releases the preclusion list on January 1, 2019, plans would have until February 1 to notify beneficiaries, at which time claims begin to be denied on April 1; if, however, a beneficiary sees a provider placed on the initial preclusion list on March 28, a new 90-day clock would begin to run, under which the plan would be given 30 days to contact the beneficiary (April 28) and claims would not be denied until June 28.

Response: First, we note that the commenter's example appears to be about the preclusion list regulation adopted in the April 2018 final rule that became applicable beginning January 1, 2019, and not about our proposed rule. CMS has addressed this topic via sub-regulatory guidance at the following link: *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/PreclusionList.html.* That guidance clarifies that if no claims history exists for the previous 12-month period, the plan is not required to notify beneficiaries. If no notification is made, the 60–90 day period is not required, although plans may choose to wait to deny claims until the claim denial/reject date included on the preclusion list file.

Second, under the amended regulations we are finalizing here and in regard to the commenter's specific scenario, if a beneficiary received a service from a precluded provider on the 89th day following publication of the list, the plan would pay the claim. The provider would not receive an additional 60–90 day period and after the 89th day would thus be unable to continue furnishing MA items and services or prescribing Part D drugs for Medicare beneficiaries. If the service was provided on the 90th day, the plan would (upon receiving the claim) deny or reject the claim and notify the provider or prescriber that he/she is precluded, as we have finalized at § 422.222(a)(1)(ii)(B) and § 423.120(c)(6)(iv)(B). In this specific scenario, we are assuming the provider is granted the 60–90 day period as there

may be a claims history with at least one beneficiary. To further clarify, in situations where there is no claims history concerning the specific provider and any beneficiaries, the 60–90 day period is not required.

Comment: Citing CMS' Patients over Paperwork initiative, a commenter requested clarification of the rationale for requiring the mailing of beneficiary notices instead of permitting email. The commenter cited the situation where a beneficiary indicates that electronic communication is his or her preferred method of communication.

Response: Per the December 14, 2018 HPMS memo, CMS will not allow different modes of communication regardless of the beneficiary's preference. We recognize that some beneficiaries may prefer email. However, we believe that using mail is the surest means of making certain that the beneficiary receives the notice, a critical consideration given the importance of the information furnished therein.

Comment: Several commenters urged CMS to add language to the sample beneficiary notification letter stating that appeal rights will not apply when a claim is denied due to a precluded prescriber. Failure to do so, a commenter contended, could lead to beneficiary confusion.

Response: In the sample notification letter, we refer the beneficiary to our sub-regulatory guidance (*https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/PreclusionList.html*), in which we outline the lack of beneficiary appeals in the situation the commenter describes. We believe this furnishes sufficient notification to beneficiaries on the issue of appeals.

Comment: A commenter stated that the sample notification letter informs stand-alone Part D plans to insert the 1–800–Medicare number but then leaves the ''hours of operation'' configurable. The commenter questioned: (1) Whether the hours should be the standard hours for 1–800–Medicare; (2) whether the stand-alone Part D enrollees should call only if they need assistance in finding another prescriber but should call plans at the plan number for further questions regarding the status of their prescriptions; (3) whether, based on the sample notice, there should be two numbers for stand-alone Part D plans; (4) whether the 1–800-Medicare number should only be furnished if assistance is needed in finding another provider; and (5) whether plans should list their customer care phone number if there are further questions regarding the status of their prescription with the plan's customer care hours of operations.

Response: We will address these operational issues via sub-regulatory guidance.

Comment: Regarding an enrollee who did not receive a notification letter (and given the previously mentioned 90-day period), a commenter sought clarification as to: (1) The requirements concerning PDE edits; (2) whether CMS will pay for the PDE; and (3) whether a new PDE edit will be created to reject PDEs submitted for precluded providers.

Response: We assume the commenter is referring to situations, per the regulations finalized in the April 2018 rule, where the beneficiary did not receive notification that his or her provider or prescriber is precluded. PDE editing will be based on the ''claim reject date,'' regardless of beneficiary notification receipt status as the timing for claim denials and/or rejections begins upon the notice being sent by the plan. (See HPMS memorandum, ''February 2019 Updates to the Drug Data Processing System (''DDPS''),'' dated January 8, 2019 and released January 9, 2019.)

Comment: A commenter expressed concern that beneficiaries will not have had adequate experience with the preclusion list initiative before receiving the mandated 60-day notification.

Response: We understand the commenter's concern. We will work with beneficiary groups to help educate potentially affected Medicare patients about the preclusion list process.

Comment: A commenter urged that the beneficiary notification letter should state that: (1) The beneficiary cannot request any review of CMS' preclusion determination; and (2) he or she must seek a non-precluded prescriber for future prescriptions.

Response: With respect to the first part of the comment, we do not believe it is helpful for the notification letter to state what the beneficiary cannot do under these circumstances. Instead, consistent with the second part of the comment, we believe it is more helpful for the notification letter to clearly explain the actions the beneficiary can and should take to ensure future payments and coverage of benefits; that is, to find another non-precluded provider to furnish similar items or services.

(9) Pharmacies and Part B Drugs

Comment: A commenter stated that Part B pharmacy claims are included in Part C reporting. The commenter sought guidance regarding—if a plan offers both Part D and Part B pharmacy benefits to its members—the Part B pharmacy drug claims process if the provider is on the preclusion list. Specifically, the commenter questioned whether the Part D processed claims will reject but Part B drug claims will be allowed to process. The commenter stated that beneficiaries may be confused if some of their claims involving a precluded provider are denied while others are processed. Another commenter, too, sought clarification as to whether MA or MA–PD plans should deny payment of Part B pharmacy prescriptions written by a precluded provider. This commenter cited the example of a beneficiary who presents a pharmacy with two prescriptions from a precluded prescriber—one for a Part D drug and one for a Part B drug; the commenter questioned whether the pharmacy should reject one prescription (Part D) and fill the other prescription (Part B).

Response: We believe this situation is likely to be rare, provided that plans are applying the preclusion list to all claims submitted by both contracted and non-contracted providers. However, we acknowledge that such a situation could arise and, if it did, would cause confusion for beneficiaries and pharmacies. To reduce confusion, therefore,, if the prescriber or provider is precluded, the plan will be prohibited from making payment regardless of whether the drug is a Part B or D drug. After consideration of these comments, we will modify the language in § 422.222(a)(1)(i) that reads ''health care item or service furnished'' to instead state ''health care item, service, or drug that is furnished, ordered, or prescribed''. To ensure consistency with this revision, we will make similar edits to § 422.222(a)(1)(ii)(A) and (C) and to 422.504(g)(1)(iv); specifically, we will include therein, as applicable, references to ''ordered,'' ''prescribed,'' and ''drugs.''

Comment: A commenter requested that CMS clarify whether the proposed replacement of the term ''individual'' with ''prescriber'' in § 423.120(c)(6) means that: (1) Type 2 NPIs—when submitted on the PDE—can be accepted as a valid submission on claims; and (2) any valid NPI—whether Individual or Organizational—can be used to adjudicate claims.

Response: Based on comments we received regarding this proposed change, we are concerned that such a revision will cause confusion that will outweigh the proposal's objective. Indeed, we note that the policy that Part D plans submit PDEs with Type I NPIs is a long-standing one that supports an important program integrity goal. For

these reasons, we are not finalizing this proposal.

Comment: Several commenters recommended that CMS explain the scope of the Part D preclusion list, indicate whether and how it applies to pharmacies, and make any necessary regulatory revisions. A commenter requested that the regulatory text clarify whether CMS intends to add to the preclusion list those pharmacies that do not prescribe drugs to Part D members but do fill member prescriptions. The commenter contended that the applicable preclusion list regulations require the denial of payments to precluded prescribers but do not extend to pharmacies that fill member prescriptions. The commenter also requested that CMS limit the preclusion list to those pharmacies that are prescribers until the regulations are modified. The commenter stated that the inclusion of non-prescribing pharmacies on the preclusion list risks exposing plan sponsors that deny payments to such pharmacies to legal claims in light of, the commenter contended, the lack of regulatory authority for those denials.

Response: Although pharmacies are indeed on the preclusion list, the regulations at 422.222 only apply to pharmacy claims for Part A or B drugs covered under Part C and supplemental items or services furnished by the pharmacy (that is, they will not affect the pharmacy's ability to dispense Part D drugs so long as the prescription is not from a precluded prescriber). Coverage of Part D drugs, whether by an MA–PD or stand-alone Part D plan, are addressed in 423.120. As such, we decline to add this requirement to regulatory text. We note that the application of these requirements to pharmacies in Part C and not Part D is due to the supplemental pharmacy benefits offered by some Part C plans. We also clarify that Part A and B drugs are typically not dispensed by the pharmacy under Part C but are furnished by the Part C provider.

Comment: A commenter stated that in its December 14 FAQ, CMS mentions that Part D plans are expected to remove precluded pharmacies from their network. However, the commenter contended, the FAQ did not furnish additional information (including the necessary rulemaking) for such a decision to be made; the FAQ, the commenter stated, merely references ''future rulemaking'' and does not contain legal authority for such terminations.

Response: The November 2, 2018 CMS-issued HPMS memo entitled ''Preclusion List Requirements'' (*https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/PreclusionList.html.*) suggests that Part D plan sponsors remove precluded pharmacies from their network as soon as possible. Thus, there is no formal requirement that Part D plan sponsors do so.

(10) Implementation Timeframe

Comment: A number of commenters urged CMS to delay implementation of all of the preclusion list requirements in their entirety (including those in the April 2018 final rule) until January 1, 2020. A commenter stated that the preclusion list policies place an extreme strain on plans' resources, especially given the end-of-year testing. Other commenters stated that CMS has not furnished sufficient responses to stakeholders' questions and has not provided adequate guidance. This, they contended, leaves numerous issues open to interpretation, which will result in beneficiary and plan confusion. To efficiently implement these rules, these commenters added, a delay until January 1, 2020 is essential. Another commenter stated that while CMS has issued guidance regarding the preclusion list, a significant number of outstanding matters remain; these must be resolved before the preclusion list can be implemented. An additional commenter expressed concern that the varying effective dates (and contradictory requirements) concerning preclusion list implementation will confuse beneficiaries, providers, prescribers, and plans. This commenter and others added that such confusion, combined with a hasty implementation, could also harm beneficiaries who are unable to access medications or needed services. Other commenters suggested an effective date for all preclusion list requirements that is: (1) At least 18 months after CMS publishes the necessary technical guidance and confirmed file layouts; (2) at least 18 months after the publication date of this final rule; (3) at least 1 year after the consolidation of the issues covered in multiple CMS guidance documents; or (4) sometime after CMS engages with stakeholders to address outstanding operational and logistical challenges.

Response: We appreciate these comments and understand the sentiments raised. We must, however, respectfully decline to delay the implementation of the preclusion list as the commenters suggest. It is imperative that the preclusion list process commence as soon as possible so as to protect the Medicare program and beneficiaries from fraud, waste, and abuse. We believe that a delay until January 1, 2020 or later would be inconsistent with our obligations to safeguard the Trust Funds and to ensure that payments are made correctly. Nonetheless, we will closely monitor the preclusion list's progress throughout 2019 and continue engaging regularly with all stakeholders to facilitate as smooth an implementation as possible.

Comment: While recommending a January 1, 2020 implementation date for all of the preclusion list requirements, several commenters suggested that CMS could instead exercise enforcement discretion in 2019 against Medicare plans for good-faith efforts they make to implement the preclusion list rules finalized in the April 2018 rule. A commenter added that CMS could refrain from sanctioning plans that fall short of implementing the preclusion list requirements until CY 2020. In a similar vein, a commenter stated that CMS should not enforce the preclusion list requirements (1) before January 1, 2020 and (2) until CMS has released guidance that clarifies the outstanding operational issues.

Response: As stated, we respectfully decline to establish a January 1, 2020 effective date for all of the preclusion list provisions. We continue to believe it is imperative to implement the preclusion list requirements as soon as possible in order to protect Medicare beneficiaries and the Trust Funds.

Comment: A commenter urged CMS not to implement the provisions in the proposed rule.

Response: As explained previously, we believe that the provisions outlined in the proposed rule are necessary to ensure that the preclusion list process satisfies our program integrity objectives without unnecessarily burdening stakeholders.

Comment: Several commenters supported the January 1, 2020 effective date for the provisions in the proposed rule.

Response: We appreciate the commenters' support, though we note that our consolidated appeals provisions will become effective 60 days after the publication of this rule.

Comment: A commenter supported having all of the proposed preclusion list provisions become effective and applicable beginning 60 days after their publication in a final rule.

Response: While we appreciate this comment, we would prefer to give stakeholders until January 1, 2020 to prepare for the provisions we are finalizing in the rule (excluding the consolidated appeals policy).

(11) Beneficiary Liability

Comment: A commenter expressed concern about the potential financial liability of beneficiaries for precluded out-of-network providers. While supporting the proposed requirement that an MA contract with CMS state that a MA enrollee must not have any financial liability for items or services furnished to the beneficiary by a precluded MA-contracted individual, the commenter noted that this would not extend to out-of-network providers. In addition, the commenter stated that the proposed rule does not allow a beneficiary to appeal a payment denial based upon a provider's inclusion on the preclusion list. Coupled together, the commenter stated, a beneficiary may have financial liability but no administrative recourse. Regarding beneficiary appeals and liability, another commenter recommended that CMS either: (1) Allow a beneficiary to appeal a payment denial for precluded out-of-network providers; or (2) require language in the proposed advance written notice to the beneficiary of his or her financial liability if he or she continues to receive services from the out-of-network provider.

Response: We thank the commenter for the support for our proposal to minimize enrollee liability for payments to network providers. We are finalizing this requirement in § 422.504(g)(1)(iv) with several grammatical revisions; we are adding the language ''Ensure that'' to the beginning of the paragraph to ensure that it properly and grammatically flows from the closing wording of the opening paragraph of § 422.504(g). In addition, as previously explained, we are adding references to ''ordered,'' ''prescribed,'' and ''drugs'' to this new paragraph in the regulation.

In addition to the protection described in § 422.504(g)(1)(iv), we also proposed and are finalizing that the prohibition on payment to a precluded provider under § 422.222(a) must begin only after advance written notice to enrollees that a provider from whom the enrollee has previously received services is on the preclusion list. As finalized at § 422.222(a)(1)(ii)(A), plans are required to provide at least 60 days' notice to enrollees within 30 days of the posting of an updated list. We believe this timeframe will allow enrollees sufficient time to locate a new provider and avoid seeking further services from a precluded provider and any potential financial liability that may result. We believe that this advance written notice and delay as to when an MA plan is prohibited from paying a precluded provider will ensure appropriate protection of the beneficiary.

CMS believes most plans will remove precluded providers and prescribers from their networks upon identifying them. Therefore, as required by § 422.222(a)(1)(ii)(A) and consistent with § 422.111(e), MA plans that choose to terminate a precluded provider must make a good-faith effort to furnish enrollees with at least 30 days' advance notice of the termination of a network provider. Further, upon the expiration of the 60-day period (at which point both the provider and beneficiary have been notified of the preclusion), if the provider is terminated from the plan's network but seeks payment from the Medicare beneficiary, the provider would be in violation of section 1848(g)(4)(A) of the Act. If the provider remains in the plan's network, however, the provider is bound to the contractual requirements within the provider's contract, with the plan prohibiting the provider from seeking payment from the beneficiary in cases where the plan denies requests for reimbursement due to the provider's precluded status. Because the beneficiary's liability would be dependent on what action the plan takes in regard to the provider's MA contract (for they are not required to terminate the MA contract in order to operationalize the payment prohibition), we believe it would be inaccurate to add language to the notice regarding the beneficiary's potential liability and therefore decline to do so.

In addition, with respect to services received from a non-contracting precluded provider, the MA plan must notify the enrollee that the provider is precluded and include in that notification the date on which the plan will not pay any further claims from that precluded provider.

Comment: A commenter stated that CMS should clarify the point at which MA plans should terminate providers. The commenter explained that MA plans may need or prefer to remain contracted with a provider for a short period of time for various reasons. The commenter stated that: (1) A requirement to terminate a contract while payments are still being made would unnecessarily complicate delivery of the plan benefit; and (2) plans should be able to retain contractual protections for themselves (including contractual obligations imposed on providers and agreed-upon pricing terms) while they are still making payments. Moreover, the commenter stated that allowing termination up until denial of the claims would conform to: (1) CMS' requirement to notify members that a plan is terminating a network provider; and (2) similar state laws.

Response: Our final rule at § 422.222 does not require an MA plan to terminate a provider from its network if or when the provider is placed on the preclusion list. Provider termination is a decision for the MA plan. MA plans may, however, not pay a precluded provider for services rendered to plan enrollees after the 60–90 day beneficiary notification period has expired.

Comment: A commenter expressed concern regarding the proposal that an MAO's contract with CMS provide that a member shall not have any financial liability for services or items furnished by a contracted provider on the preclusion list. The commenter explained that this provision would confront plans with inconsistent requirements—specifically, that plans must not pay providers' claims while also requiring that they hold members harmless if the provider bills the member. If the provider indeed does the latter, the commenter continued, plans might have to pay the provider (so as to hold the member harmless); this would conflict with the requirement not to pay a claim. Alternatively, plans might have to reimburse a member who has paid the provider, effectively allowing the provider to circumvent the preclusion list. The commenter recommended that, in lieu of the ''hold harmless'' provision, CMS should either: (1) Prohibit the precluded provider from billing or otherwise seeking payment from the member; or (2) make the ''hold harmless'' obligation inapplicable (i) to services and items furnished by precluded providers after their contracts have been terminated or (ii) to claims the MAO must deny under § 422.222(a)(1).

Response: Under § 422.222(a)(1)(ii)(C), the MA plan may pay precluded providers for up to 60 days after the MA plan has notified enrollees that the provider has been precluded. We anticipate that MA organizations will also use this period to assist affected enrollees in transitioning to new providers or, if a new primary care provider is necessary for the enrollee to access plan covered services, to assign a new primary care provider to each affected enrollee. The plan's ability to pay a provider for up to 60–90 days after preclusion will not violate the MAO's contract with CMS and is an important beneficiary protection. At the conclusion of the 60-day period, the provider will no longer be eligible for payment from the plan and will be prohibited from pursuing payment from the beneficiary as stipulated by the terms of the contract between CMS and

the plan per 422.504(g)(1)(iv). Therefore, the provider would hold financial liability for furnished, ordered, or prescribed services and items after the close of the 60 day period, at which point the provider and the beneficiary would have already received notification of the preclusion. To formally incorporate this policy in regulatory text, we are also finalizing a new paragraph (g)(1)(v) in § 422.504; this paragraph requires that the MA plan's provider agreements contain a provision acknowledging the preclusion list requirements, prohibiting the precluded network provider from seeking payment from the enrollee, and providing that the provider will hold financial liability for any items, services, or drugs the provider furnishes, orders, or prescribes after the prohibition on payment begins (*i.e.,* after expiration of the 60–90 day period). This will make clear that the MA organization must agree to this requirement.

If the MA organization's participation agreement with the precluded provider is terminated, we recognize that the MA organization will not have a contractual means to prohibit the precluded provider from seeking payment directly from the enrollee. We encourage MA organizations to provide sufficient information and assistance to enrollees so that they look for new providers from whom to receive covered services. We further clarify that once the 60-day period ends and the provider's network contract has been terminated (at which point both the provider and beneficiary have been notified of the preclusion), there is no legal mechanism to apply the hold harmless provision nor would CMS or the plan be able to prohibit the provider from seeking payment from the beneficiary.

Comment: A commenter concurred with the proposal that the beneficiary be held harmless for financial liability if his or her provider is included on the preclusion list. Noting that the policy only applied to contracted providers, however, the commenter stated that members who use non-contracted providers that are included on the preclusion list are vulnerable to inappropriate demands for payments sent directly to them by unscrupulous providers. The commenter added that further communication and transparency concerning all providers on the preclusion list would help minimize inappropriate billing.

Response: We concur with the commenter and will work with stakeholders, including the plans and beneficiary groups, to consider effective means of preventing the situations that the commenter describes.

Comment: While supporting the limitation on beneficiary liability, a commenter encouraged CMS to expand this protection to non-contracted entities in the following two circumstances: (1) When the provider was a contracted individual or entity prior to their preclusion but whose contract was terminated as a result of the preclusion; and (2) when the MA is a PPO and offers out-of-network coverage.

Response: As noted in the previous response, we will work with stakeholders regarding effective methods to protect beneficiaries who, through no fault of their own, receive services from a precluded provider. We continue to believe, however, that the notification of enrollees and the period available to pay precluded providers will ensure that most MA patients of a precluded provider will have sufficient time to transition to a new qualified provider who can be paid by their MA plan. In regard to the commenter's suggestion of expanding the limitation on beneficiary liability, we note that once a provider's network contract is terminated, there is no legal mechanism to apply the hold harmless provision nor would CMS or the plan be able to prohibit the provider from seeking payment from the beneficiary.

(12) Appeals

Comment: Several commenters expressed support for the proposals to: (1) Shorten the preclusion list appeal timeframe from 9 months to 5 months; and (2) place providers and prescribers on the preclusion list after their first level of appeal. In both of these cases, a commenter stated, CMS has taken common sense steps to reduce administrative burden on MAOs and Part D plans, to ensure that precluded providers and prescribers do not continue to provide care and/or prescribe medications, and to consider the best interests of beneficiaries.

Response: We appreciate the commenters' support.

Comment: A commenter stated that notwithstanding the proposal that beneficiaries may not appeal a payment denial based on their provider's or prescriber's preclusion, CMS recently issued different guidance. Specifically, the commenter stated that in a December 14 FAQ, CMS declined to inform beneficiaries of their lack of appeal rights but stated that an enrollee may seek a coverage decision from the plan if there is a question regarding coverage for an item, service, or drug. The commenter accordingly sought clarification on a number of issues: (1) Whether enrollees will be permitted to appeal the denial of a claim (due to a provider's preclusion) during CY 2019 given that beneficiary appeals were not addressed in the April 2018 final rule applicable to CY 2019; (2) if the answer to the prior issue is yes, how CMS intends to notify beneficiaries of the change in policy for CY 2020; (3) whether, based on the language in the December 14 FAQ, the determination of a provider's preclusion constitutes a coverage decision that is subject to standard appeal rights; and (4) whether a beneficiary who did not receive notice that his or her provider was excluded and accordingly continued to use that provider could appeal the denial of the claim. Another commenter also raised the first, second, and fourth issues, while questioning whether the beneficiary can at least appeal the denial of the claim (given that he or she cannot appeal the provider's preclusion status).

Response: We clarify that the cited guidance was issued based on the April 2018 final rule. Therefore, that guidance is not fully applicable to this final rule and the amendments we are making to §§ 422.222 and 423.120.

A Part D claim that is rejected at the point-of-sale does not constitute a coverage determination; thus, there are no Part D appeal rights. As with claims from prescribers on the OIG exclusion list, a claim rejected at point-of-sale because the prescriber is on the preclusion list does not return the 569 reject code. In other words, the network pharmacy does not deliver the pharmacy notice that instructs an enrollee how to request a coverage determination. As previously noted in this preamble, a claim rejection at point-of-sale due to preclusion is not a Part D coverage determination, so the enrollee would not have appeal rights. This having always been the case, nothing has changed between CY 2019 and CY 2020. As previously stated in this preamble, we are finalizing § 422.222(a)(4) to state that a beneficiary enrolled in an MA plan (or a cost plan or PACE organization under the incorporation of the MA regulation into those programs at §§ 417.478 and 460.86) will not be able to appeal a payment denial that is based on an individual or entity's placement on the preclusion list.

Finally, we note that § 422.222(a)(1)(ii)(A), as amended by this final rule, requires an MA plan to issue a notice to affected enrollees when a provider is placed on the preclusion list. The prohibition on payment will begin the earlier of 60 days after this notice or 90 days after the provider was placed in the preclusion list. An MA plan that fails to provide the notices required by this regulation will be in violation of its responsibilities such that CMS may take necessary enforcement action.

Comment: A commenter supported making the proposed appeals process effective 60 days after publication of this final rule.

Response: We appreciate the commenter's support.

Comment: A commenter urged CMS to permit limited beneficiary appeals of denials of claims based upon a provider or prescriber's preclusion. The commenter stated that if the beneficiary notice required at § 422.222(a)(1)(ii)(A) described previously was incomplete or ineffective, the beneficiary should not be responsible for payment. The commenter added that CMS should consider mechanisms to protect beneficiaries from liability in such circumstances.

Response: Under the regulation we are finalizing at § 422.222(a)(4), denials of payment based on a provider's or prescriber's preclusion cannot be resolved through the beneficiary appeals process as outlined in Subpart M of 42 CFR part 423. If payment is denied because of the prescriber's or provider's preclusion, the enrollee should find another provider in the area to furnish these services and to contact the plan if assistance is needed. (This is explained in the beneficiary notice.) Further, a request for payment by a contract provider where an enrollee is held harmless does not constitute an organization determination.

Concerning an incomplete or ineffective notice, the provider or prescriber would still have been made aware of the preclusion. Indeed, this further supports our rationale for allowing claims to be paid without penalty for 60 days following the issuance of the notice to the beneficiary.

In regard to Part C, following the 60-day period and once a provider's network contract is terminated, there is no legal mechanism to apply the hold harmless provision nor would CMS or the plan be able to prohibit the provider from seeking payment from the beneficiary if the provider is terminated from the plan's network. However, if the provider remains in the plan's network, the provider must comply with contractual requirements prohibiting the provider from seeking payment from the beneficiary in cases where the plan denies requests for reimbursement due to the provider's precluded status.

We are finalizing our proposed changes concerning appeals with one exception. We are deleting the phrase ''by CMS'' in proposed § 422.222(a)(2)(ii)(B) and § 423.120(c)(6)(v)(B)(*2*). This is to clarify that Administrative Law Judges and the Department of Appeals Board, which, as applicable, consider the appeals in question, are not part of CMS.

(13) Miscellaneous Comments

Comment: A commenter suggested that the relevant notice provisions and payment preclusions in § 422.222(a)(1) be referenced in the PACE regulation by including an explicit cross reference in § 460.86. This would, the commenter stated, ensure that PACE organizations know where in the CFR to find more detailed requirements related to the preclusion list.

Response: We appreciate this comment and may consider it for future rulemaking. At this time, we believe that the PACE regulation is sufficient. We explained in the April 2018 final rule, in our proposed rule, and in this final rule how the requirements in § 422.222 are incorporated into the requirements for the PACE program.

Comment: A commenter supported the discretion given to plans to not include a particular prescriber on the preclusion list when CMS determines that exceptional circumstances exist regarding beneficiary access to prescriptions. The commenter recommended that CMS also provide similar discretion to MA plans when CMS determines the previously referenced exceptional circumstances exist.

Response: We clarify that only CMS has the discretion not to place a provider on the preclusion list due to access to care concerns. Plans can notify CMS if they believe there will be access to care issues by removing a particular provider from their network, and CMS will notify the plan of its determination regarding the preclusion. Nonetheless, we agree with the commenters' general rationale that an exception should be made for MA regarding access to care concerns. We are therefore adding a new paragraph (a)(6) to § 422.222 that mirrors the access to care exception provided at § 423.120(c)(6)(vi); specifically, CMS will have the discretion not to include a particular individual or entity on (or, if warranted, remove the individual from) the preclusion list should it determine that exceptional circumstances exist regarding beneficiary access to MA items, services, or drugs. In making a determination as to whether such circumstances exist, CMS takes into account: (i) The degree to which beneficiary access to MA services, items, or drugs would be impaired; and (ii) any other evidence that CMS deems relevant to its determination.

Comment: Concerning the 10-year period for the preclusion list, a commenter recommended that CMS set a lower default preclusion period of 3 years and use aggravating or mitigating factors to adjust the period as applicable. The commenter was concerned that under the proposed rule, any felony conviction automatically defaults to a 10-year preclusion period. Consistent with the March 1, 2016 proposed rule published in the **Federal Register** titled ''Medicare, Medicaid, and Children's Health Insurance Programs; Program Integrity Enhancements to the Provider Enrollment Process'' (CMS–6058–P), the commenter stated that the 10-year period should be maximum, not mandatory, unless the party in question is excluded by the OIG for a longer period. The commenter stated that the 10-year default period is greater than the OIG mandatory exclusion of 5 years and the general default of 3 years of permissive exclusions. Moreover, the commenter stated, OIG mandatory exclusions only cover specific conduct and not all felonies. The commenter added that CMS should provide parameters regarding what types of felonies fall under this section; the commenter stated that this would be consistent with felony determinations under § 424.535(a)(3).

Response: We note that our proposed provisions do not automatically require a 10-year preclusion list period for every felony conviction. Under proposed § 423.120(c)(6)(vii), for instance, a 10-year period will be used unless CMS determines that a shorter timeframe is warranted based upon CMS' consideration of several factors. In each case, CMS will examine whether a period of less than 10 years is justified. Insofar as the types of felonies that may come within the purview of these provisions, we will consider further clarification via sub-regulatory guidance.

Comment: Several commenters stated that, according to their understanding, CMS would undertake a three-step process for implementing the preclusion list: (1) Beginning on January 1, 2019, the preclusion list will go into effect without the proposals outlined in the proposed rule; (2) 60 days following

publication of CMS–4185–F, Medicare plans will be required to implement the new consolidated appeals provisions; and (3) any other changes in the proposed rule that are eventually finalized will not become effective until January 1, 2020. The commenters expressed several concerns about this process. First, they believed that it saddles Medicare plans with managing multiple deadlines and effective dates despite long-term planning already underway. Second, the process involves changing and uncertain rules, which could confuse stakeholders (including beneficiaries) as to which policies apply at which time (for example, a beneficiary may be uncertain as to whether or when he or she has appeal rights); this, the commenters believed, could interrupt beneficiary care and cause beneficiary frustration with their Medicare plans and providers.

Response: While we appreciate the commenters' concerns, we stress that we have worked very closely with the plans and other stakeholders to: (1) Prepare them for the preclusion list's implementation; and (2) develop sub-regulatory guidance to address their questions. We are closely and diligently monitoring the progress of the implementation. We will continue regular communication with stakeholders and expeditiously address issues if or as they develop.

Comment: A commenter stated that the previously mentioned HPMS memo sought to impose requirements that go beyond the provisions of the April 2018 final rule. The commenter contended that: (1) These additional requirements must be promulgated through notice-and-comment rulemaking; and (2) CMS should withdraw the HPMS memo and/or clarify that it does not create binding requirements.

Response: We respectfully disagree. The HPMS memo focuses on operational details that are most appropriately developed and disseminated through sub-regulatory guidance.

Comment: Several commenters supported CMS' elimination of the provider enrollment requirements for MA providers and Part D prescribers.

Response: We appreciate the commenters' support.

Comment: A number of commenters supported the implementation of the preclusion list requirements as a whole.

Response: We appreciate the commenters' support.

Comment: Numerous commenters stated that CMS must work with the industry and other stakeholders to help ensure smooth execution of the preclusion list with as little disruption in beneficiary care as possible.

Response: We agree with the commenters. We have worked closely with stakeholders to ensure an effective implementation of the preclusion list and will continue to do so.

Comment: Several commenters stated that CMS must make certain that the preclusion list: (1) Is updated frequently to minimize the time between when a provider is precluded and the time that information is available to plans and providers; and (2) contains information needed to properly identify a precluded prescriber (for example, an NPI).

Response: We agree with the commenters. We are striving to ensure that preclusion list updates are appropriately made and that the preclusion list file contains sufficient identifying data.

Comment: A commenter questioned whether Medicare plans will be limited in the number of users granted access to the preclusion list. The commenter stated that PBMs that process and pay claims and others need access to this file. Although the commenter contended that CMS indicated in its December 14 sub-regulatory guidance that it will not grant access to the preclusion list to PBMs, the commenter urged CMS to reconsider this position, perhaps by making the preclusion list public.

Response: We state respectfully that CMS will not make the preclusion list public. The list contains sensitive data (such as revoked provider information), and CMS historically has not shared this information publicly. Nonetheless, CMS is exploring secure means (other than public release) to make the data available to PBMs and other plan subcontracted entities.

Comment: A commenter recommended that CMS work with plans to develop an automated process so that preclusion list requirements can be better implemented and operationalized.

Response: We are always receptive to plan feedback regarding file delivery and format. We are available to work with plans to implement enhancements that would make the process more efficient. We believe, however, that such enhancements are best considered once a baseline has been implemented by the applicable deadline.

Comment: A commenter urged CMS to encourage plans to educate beneficiaries about the preclusion list so that the latter understand the concept before they perhaps encounter it.

Response: We agree and have indeed suggested that plans educate their enrollees regarding the preclusion list for the reason the commenter states.

Comment: A commenter questioned whether there will be a link to the preclusion list or whether CMS will transmit the list to plans and MA organizations.

Response: Plans are granted access to the list via a secure website and file transfer process.

Comment: A commenter encouraged CMS to be flexible in overseeing and enforcing the preclusion list, for stakeholders have been using their best efforts to comply with the changing requirements and need time to acclimate to the new processes.

Response: We appreciate this comment and recognize that stakeholders have been making efforts to prepare for the preclusion list's implementation. We will closely monitor the progress of this implementation.

Comment: A commenter contended that the proposed changes (especially the reduced timeline for the mandatory denial of claims) will cause several difficulties without enhancing program integrity. First, they will significantly increase plan administrative costs. Second, beneficiaries could be harmed due to disruptions in their medication. Third, beneficiaries could become dissatisfied with the timeframes in which they must seek a new provider. Fourth, the proposed rule contains no protections that could mitigate the above-referenced problems. The commenter accordingly recommended that CMS retain the standards established in the April 2018 final rule and engage MAOs (and other stakeholders) in developing means of aligning preclusion list processes with those for the OIG exclusion list.

Response: While we appreciate the commenter's concerns, we believe the changes in this rule facilitate a more patient-minded approach. We reiterate that enrollees will have 60–90 days' prior notification that their provider is precluded. During that period, claims and prescriptions associated with the precluded provider can be paid by the Part C or D plan. This will give the enrollee time to transfer to a new, non-precluded provider. Indeed, we note that Part C and D plans are currently prohibited from paying for claims and prescriptions associated with excluded providers. The additional administrative burden for a plan to check the preclusion list is not, in our view, a significant new requirement. While this rule establishes a beneficiary notice timeframe, we have simultaneously streamlined the date that a plan is to reject/deny claims for each version of the monthly preclusion list, rather than require plans to track timeframes for

rejections/denials on a beneficiary basis. If plans were required to implement the preclusion list in the manner that the OIG exclusion list is operationalized, there may be no beneficiary notification period. For these reasons, we respectfully decline to adopt the commenter's suggestion.

Comment: A commenter stated that there is insufficient technical guidance for dual-eligible special needs plans (D–SNPs), their PBMs, and other delegated entities to sufficiently test and implement the preclusion list process by January 1, 2019. The commenter urged CMS to extend the first review period for D–SNPs to at least 180 days; this would enable D–SNPs and CMS to ensure that systems are appropriately configured and operational policies established prior to any payment denials.

Response: We believe that the commenter is suggesting a minimum 180-day delay in the implementation of the preclusion list as a whole. As stated previously, we respectfully decline to do so. However, we will work closely with D–SNPs concerning this implementation and will issue sub-regulatory guidance to assist D–SNPs in this regard.

Comment: A commenter questioned whether any of the fields are conditionally required (for example, whether a date of birth for businesses or an EIN is required).

Response: CMS will issue sub-regulatory guidance on this issue as soon as feasible.

Comment: A commenter questioned whether there is a communication process for questionable data records (for example, for missing required fields such as an NPI or a missing effective date).

Response: CMS has issued sub-regulatory guidance that clarifies the process for communicating questionable data records. It can be accessed at the following link: *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/PreclusionList.html.*

Comment: A commenter sought clarification as to when PDE guidance will be available.

Response: We refer the commenter to the PDE guidance issued in the previously referenced HPMS memorandum, ''February 2019 Updates to the Drug Data Processing System (''DDPS''),'' dated January 8, 2019 and released January 9, 2019.

Comment: A commenter stated that the proposed rule lacks a ''look-back'' period indicating which plan members must be notified of a precluded provider. The commenter recommended that CMS revise proposed §§ 422.222(a)(1)(ii)(A) and 423.120(c)(6)(iv)(A) to clarify that plans need only notify a member who has received services from a precluded provider in the 12 months prior to the date the provider was added to the preclusion list. Codifying a ''look back'' period in regulation, rather than merely via sub-regulatory guidance, will provide clarity to plans.

Response: While we appreciate this suggestion, we respectfully decline to establish a formal look-back period in this rule. We must retain the flexibility (especially during the early stages of the preclusion list's implementation) to carefully monitor the program and to make any revisions (such as a look-back period) only after a careful deliberation.

Comment: Several commenters stated that CMS should clarify each of the provider types and specialties that will be on the list.

Response: We appreciate this comment and may consider furnishing such clarification, as needed, in subregulatory guidance.

Comment: Several commenters recommended that CMS detail the data sources used to place dentists who have never enrolled in Medicare on the preclusion list.

Response: Using CMS' internal data and systems (which includes, but is not limited to, the Provider Enrollment, Chain, and Ownership System and the National Plan and Provider Enumeration System), we will screen any prescriber or provider that could potentially prescribe Part D drugs or furnish MA services or items to a Medicare beneficiary through an MA plan.

Comment: Several commenters recommended that when CMS notifies providers that they are precluded, CMS should require those providers to inform patients that they do not accept Medicare beneficiaries and that their claims will not be processed. A commenter believed that this approach would be particularly appropriate if there is no claim history (for example, new patient or referral) and thus no ability for plans to notify beneficiaries.

Response: We appreciate this comment and may consider it for future rulemaking as appropriate.

Comment: Several commenters urged CMS to clarify whether urgent and emergency services are exempt from the requirement that MA plans and delegated entities deny claims for services furnished by precluded providers.

Response: Urgent and emergency services are not exempt from the claim denial requirements of § 422.222.

Comment: A commenter expressed support for the proposals to add language to the regulatory text concerning the following policies: (1) Beneficiaries may not appeal payment denials based on a provider's preclusion; and (2) unenrolled prescribers and providers should remain precluded for the same length of time as the reenrollment bar that CMS could have imposed had that prescriber or provider been enrolled and then revoked.

Response: We appreciate the commenter's support.

Comment: A commenter contended that CMS' proposed changes to its preclusion list policies would create additional complexities and be of limited value. The commenter added that the separately required beneficiary notices (and the claims denial deadlines triggered thereby) are inconsistent with CMS' goal of operationalizing the preclusion list in the same manner as the OIG exclusion list. Under the exclusion list process, the commenter stated, CMS makes the exclusion list public, updates it monthly, posts it 15 days prior to the exclusion effective date, and expects plans to deny claims as of the effective date. The commenter suggested that CMS make the preclusion list public and implement it similar to the exclusion list. This approach, the commenter believed, would alleviate inconsistencies and stakeholders' concerns.

Response: For reasons stated previously, CMS is unable to make the preclusion list public. Moreover, we do not believe it is possible to implement the preclusion list in a fashion that mirrors the OIG exclusion list. We believe that the preclusion list, upon full implementation, will impact a much larger provider population than the OIG exclusion list, for the intent of the preclusion list was to create an effective alternative to enrollment. The criteria for a provider to become precluded are therefore different and broader than those for exclusion. For this reason, we believe the beneficiary notice period is essential to protect beneficiaries from major disruptions of care. We note also that CMS has added data fields to the file to increase consistency between the notification period and the claims rejection/denial date.

Comment: A commenter questioned whether a provider must inform beneficiaries if they learn that another provider has been excluded. The commenter cited the example of a beneficiary who attempts to fill a prescription at a pharmacy retail location and the prescription is denied

due to the provider being excluded. The commenter sought clarification concerning the pharmacy's responsibility (if any) to notify the beneficiary of the excluded provider.

Response: We appreciate this comment but believe it is outside the scope of this rule.

Comment: Several commenters noted that in an FAQ issued December 14, 2018 (see (*https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/PreclusionList.html.*), CMS stated that subcontractors will not be granted access to the preclusion list and that MAOs will have to share the list with subcontractors as needed. Some subcontractors, the commenters noted, process all claims and credentialing activities, which makes direct access to the preclusion list imperative. Without such access, the commenters stated, downstream entities will have to work through MA organizations, which could delay enrollee notification. In sum, the commenters requested that: (1) Subcontractors and delegated entities be provided access to the preclusion list; and (2) the enforcement date for subcontractors to use the preclusion list be delayed until subcontractors have access to it.

Response: As explained earlier, CMS is unable to publicize preclusion data. However, CMS is exploring other secure means of making the data available to PBMs and other plan subcontracted entities. We must, however, respectfully decline to delay the implementation of the preclusion list as the commenter suggests.

d. Final Provisions

Given the foregoing, we are finalizing all of our proposed preclusion list provisions as proposed except as follows:

- Our proposed revisions to § 423.120(c)(6)(i), (ii), and (vi) that would change the term ''individual'' to ''prescriber'' will not be finalized.
- Our proposed change of the phrase ''individual NPI of the prescriber'' to ''NPI of the prescriber'' in § 423.120(c)(6)(iii) will not be finalized.
- In § 422.222(a)(1)(i), we are changing the language ''health care item or service furnished'' to ''health care item, service, or drug that is furnished, ordered, or prescribed''. We are making similar edits to § 422.222(a)(1)(ii)(A) and (C) and to § 422.504(g)(1)(iv); specifically, we will include therein, as applicable, references to ''ordered,'' ''prescribed,'' and ''drugs.''
- We are deleting the phrase ''by CMS'' in proposed § 422.222(a)(2)(ii)(B) and § 423.120(c)(6)(v)(B)(*2*). This is to clarify that Administrative Law Judges and the Department of Appeals Board (which would, applicable, consider the appeals in question jointly) are not part of CMS.
- We are clarifying the opening paragraphs of §§ 423.120(c)(6)(iv) and 422.222(a)(1)(ii) to state that §§ 423.120(c)(6)(iv) and 422.222(a)(1)(ii) do not apply if the prescriber or provider is currently excluded by the OIG.
- We are revising §§ 423.120(c)(6)(iv)(B) and 422.222(a)(1)(ii)(B) as follows:

++ The existing versions of these paragraphs will be incorporated into new paragraphs §§ 423.120(c)(6)(iv)(B)(*1*) and 422.222(a)(1)(ii)(B)(*1*), respectively. Also, we are inserting the following language at the beginning of these respective new paragraphs: ''Subject to paragraph (c)(6)(iv)(B)(*2*) of this section'' and ''Subject to paragraph (a)(1)(ii)(B)(*2*) of this section''.

++ In new paragraphs §§ 423.120(c)(6)(iv)(B)(*2*) and 422.222(a)(1)(ii)(B)(*2*), we will state that paragraph (B)(*1*) will apply only upon receipt of a claim from, respectively, a precluded provider (either contracted or non-contracted) in Medicare Part C or upon a prescriber writing a prescription in Medicare Part D when: (i) The MA organization or plan sponsor has enough information on file to either copy the provider or prescriber on the notification previously sent to the beneficiary or send a new notice informing the provider or prescriber that they may not see plan beneficiaries due to their preclusion status; and (ii) the claim is received after the claim denial or reject date in the preclusion file.

- To clarify the applicability of § 422.222, we are changing the title of this section from ''Preclusion list'' to ''Preclusion list for contracted and non-contracted individuals and entities.''
- We are adding a new paragraph (a)(6) to § 422.222 that would mirror the existing version of § 423.120(c)(6)(vi) and state as follows:

++ The opening paragraph will read: ''CMS has the discretion not to include a particular individual or entity on (or, if warranted, remove the individual or entity from) the preclusion list should it determine that exceptional circumstances exist regarding beneficiary access to MA items, services, or drugs. In making a determination as to whether such circumstances exist, *CMS* takes into account''

++ Paragraph (a)(6)(i) will read: ''The degree to which beneficiary access to MA items, services, or drugs would be impaired; and

++ Paragraph (a)(6)(ii) will read: ''Any other evidence that CMS deems relevant to its determination.''

++ We are adding the language ''Ensure that'' to the beginning of § 422.504(g)(1)(iv).

++ We are adding a new § 422.504(g)(1)(v) that would state as follows: ''Ensure that the plan's provider agreement contains a provision stating that after the expiration of the 60-day period specified in § 422.222:

—The provider will no longer be eligible for payment from the plan and will be prohibited from pursuing payment from the beneficiary as stipulated by the terms of the contract between CMS and the plan per § 422.504(g)(1)(iv); and

—The provider will hold financial liability for services, items, and drugs that are furnished, ordered, or prescribed after this 60-day period, at which point the provider and the beneficiary will have already received notification of the preclusion.''

D. Implementing Other Changes

1. Clarification Regarding Accreditation for Quality Improvement Programs

Section 1852(e)(4) of the Act requires the Secretary to deem that an MA organization has met all of the requirements for any one out of the six program areas listed in section 1852(e)(4)(B) of the Act if the MA organization is accredited in that area by an accrediting organization that has been approved by CMS and that uses the same (or stricter) standards than CMS uses to evaluate compliance with the applicable requirements. An amendment to the Act to revise subsection (e) made by section 722(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 appears not to have been fully incorporated into the provisions governing the authority to deem compliance with section 1852(e)(3) of the Act by an MA organization based on accreditation by an approved accreditation entity. We direct readers to the proposed rule for additional discussion (83 FR 55041). In the proposed rule, we clarified that an MA organization may be deemed to have satisfied the requirements of section 1852(e)(3) of the Act and the paragraphs of § 422.152 related to section 1852(e)(3) of the Act based on the review of an approved accreditation organization. We received one comment thanking us for the clarification. We will implement the clarified scope of the regulation going forward.

2. Delete the Reference to Quality Improvement Projects in § 422.156(b)(1)

Section 1852(e) of the Act requires each MA organization to have an ongoing Quality Improvement (QI) Program for the purpose of improving the quality of care provided to its enrollees. Our regulations at § 422.152 outline the QI Program requirements MA organizations. Section 422.152(a)(3) requires each MA organization to conduct quality improvement projects (QIPs) for its enrollees, and § 422.152(d) establishes the requirements for the QIPs. Effective January 1, 2019, CMS eliminated the requirements for QIPs in §§ 422.152(a)(3) and 422.152(d) in the April 2018 final rule (83 FR 16440). However, the reference to QIPs was not deleted in § 422.156(b)(1), which says QIPs are exempt from the process for deeming compliance based on accreditation.

We proposed a technical correction that would delete the phrase ''the quality improvement projects (QIPs) and'' from § 422.156(b)(1). We did not receive any comments on the proposal. We are finalizing the technical correction without modification in this final rule. We direct readers to the proposed rule for additional discussion (83 FR 55041).

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a ''collection of information,'' as defined under 5 CFR 1320.3(c) of the PRA's implementing regulations, is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection requirement (ICR) should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In the November 1, 2018 (83 FR 54982) proposed rule, we solicited public comment on our proposed information collection requirements, burden, and assumptions. As discussed in section III.B.1. of this final rule, we received comments pertaining to Evidence of Coverage (EOC) notifications and provider directory requirements. Based on internal review, we have revised several cost estimates (see Wage Data). As explained in section III.B.4. of this final rule, we have also added burden related to Medicare Parts A and B claims data extracts.

A. Wage Data

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' (BLS's) May 2017 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/current/oes_nat.htm*). In this regard, Table 2 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage. The adjusted wages are used to derive our cost estimates.

TABLE 3—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and overhead ($/hr)	Adjusted hourly wage ($/hr)
Business Operation Specialist	13–1199	$36.42	$36.42	$72.84
Lawyer	23–1011	68.22	68.22	136.44
Software Developers and Programmers	15–1130	49.27	49.27	98.54

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is a necessary rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. We believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

While we did not receive any public comments pertaining to our proposed wage estimates, based on internal review we have changed our proposed Programmer respondent type (BLS occupation code 15–1311 at $40.95/hr) to Software Developers and Programmers (BLS occupation code 15–1130 at $49.27/hr). The change adds $8.32/hr (mean) to our proposed Programmer-specific cost estimates and $16.64/hr (adjusted). The change affects sections III.B.2.a.(2), III.B.2.b.(2), and III.B.3.a.(2) of this final rule.

We have also corrected the occupation code for Business Operations Specialists from 13–000 to 13–1199. This correction adds $1.88/hr (mean) to our proposed Business Operations Specialist-specific cost estimates and $3.76/hr (adjusted). The change affects sections III.B.2.a.(2), III.B.2.b.(2), III.B.3.a.(1), and III.B.4. of this final rule.

We are not making any changes to the proposed Lawyer respondent type (BLS occupation code 23–1011 at $68.22/hr (mean) and $136.44/hr (adjusted)).

B. Information Collection Requirements (ICRs)

The following ICRs are listed in the order of appearance in section II. of this final rule.

1. ICRs Regarding the Requirements for Medicare Advantage Plans Offering Additional Telehealth Benefits (§ 422.135)

As described in section II.A.1. of this final rule, section 50323 of the Bipartisan Budget Act of 2018 allows MA plans the ability to provide MA additional telehealth benefits to enrollees starting in plan year 2020 and treat them as basic benefits. In this rule, we are finalizing—with slight modifications—most proposed requirements at § 422.135, which will authorize and set standards for MA plans to offer MA additional telehealth benefits. More specifically, we are finalizing our requirement that MA plans must advise enrollees that they may receive the specified Part B service(s) either through an in-person visit or through electronic exchange (§ 422.135(c)(2)). As discussed in section II.A.1. of this final rule, based on public comments we are not finalizing

the portion of proposed § 422.135(c)(2) that referenced the EOC document as the required vehicle for this notification. Instead, we intend to address the EOC in future sub-regulatory guidance.

MA plans will be required to make information about the coverage of additional telehealth benefits available to CMS upon request (finalized at § 422.135(c)(4)). We do not anticipate requesting this information from more than nine MA plans in a given year because historically we have not received a large number of complaints about coverage of benefits that might warrant our request for information from many plans. However, we reserve the right to ask for this information. Since we estimate fewer than 10 respondents, the information collection requirement is exempt (5 CFR 1320.3(c)) from the requirements of the PRA.

As discussed in section II.A.1. of this final rule, based on public comments we are not finalizing our proposed provider directory requirements under proposed § 422.135(c)(3). We have therefore modified our discussion of potential information collection requirements and assumptions related to provider directories, as it is no longer necessary to address them in the context of this final rule. Similar to the EOC, we intend to address the provider directory in future sub-regulatory guidance.

This final rule is consistent with our proposed rule in that neither set out any burden related to MA plans offering MA additional telehealth benefits.

2. ICRs Regarding Integration Requirements for Dual Eligible Special Needs Plans (§ 422.107)

The following requirements and burden will be submitted to OMB for approval under control number 0938–0753 (CMS–R–267).

As described in section II.A.2.a. of this final rule, we are establishing new requirements in accordance with amendments to section 1859(f)(8) of the Act (made by section 50311(b) of the Bipartisan Budget Act of 2018), which stipulates that all dual eligible special needs plans (D–SNPs) meet certain new minimum criteria for Medicare and Medicaid integration for 2021 and subsequent years. We are also codifying the various forms of integrated care provided by D–SNPs that have evolved since their establishment nearly 15 years ago.

In § 422.107(d), any D–SNP that is not a fully integrated dual eligible special needs plan (FIDE SNP) or a highly integrated dual eligible special needs plan (HIDE SNP), as defined in § 422.2, will be subject to an additional contracting requirement. Under the additional contracting requirement, the D–SNP must notify the state Medicaid agency and/or individuals or entities designated by the state Medicaid agency of hospital and skilled nursing facility (SNF) admissions for at least one group of high-risk full-benefit dual eligible individuals, as determined by the state Medicaid agency.

In addition, we are modifying existing requirements for the contract between states and D–SNPs at § 422.107(c). The modifications will include requirements that the contract between the D–SNP and the state: (1) Document the D–SNP's responsibility to coordinate the delivery of Medicaid benefits for individuals who are eligible for such services and, if applicable, to provide coverage of Medicaid services for those eligible; (2) specify the categories and criteria for eligibility for dual eligible individuals to be enrolled in the plan; and (3) specify the Medicaid benefits covered by the MA organization offering the D–SNP under a capitated contract with the State Medicaid agency or by the D–SNP's parent organization or another entity that is owned and controlled by its parent organization. We are also finalizing a new requirement that the contract between a D–SNP that is an applicable integrated plan, as defined in § 422.561, and the state document the D–SNP's use of the unified appeals and grievance procedures required under §§ 422.629 and 422.630, 438.210, 438.400, and 438.402, as finalized in this rule.

The primary burden arising from the modifications to the contracting provisions between states and D–SNPs will consist of the following:

- Burden to states to—

++ Execute D–SNP contract modifications regarding new and modified requirements under § 422.107(c) and the notification requirement at § 422.107(d), as detailed in section II.A.2.a.(2). of this final rule; and

++ Establish the terms of the notification at § 422.107(d), including its method, timing, and scope, and receive such notification from D–SNPs about high-risk enrollees' hospital and SNF admissions (if the state contracts with D–SNPs that are not FIDE SNPs or HIDE SNPs, as those terms are defined in § 422.2).

- Burden to D–SNPs to—

++ Execute a contract modification with the state Medicaid agency regarding new and modified requirements under § 422.107(c) and the notification requirement at § 422.107(d), as detailed in section II.A.2.a.(2). of this final rule; and

++ Notify the state Medicaid agency or its designee(s) about the hospital and SNF admissions for the state-identified population of high-risk enrollees (if the D–SNP is not a FIDE SNP or HIDE SNP, as those terms are defined in § 422.2).

a. Burden to States

(1) Contract Modifications With D–SNPs (§ 422.107)

For the initial year, we expect it will take 24 hours at $136.44/hr for a lawyer to update the state Medicaid agency's contract with every D–SNP in its market to address the changes to § 422.107 made by this final rule. Since half of the cost will be offset by federal financial participation for Medicaid administrative activities, we have adjusted our estimates for state agencies by 50 percent. Given the market penetration of D–SNPs in certain states relative to others, we recognize that this estimate reflects an average cost across all states and territories with D–SNPs. We expect that the state Medicaid agency will establish uniform contracting requirements for all D–SNPs operating in their market. As of June 2018, there were 42 states, plus the District of Columbia and Puerto Rico, in which D–SNPs were available to MA enrollees.[41] In aggregate, we estimate a one-time burden of 1,056 hours (44 respondents × 24 hr/response) at an adjusted cost of $72,040 (1,056 hr × $136.44/hr × 0.50). Over the course of OMB's anticipated 3-year approval period, we estimate an annual burden of 352 hours (1,056 hr × ⅓) at a cost of $24,013 ($72,040 × ⅓). We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires.

In future years, we anticipate minimal burden associated with modifications to contract terms consistent with the changes we are finalizing to § 422.107(c)(1) through (3). While it is possible more states will move toward increased integration by contracting with applicable integrated plans and would therefore need to modify their state Medicaid agency contracts with D–SNPs consistent with the changes we are finalizing to § 422.107(c)(9), we are unable to reliably estimate the additional burden in subsequent years. In addition, while we recognize that, over time, states could modify the newly required contract term at

[41] Centers for Medicare & Medicaid Services (2018, June). SNP Comprehensive Report. Retrieved from *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Special-Needs-Plan-SNP-Data.html.*

§ 422.107(d) to require notification about admissions for certain high-risk enrollees (for example, by expanding the population of high-risk full-benefit dual eligible individuals to whom this notification applies), we do not believe that such a contract change will have a material impact on time and effort and, therefore, will already be accounted for in the burden estimate for the overall contract that the state Medicaid agency has with each D–SNP.

Given the lack of material impact and the uncertainty involved in estimating state behavior, we are estimating a minimum of zero burden in subsequent years on plans. The maximum burden will be the estimated first year cost. However, we believe the maximum estimate is unlikely to be accurate since we expect any changes to contracting requirements to be iterative compared to the first year update.

We solicited public comment on our assumptions in the proposed rule and whether there are reasonable ways of modeling state behavior. We received no comments on our information collection requirements, burden estimates, and assumptions and are finalizing them without modification.

(2) Notification (§ 422.107(d))

To address differences among the states in available infrastructure, population sizes, and mix of enrollees, this rule provides broad flexibility to identify the groups for which the state Medicaid agency wishes to be notified and how the notification should take place. These flexibilities include: (1) Consideration of certain groups who experience hospital and SNF admissions; (2) protocols and timeframes for the notification; (3) data sharing and automated or manual notifications; and (4) use of a stratified approach over several years starting at a small scale and increasing to a larger scale. This final rule also allows states to determine whether to receive notifications directly from D–SNPs or to require that D–SNPs notify a state designee such as a Medicaid managed care organization, section 1915(c) waiver case management entity, area agency on aging, or some other organization.

Some states, using a rich infrastructure and a well-developed automated system, may fulfill this notification requirement with minimal burden, while states with less developed or no infrastructure or automated systems may incur greater burden. Furthermore, the burden, especially to those states starting on a small scale, may differ significantly from year to year. Because of the flexibilities provided in this final rule, we expect that states will choose strategies that are within their budget and best fit their existing or already-planned capabilities. We expect any state choosing to receive notification itself of such admissions to claim federal financial participation under Medicaid for that administrative activity.

As of June 2018, there were 42 states, plus the District of Columbia and Puerto Rico, in which D–SNPs were available to MA enrollees. We estimate that there are nine (9) states and territories with D–SNPs that are all expected to qualify as either FIDE SNPs or HIDE SNPs—Arizona, Florida, Hawaii, Idaho, Massachusetts, Minnesota, New Jersey, New Mexico, and Puerto Rico. We do not expect these states to establish a notification system under this final rule because none of their D–SNPs will be subject to the state notification requirement at § 422.107(d). We estimate that nine additional states that primarily use managed care for long-term services and supports (LTSS) (Michigan, New York, North Carolina, Ohio, Oregon, Pennsylvania, Tennessee, Texas, and Virginia) will delegate receipt of this information to their Medicaid managed care organizations. We also estimate that approximately half of the remaining 26 states (42 states—16 states, excluding the District of Columbia and Puerto Rico) or 13 states will build an automated system for receiving notification of hospital and SNF admissions consistent with this final rule.

We estimate that, on average, this work could be accomplished in a month with one software developer/programmer to build an automated system and one business operations specialist to define requirements. We estimate a one-time burden of 4,160 hours (13 states × 40 hr/week × 4 weeks × 2 FTEs). Since half of the cost will be offset by 50 percent federal financial participation for Medicaid administrative activities, we estimate an adjusted cost of $178,235 [((2,080 hr × $98.54/hr) + (2,080 hr × $72.84/hr)) × 0.50]. Over the course of OMB's anticipated 3-year approval period, we estimate an annual burden of 1,386.667 hours (4,160 hr × ⅓) at a cost of $59,412 ($178,235 × ⅓). We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires.

Because of the possible wide variability in states' approaches in implementing this requirement, we solicited comment in the proposed rule and requested suggestions for modeling state approaches and costs related to this provision. Given the uncertainty involved in estimating state behavior, we estimated a minimum of zero burden in subsequent years on plans and a maximum burden that is the estimated first-year cost. We received no comments and are finalizing our time estimates without change. Our proposed cost estimates have been revised to account for the changes discussed in section III.A. of this final rule.

b. Burden on Plans

(1) Contract Modifications With State Medicaid Agencies (§ 422.107)

For the initial year, we expect it will take 8 hours at $136.44/hr for a lawyer to update their plan's contract with the state Medicaid agency to reflect the revised and new provisions finalized in this rule at § 422.107(c)(1)–(3), (c)(9), and (d). We are unable to differentiate how these provisions impact individual D–SNP contracts due to the ways contracts are structured. For example, some contracts will include FIDE SNPs, HIDE SNPs, and other D–SNPs, while others may include only a subset of these D–SNP types. The specific requirements for the content of and scope of changes to the contract vary somewhat based on the type of D–SNP the plan is. However, it is reasonable to project that every D–SNP contract will require contract modifications with the state Medicaid agency.

There are 190 D–SNP contracts as of June 2018.[42] In aggregate, we estimate a one-time burden of 1,520 hours (190 D–SNPs × 8 hr/modification) at a cost of $207,389 (1,520 hr × $136.44/hr). Over the course of OMB's anticipated 3-year approval period, we estimate an annual burden of 507 hours (1,520 hr × ⅓) at a cost of $69,130 ($207,389/3). We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires.

We believe that we have no reasonable way of estimating or illustrating burden in later years. The expected behavior among states is unknown relative to how often they will modify their contracts with D–SNPs on this particular matter. For example, state Medicaid agencies may remain satisfied with the initial year selection of high-risk groups and see no reason to modify their contracts in later years. In contrast, other state Medicaid agencies may seek to expand the notification requirement

[42] Centers for Medicare & Medicaid Services (2018, June). *SNP Comprehensive Report.* Retrieved from *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Special-Needs-Plan-SNP-Data.html.*

to encompass additional groups of high-risk dual eligible individuals and may therefore modify their contracts on this basis. Given the uncertainty involved in estimating state behavior, we are estimating a minimum of zero burden in subsequent years on plans. The maximum burden will be the first year costs.

We received no comments on our assumptions in the proposed rule or on ways to reasonably model state behavior and are finalizing our proposed estimates without modification. However, we are finalizing our burden estimates to reflect the omission of the burden associated with §§ 422.107(c)(1) through (3) and 422.107(c)(9) in the proposed rule.

(2) Notifications to State Medicaid Agencies or Their Designees (§ 422.107(d))

We have noted previously in section II.A.2.a. of this final rule the broad flexibility in notification options for states. We also note that MA organizations are already required to have systems that are sufficient to organize, implement, control, and evaluate financial and marketing activities, the furnishing of services, the quality improvement program, and the administrative and management aspects of their organization (§ 422.503(b)(4)(ii)). Independent of the state Medicaid agency's selection of high-risk populations, protocols, and notification schedules, an MA organization's most likely method of sharing this notification will be through the use of an automated system that could identify enrollees with criteria stipulated by the states and issue electronic alerts to specified entities. We do not believe that this work is very complex. Therefore, we estimate it could be accomplished in a month with one software developer/programmer to update systems and one business operations specialist to define requirements. The burden will be at the contract, not the plan, level for a subset of D–SNP contracts that are not FIDE SNPs or HIDE SNPs and to which the notification requirements are applicable. As noted previously, there are 190 D–SNP contracts as of June 2018, of which 37 contracts, or 12.7 percent (about one-eighth), are FIDE SNPs.[43] While we do not have a precise count of D–SNPs that will likely meet the definition of a HIDE SNP, we estimate that another 12.7 percent of the 190 D–SNP contracts will be HIDE SNP contracts. Therefore, we expect that the number of contracts needing modification is 190 D–SNP contracts, less 37 FIDE SNP contracts, less 37 HIDE SNP contracts, or 116 D–SNP contracts. Accordingly, we estimate a one-time burden of 37,120 hours (116 contracts × 40 hr × 4 weeks × 2 FTEs) at a cost of $3,180,813 [(18,560 hr × $98.54/hr) + (18,560 hr × $72.84/hr)]. Over the course of OMB's anticipated 3-year approval period, we estimate an annual burden of 12,373 hours (37,120 hr × ⅓) at a cost of $1,060,271 ($3,180,813 × ⅓). We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires.

c. Summary of Burden Related to Integration Provisions for Dual Eligible Special Needs Plans

Table 4 summarizes the burden for the aforementioned provisions.

TABLE 4: ANNUAL BURDEN OF D-SNP INTEGRATION REQUIREMENTS

Item	Number of Respondents	Hours per Response	Total Hours[1]	Cost ($/hr)	Total Cost ($)
Initial update by state Medicaid agency of its contracts with D-SNPs	44	24	352	136.44	24,013
Initial establishment of system for notification of hospital and SNF admissions by state Medicaid agency	13	160	1,387	Varies	59,412
Subtotal (State Burden)	*44*	*Varies*	*1,738*	*Varies*	*83,425*
Initial update by D-SNPs of their contracts with the state Medicaid agency	190	8	506.67	136.44	69,130
Initial notification of hospital and SNF admissions by D-SNPs to state Medicaid agency	116	160	12,373	Varies	1,060,271
Subtotal (D-SNP Burden)	*190*	*Varies*	*12,881*	*Varies*	*1,129,401*
TOTAL	**234**	**Varies**	**14,619**	**Varies**	**1,212,826**

3. ICRs Regarding Unified Grievance and Appeals Procedures for Dual Eligible Special Needs Plans and Medicaid Managed Care Plans at the Plan Level (§§ 422.560 through 422.562, 422.566, 422.629 Through 422.634, 438.210, 438.400, and 438.402)

As described in section II.A.2.b. of this final rule, we are establishing for inclusion in contracts for applicable integrated plans, as defined in § 422.561, no later than 2021, procedures unifying Medicare and Medicaid grievances and appeals procedures in accordance with the newly enacted amendments to section 1859(f)(8)(B) and (C) of the Act. In this final rule, § 422.562(a)(5) requires that all dual eligible special needs plans (D–SNPs) provide assistance to beneficiaries with Medicaid coverage issues, appeals and grievances. When ready, the requirements and burden associated with these requirements will be submitted to OMB for approval under control number 0938–0753 (CMS–R–267).

As of June 2018, our Special Needs Plan Comprehensive Report lists 190 D–SNP contracts with 412 D–SNP plans that have at least 11 members.[44] The universe of D–SNPs to which our unified grievance and appeals procedures will apply is comprised of D–SNPs that are either fully integrated dual eligible special needs plans (FIDE SNPs) or highly integrated dual eligible special needs plans (HIDE SNPs) with exclusively aligned enrollment—that is, where all of the plan's membership receives Medicare and Medicaid benefits from the same organization. Currently, exclusively aligned enrollment occurs in only eight states: Florida, Idaho, Massachusetts, Minnesota, New Jersey, New York, Tennessee, and Wisconsin. Currently, there are only 37 D–SNPs operating under 34 contracts with 150,000 enrollees that could be classified as FIDE SNPs or HIDE SNPs which operate

[43] Centers for Medicare & Medicaid Services (2018, June). *SNP Comprehensive Report.* Retrieved from *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Special-Needs-Plan-SNP-Data.html.*

[44] See *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Special-Needs-Plan-SNP-Data-Items/SNP-Comprehensive-Report-2018-06.html?DLPage=1&DLEntries=10&DLSort=1&DLSortDir=descending.*

in states with exclusively aligned enrollment. The 150,000 enrollment figure for contract year 2018 is projected to grow to 172,000 (150,000 x 1.145) enrollees by 2021, the first year that compliance with these provisions will be required.[45] While unifying grievance and appeals provisions will necessitate states with exclusively aligned enrollment policies to modify their Medicaid managed care plan contracts to incorporate the new requirements, it will impose this burden on fewer than 10 states, thereby falling below the threshold for PRA purposes.

We believe that our requirements at §§ 422.629, 422.630, and 422.631 related to integrated organization determinations and integrated grievances should not be altogether unfamiliar to applicable integrated plans because, in general terms, we are adopting whichever of the current MA D–SNP or Medicaid managed care plan contract requirements under part 422 subpart M (Medicare Advantage) and part 438 subpart F (Managed Care), respectively, is more protective of the rights of the beneficiary or provides the most state flexibility, consistent with the statutory requirements of section 1859(f)(8) of the Act. Furthermore, we believe that by unifying Medicare and Medicaid integrated organization determination and grievance requirements for applicable integrated plans (that is, FIDE SNPs and HIDE SNPs with exclusively aligned enrollment), we are reducing duplicative reviews and notices, thereby ultimately reducing the level of burden on these organizations. We detail the following:

- In section III.B.3.a. of this final rule, the burden associated with the implementation of our integrated organization determination and integrated grievance procedures (§§ 422.629, 422.630, and 422.631).
- In section III.B.3.b. of this final rule, that the information collection activities undertaken to administer our unified appeals procedures (§§ 422.629, 422.633, and 422.634) are exempt from the PRA.
- In section III.B.3.c. of this final rule, that the requirement for all D–SNPs to assist enrollees with Medicaid coverage issues and grievances in § 422.562(a)(5) is also exempt from the PRA.

[45] Table IV.C1, ''Private Health Enrollment'' in 2018 Trustee Report, accessible at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2018.pdf.*

a. Integrated Organization Determinations and Integrated Grievances (§§ 422.629, 422.630, and 422.631)

Section 422.631 requires that each applicable integrated plan issue one integrated organization determination, so that all requests for benefits from and appeals of denials of coverage by applicable integrated plans will be subject to the same integrated organization determination process. Section 422.631(d)(1) requires that an applicable integrated plan send an integrated notice when the integrated organization determination is adverse to the enrollee. The notice must include information about the determination, as well as information about the enrollee's appeal rights for both Medicare and Medicaid covered benefits. Though integrating information on Medicare and Medicaid appeal rights will be a new requirement, we note that the requirement for a notice and the content of the notice largely align with current requirements in Medicaid (§ 438.404(b)) and MA (§ 422.572(e)). We believe that the provision will have minimal impact on plans based on our understanding of how plans that will meet the definition of an applicable integrated plan under this final rule currently handle coverage determinations for full-benefit dual eligible individuals receiving Medicare and Medicaid services through the plan. Currently, if such a plan were to deny or only partially cover a Medicaid service never covered by Medicare (like a personal care attendant or a clear request for Medicaid coverage), it will only issue a Medicaid denial (one notice). Under this final rule, it will do the same (that is, issue one notice). On the other hand, if the plan denied a service that is covered under either Medicare or Medicaid, such as home health services, we believe that the plan covering both Medicare and Medicaid benefits in most, if not all, states will issue an integrated determination notice that includes information about the application of Medicare and Medicaid coverage criteria to the requested service and how to appeal under both Medicare and Medicaid (one notice). This final rule codifies this practice for applicable integrated plans.

Also under § 422.568(d), if the plan covers a service such as durable medical equipment or home health services under Medicaid, but denies the same service under Medicare's rules, it must issue a Medicare denial even though the service was actually covered by the plan based on its Medicaid contract. Under this final rule, a plan covering both Medicare and Medicaid benefits will no longer need to issue a notice in this situation. We do not have data to estimate the number of instances in which D–SNPs currently issue denial notices related to overlap services; therefore, we are unable to reliably estimate the reduction in plan burden resulting from our unified appeals requirements. We solicited feedback on the burden imposed on integrated plans by having to send such a Medicare denial notice when the service is covered by the plan under Medicaid rules in the proposed rule. We did not receive any comment.

We are developing a model integrated denial notice form for use by applicable integrated plans. When ready, the model form and its associated requirements and burden will be submitted to OMB for approval. It will also be made available to the public for review/comment under the standard PRA process which includes the publication of 60- and 30-day **Federal Register** notices and the posting of the collection of information documents on our PRA website. Additionally, changes to the procedures for applicable integrated plans will be reflected in the current Notice of Denial of Medical Coverage form and instructions (OMB control number 0938–0892; CMS–10003), but will not impact this rule's burden estimates. As we did not finalize the necessary revisions for this notice at the time of the proposed rule's publication date, we did not set out such burden or solicit such comments. We are in the process of publishing a stand-alone 60-day **Federal Register** notice that set outs the revised form and form instructions.

Under § 422.629(g), applicable integrated plans must send a notice of acknowledgment for all integrated grievances and integrated reconsiderations. Medicaid managed care organizations are currently required to send this notice under § 438.406(b)(1), whereas MA plans are not currently required to send this notice. Under this final rule, applicable integrated plans must now send this notice for all grievances and appeals, not only those pertaining to Medicaid issues. Section 422.630(e) requires that applicable integrated plans issue a notice upon resolution of the integrated grievance, unless the integrated grievance was made orally and it did not concern quality of care, and the enrollee did not request a written response. A beneficiary's integrated grievance and the subsequent information collection activities necessitated by that grievance are exempt from the requirements of the PRA since the grievance would be submitted in response to an

administrative action against a specific individual (5 CFR 1320.4). However, the impact related to these requirements is estimated in section IV.B.3. of this final rule.

We believe this final rule will result in a reduction in the number of grievance reviews conducted by applicable integrated plans detailed under § 422.629(k)(2) due to the elimination of duplicative grievance reviews for Medicare and Medicaid overlap issues. We do not estimate this burden reduction as this information collection activity is exempt under 5 CFR 1320.4 from the requirements of the PRA since it occurs as part of an administrative action. However, the impact from changes to these activities are estimated in section IV.B.3. of this final rule.

We estimate negligible impacts on information collection activities involved in unifying grievances associated with our provisions at § 422.630. Under § 422.630(b), applicable integrated plans will be required to accept grievances filed at any time consistent with the Medicaid standard at § 438.402(c)(2)(i). This change will have the net effect of permitting enrollees to file a grievance for a Medicare-covered service outside of the current 60-day timely filing standard, as measured from the date of the event or incident that precipitated the grievance. The provision will effectively eliminate the timely filing period for Medicare-related grievances. We do not expect this requirement to increase the volume of grievances that an applicable integrated plan will be responsible for handling since we believe that the timeframes for filing Medicare grievances were designed to be consistent with current practice and were set in place only to eliminate complaint outliers.

Under § 422.630(c), enrollees of applicable integrated plans may file integrated grievances with the plan orally or in writing, in alignment with current Medicare and Medicaid requirements, or with the state, in states that have existing processes for accepting Medicaid grievances in place in accordance with § 438.402(c)(3). Because this provision simply extends an existing avenue for filing grievances, in states where it exists, for enrollees to file Medicaid benefits grievances with the state, we do not expect an increase in the volume of grievances that either states or applicable plans will be responsible for handling.

Section 422.630(d) will permit an enrollee to file an expedited grievance, which is available under current law for Medicare-covered, but not Medicaid-covered, benefits. We estimate that the availability of an expedited grievance for Medicaid benefits will have a negligible impact on information collection activities because applicable integrated plans will already have procedures in place to handle expedited grievances for Medicare-covered services, which could be leveraged for Medicaid-covered services. Furthermore, the availability of the expedited resolution pathway (where under current law there is only one resolution pathway for Medicaid-covered services) will have no impact on the volume of grievances.

Section 422.630(e)(1) will require that an applicable integrated plan resolve a standard (non-expedited) grievance within 30 days consistent with the MA standard (§ 422.564(e)); under Medicaid (§ 438.408(b)), the timeframe is established by the state but may not exceed 90 calendar days from day the plan receives the grievance. We estimate that this change in timeframe will have a negligible impact on information collection activities because applicable integrated plans already have business processes in place to comply with a 30-day timeframe under MA.

Section 422.630(e)(2) requires an applicable integrated plan, when extending the grievance resolution timeframe, to make reasonable efforts to notify the enrollee orally and send written notice of the reasons for the delay within 2 calendar days. We do not believe that this provision will have more than a negligible impact on plans since it adopts existing MA requirements for how an applicable integrated plan must notify an enrollee of an extension and the existing Medicaid managed care requirement for the timeliness standard. Thus, applicable integrated plans will already have business processes in place to comply with these requirements.

Although we do not estimate burden for applicable integrated plans related to information collection activities involved in unifying grievances associated with our provisions at §§ 422.629 and 422.630, some of the individual provisions in §§ 422.629 (general requirements), 422.630 (integrated grievances), and 422.631 (integrated organization determinations) will necessitate operational and systems changes on the part of applicable integrated plans. The following sections set out our burden estimates related to updates to policies and procedures and recordkeeping and storage.

(1) Updates to Policies and Procedures

We estimate a one-time burden for each applicable integrated plan to update its policies and procedures to reflect the new integrated organization determination and grievance procedures under §§ 422.629, 422.630 and 422.631. We anticipate this task will take a business operation specialist 8 hours at $72.84/hr. In aggregate, we estimate a one-time burden of 272 hours (8 hr × 34 contracts) at a cost of $19,812 (272 hr × $72.84/hr). Over the course of OMB's anticipated 3-year approval period, we estimate an annual burden of 91 hours (272 hr × ⅓) at a cost of $6,604 ($19,812 × ⅓). We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires.

(2) Recordkeeping and Storage

D–SNPs, like other MA plans, are currently required to maintain records for grievances (§ 422.504(d)). However, § 422.629(h) will require the maintenance of specific data elements consisting of: A general description of the reason for the integrated grievance; the date of receipt; the date of each review or, if applicable, the review meeting; the resolution at each level of the integrated grievance, if applicable; the date of resolution at each level, if applicable; and the name of the enrollee for whom the integrated grievance was filed.

We estimate a one-time burden for applicable integrated plans to revise their systems for recordkeeping related to integrated grievances. We anticipate this task will take a software developer/programmer 3 hours at $98.54/hr. Three hours is consistent with the per-response time estimated in the May 2016 Medicaid Managed Care final rule (81 FR 27498). In aggregate, we estimate a one-time burden of 102 hours (3 hr × 34 contracts) at a cost of $10,051 (102 hr × $98.54/hr). Over the course of OMB's anticipated 3-year approval period, we estimate an annual burden of 34 hours (102 hr × ⅓) at a cost of $3,350 ($10,051 × ⅓). We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires.

We do not expect the cost of storage to change under § 422.629(h)(3) since D–SNPs are currently required to store records under § 422.504(d), and the provision will not impose any new or revised storage requirements or burden.

We received no comments on our assumptions for estimating the burden associated with the operational and systems changes necessitated by §§ 422.629, 422.630, and 422.631.

However, we are updating our proposed burden estimates to reflect several omissions and minor modifications to two occupational codes

and corresponding adjusted hourly wages. Table 5 summarizes the burden resulting from these provisions.

b. Unified Appeals Procedures (§§ 422.629, 422.633, and 422.634)

A beneficiary's appeal of an adverse integrated coverage determination and the subsequent information collection activities necessitated by that appeal are exempt from the requirements of the PRA since the appeal would be submitted in response to an administrative action against a specific individual (5 CFR 1320.4). In the case of this final rule, the exemption covers any information collection activities undertaken after the adverse integrated organization determination by an applicable integrated plan, including: acknowledgement of integrated reconsiderations under § 422.629(g), recordkeeping related to integrated appeals at § 422.629(h), and notification of the applicable integrated plan's integrated reconsideration determination at § 422.633(f)(4).

c. Assisting With Medicaid Coverage Issues and Grievances (§ 422.562(a)(5))

We have not calculated the burden for all D–SNPs to assist enrollees with the filing of their grievance or appeal as required in § 422.562(a)(5). Since the provision of such assistance is a usual and customary business practice it is exempt from the PRA under 5 CFR 1320.3(b)(2). We believe that this function would be performed in the absence of federal regulation.

d. Summary

The burden associated with the individual components of our provisions for unified grievance and appeals procedures for applicable integrated plans are summarized in Table 5.

TABLE 5—SUMMARY OF D–SNP UNIFIED GRIEVANCE AND APPEALS PROCEDURES BURDEN

[OMB Control Number 0938–0753, CMS–R–267]

Item	Regulation	Number of respondents	Hours per respondent	Total hours [1]	Hourly wage	Total cost ($)
Updates to Policies and Procedures	422.629, 422.630, and 422.631.	34	8	91	72.84	6,604
Recordkeeping	422.629(g)	34	3	34	98.54	3,350
Total		34	Varies	125	Varies	9,954

4. ICRs Regarding Prescription Drug Plan Sponsors' Access to Medicare Parts A and B Claims Data Extracts (§ 423.153(g))

The following requirements and burden will be submitted to OMB for approval under control number 0938–TBD [46] (CMS–10691).

As described in section II.A.3. of this final rule, section 50354 of the Bipartisan Budget Act of 2018 requires the establishment of a process under which the sponsor of a PDP that provides prescription drug benefits under Medicare Part D may request, beginning in plan year 2020, that the Secretary provide on a periodic basis and in an electronic format standardized extracts of Medicare Parts A and B claims data about its plan enrollees. In this final rule we add a new § 423.153(g) to implement the process for requesting this data. The provision will allow the PDP sponsor to submit a request to CMS for claims data for its enrollees and to attest that it will adhere to the permitted uses and limitations on the use of the Medicare claims data that are listed in § 423.153.

At the time of the proposed rule's publication date, we did not finalize the operational aspects of this provision. Therefore, we did not set out such burden or request comment in the Collection of Information section of that rule. However, since that time, we have finalized the operational aspects and published a stand-alone 60-day **Federal Register** notice that set out the requirements and burden associated with the request and attestation (November 30, 2018; 83 FR 61638). Comments were received and are responded to below. We are also realigning the proposed provision with this final rulemaking by setting out such requirements and burden below. In this regard we will not be publishing a stand-alone 30-day **Federal Register** notice.

Section 423.153(g)(1)(i) states that beginning in plan year 2020, a PDP sponsor may submit a request to CMS for claims data on enrollees in its prescription drug plans. In addition, § 423.153(g)(5) provides that as a condition of receiving the requested data, the PDP sponsor must attest that it will adhere to the permitted uses and limitations on the use of the Medicare claims data. In the stand-alone notice we anticipated that the data request and attestation will be combined into a single submission. We continue to estimate it will take a business operations specialist 1 minute at $72.84/hr to complete the request for data and the attestation. As mentioned in section III.A. of this rule, we are updating the hourly wage associated with the business operations specialist.

Currently, there are 63 PDP sponsors and we estimate that all PDP sponsors would initially submit a request and attestation. We also estimate that each year approximately 1 to 5 PDP sponsors would start requesting CMS claims data for its enrollees. For purposes of impact estimates we assume the maximum, 5 PDP sponsors per year. We estimate it will take a business operations specialist 1 minute to complete the request for data and the attestation. We also estimate that each year approximately 1 to 5 PDP sponsors will request that CMS stop sending claims data for its enrollees. For purposes of impact estimates we assume the maximum, 5 sponsors, will request discontinuation. We estimate it will take a business operations specialist 1 minute (1/60 hr) to submit a request to CMS to stop sending claims data for its enrollees.

For first year sponsor requests we estimate a burden of 63/60 hours (1 hour and 3 minutes) (63 sponsors × 1/60 hr/response) at an aggregate cost of $76.48 (63 sponsors × 1/60 hr × $72.84/hr).

In subsequent years we estimate a burden of 10/60 hours (1/60/hr × (5 requests for data + 5 requests for discontinuation) at an aggregate cost of $12.14 (10/60 × 72.84).

The aggregate impact over 3 years is 83/60 hour (63/60 for the first year + 10/60 × 2 for the next 2 years) at a cost $100.76 ($76.48 for the first year + $12.14 × 2 for the next 2 years). When

[46] Currently, the control number is to be determined (TBD). OMB will assign the control number upon their approval of this new information collection request. Approval can be monitored at reginfo.gov without any login or password.

annualized over 3 years, the annual impact is 28/60 hr (83/60 divided by 3) at a cost of $33.59.

While we received a few comments, none of them were related to the PRA or any of our collection of information requirements or burden estimates. Nonetheless, we considered the comments since they were rule-related and have responded to them under the appropriate sections of this preamble, namely section II.A.3. of this final rule.

5. ICRs Regarding Medicare Advantage and Part D Prescription Drug Plan Quality Rating System (§§ 422.162(a) and 423.182(a), 422.166(a) and 423.186(a), 422.164 and 423.184, and 422.166(i)(1) and 423.186(i)(1))

As described in section II.B.1. of this final rule, we are finalizing: Measure updates for the 2022 and 2023 Star Ratings, enhancements to the cut point methodology for non-CAHPS measures, and a policy for calculating the Part C and D Star Ratings when extreme and uncontrollable circumstances occur. The provisions will not change any respondent requirements or burden pertaining to any of CMS's Star Ratings-related PRA packages, including: OMB control number 0938–0732 for CAHPS (CMS–R–246), OMB control number 0938–0701 for HOS (CMS–10203), OMB control number 0938–1028 for HEDIS (CMS–10219), OMB control number 0938–1054 for Part C Reporting Requirements (CMS–10261), and OMB control number 0938–0992 for Part D Reporting Requirements (CMS–10185). Since the provisions will not impose any new or revised information collection requirements or burden, we are not making changes under any of the aforementioned control numbers.

6. ICRs Regarding Improving Clarity of the Exceptions Timeframes for Part D Drugs (§§ 423.568, 423.570, and 423.572)

To establish greater certainty in the Part D exceptions process, we limited the amount of time an exception request can be held in a pending status while the Part D plan sponsor attempts to obtain the prescriber's supporting statement; specifically, that a plan must notify the enrollee (and the prescriber involved, as appropriate) of its decision on an exceptions request no later than 72 hours (24 hours for expedited) of receipt of the prescriber's supporting statement or 14 calendar days after receipt of the request, whichever occurs first.

These provisions will not impose any new or revised information collection requirements or burden. Consequently, the provisions are not subject to the PRA. We did not receive any comments pertaining to our position that the proposed provisions are not subject to the PRA. Consequently, we are finalizing our position without change.

7. ICRs Regarding Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in MA, Cost Plans, and PACE (§§ 422.222 and 423.120(c)(6))

As described in section II.C.1. of this final rule, the provisions in §§ 422.222 and 423.120(c)(6) will not involve activities for plan sponsors and MA organizations outside of those described in the previously referenced April 2018 final rule (83 FR 16440). The provisions are, generally speaking, clarifications of intended policy and will not impose any new or revised information collection requirements or burden. Consequently, the provisions are not subject to the PRA.

We did not receive any comments pertaining to our position that the proposed provisions are not subject to the PRA. Consequently, we are finalizing our position without change.

C. Summary of Information Collection Requirements and Burden

TABLE 6: ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

Regulatory Reference	OMB Control Number (CMS ID Number)	0938-0753 (CMS-R-267)	Total Number of Responses	Hours Per Response	Total Hours[2]	Wages ($/hr)	Total Cost ($)[1]
§ 422.107 (Initial update of States of their Contracts with D SNPs)	0938-0753 (CMS-R-267)	44	1	24	352	136.44	24,013
§ 422.107 (Initial notification systems for State Medicaid Agencies)	0938-0753 (CMS-R-267)	13	1	160	1387	85.69[3]	59,412
Subtotal (State Burden)		*44*	*1*	*Varies*	*1,739*	*Varies*	*83,425*
§ 422.107 (Initial updates of D-SNPs of their Contracts with the State)	0938-0753 (CMS-R-267)	190	1	8	507	136.44	69,130
§ 422.107 (Initial notification of D-SNPs to Medicaid Agencies)	0938-0753 (CMS-R-267)	116	1	160	12,373	85.69[3]	1,060,271
§§ 422.629, 422.630, and 422.631 (Updates to D-SNP policies and procedures)	0938-0753 (CMS-R-267)	34	1	8	91	72.84	6,604
§ 422.629(g) (Recordkeeping)	0938-0753 (CMS-R-267	34	1	3	34	98.54	3,350
§§ 423.153(g)(1)(i) and (g)(5) (Data requests and attestation)	0938-TBD (CMS-10691)	28	1	1 min (1/60 hr)	28/60	72.84	34
Subtotal (Private Sector)		*190*	*1*	*Varies*	*13,005*	*Varies*	*1,139,389*
Total		*Varies*	*1*	*Varies*	*14,744*	*Varies*	*1,222,814*

NOTES:

1. For state burdens, reflects 50 percent reduction to Federal Matching program.
2. Reflects division by 3 to annualize a one-time update over 3 years.
3. Average of $72.84 and $98.54, the wages of a business operations specialist and programmer working simultaneously on this task.

IV. Regulatory Impact Analysis

A. Statement of Need

This final rule implements specific provisions of the Bipartisan Budget Act of 2018 related to MA additional telehealth benefits, MA dual eligible special needs plans (D–SNPs), and Part D sponsors' access to Medicare claims data. The rule will also improve quality and accessibility; clarify certain program integrity policies; reduce burden on providers, MA organizations, and Part D sponsors through providing additional policy clarification; and implement other technical changes regarding quality improvement. Although satisfaction with the MA and Part D programs remains high, these changes are necessary to implement certain provisions of the Bipartisan Budget Act of 2018 and are responsive to input we received from stakeholders while administering the programs, as well as through our requests for comment. We decided to modify the MA and Part D Prescription Drug Plan Quality Rating System in response to comments from the proposed rule entitled Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, The Medicare Prescription Drug Benefit Programs, and the PACE program (November 28, 2017, 82 FR 56336).

In this final rule, our policies continue to drive affordable private plan options for Medicare beneficiaries that meet their unique healthcare needs, such as supporting innovation in telehealth among MA plans to provide more options and additional benefits for MA enrollees. These provisions align with the Administration's focus on the interests and needs of beneficiaries, providers, MA plans, and Part D sponsors.

B. Overall Impact

We examined the impact of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), Executive Order 13272 on Proper Consideration of Small Entities in Agency Rulemaking (August 13, 2002), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

The RFA, as amended, requires agencies to analyze options for regulatory relief of small businesses, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions.

This final rule affects MA plans and Part D sponsors (North American Industry Classification System (NAICS) category 524114) with a minimum threshold for small business size of $38.5 million (*http://www.sba.gov/content/small-business-size-standards*). This final rule additionally affects hospitals (NAICS subsector 622) and a variety of provider categories, including physicians and specialists (NAICS subsector 621).

To clarify the flow of payments between these entities and the federal government, note that MA organizations submit bids (that is, proposed plan designs and projections of the revenue needed to provide those benefits, divided into three categories—basic benefits, supplemental benefits, and Part D drug benefits) in June 2019 for operation in contract year 2020. These bids project payments to hospitals, providers, and staff as well as the cost of administration and profits. These bids in turn determine the payments from the Medicare Trust Fund to the MA organizations that pay providers and other stakeholders for their provision of covered benefits to enrollees. Consequently, our analysis will focus on MA organizations.

There are various types of Medicare health plans, including MA plans, Part D sponsors, demonstrations, section 1876 cost plans, PDPs, and PACE plans. Forty-three percent of all Medicare health plan organizations are not-for-profit, and 31 percent of all MA plans and Part D sponsors are not-for-profit. (These figures were determined by examining records from the most recent year for which we have complete data, 2016.)

There are varieties of ways to assess whether MA organizations meet the $38.5 million threshold for small businesses. The assessment can be done by examining net worth, net income, cash flow from operations, and projected claims as indicated in their bids. Using projected monetary requirements and projected enrollment for 2018 from submitted bids, 32 percent of the MA organizations fell below the $38.5 million threshold for small businesses. Additionally, an analysis of 2016 data—the most recent year for which we have actual data on MA organization net worth—shows that 32 percent of all MA organizations fall below the minimum threshold for small businesses.

Executive Order 13272 requires that the Department of Health and Human Services (HHS) thoroughly review rules to assess and take appropriate account of their potential impact on small business, small governmental jurisdictions, and small organizations (as mandated by the RFA).

If a final rule may have a significant economic impact on a substantial number of small entities, then the final rule must discuss steps taken, including alternatives, to minimize burden on small entities. The RFA does not define the terms ''significant economic impact'' or ''substantial number.'' The Small Business Administration (SBA) [47] advises that this absence of statutory specificity allows what is ''significant'' or ''substantial'' to vary, depending on the problem that is to be addressed in the rulemaking, the rule's requirements, and the preliminary assessment of the rule's impact. To ensure that a broad range of impacts are fully considered in the analysis, we consider ''substantial number'' to mean 5 percent or more of the affected small entities within an identified industry.

The 1984 HHS Handbook, On Developing Low Burden and Low Cost Regulatory Proposals, set forth the following definitional narrative for the term ''significant economic impact'' and is still applicable: A rule has a significant economic impact on the small entities it affects, if it significantly affects their total costs or revenues. If the economic impact is expected to be similar for all affected small entities and those entities have similar costs and revenues, then an average impact can be calculated. If the average annual impact on small entities is 3 to 5 percent or more, then we consider the rule has a significant economic impact on small entities.

While a significant number (more than 5 percent) of not-for-profit organizations and small businesses are affected by this final rule, the impact is not significant. To assess impact, we use the data in Table 17, which show that the raw (not discounted) net cost of this final rule over 10 years is $24.1 million. Comparing this number to the total monetary amounts projected to be needed just for 2020, based on plan submitted bids, we find that the impact

[47] The Regulatory Flexibility Act An Implementation Guide for Federal Agencies, pages 17–19. Issued by SBA's Office of Advocacy, and accessible at *www.sba.gov/advo.*

of this rule is significantly below the 3 to 5 percent threshold for significant impact. Had we compared the 2020 impact of the rule to projected 2020 monetary need, the impact would still be less.

Consequently, the Secretary has determined that this final rule will not have a significant economic impact on a substantial number of small entities, and we have met the requirements of Executive Order 13272 and the RFA. In addition, section 1102(b) of the Act requires us to prepare a regulatory analysis for any final rule under title XVIII, title XIX, or Part B of Title XI of the Act that may have significant impact on the operations of a substantial number of small rural hospitals. We are not preparing an analysis for section 1102(b) of the Act because the Secretary certifies that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of UMRA also requires that agencies assess anticipated costs and benefits before issuing any final rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2019, that threshold is approximately $154 million. This final rule is not anticipated to have an effect on state, local, or tribal governments, in the aggregate, or on the private sector of $154 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. Since this final rule does not impose any substantial costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

If regulations impose administrative costs on reviewers, such as the time needed to read and interpret this final rule, then we should estimate the cost associated with regulatory review. There are currently 750 MA contracts (which also includes PDPs), 50 state Medicaid agencies, and 200 Medicaid managed care organizations (1,000 reviewers total). We assume each entity will have one designated staff member who will review the entire rule. Other assumptions are possible.

Using the wage information from the Bureau of Labor Statistics (BLS) for medical and health service managers (code 11–9111), we estimate that the cost of reviewing this final rule is $107.38 per hour, including fringe benefits and overhead costs (*http://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed, we estimate that it will take approximately 12.5 hours for each person to review this final rule. For each entity that reviews the rule, the estimated cost is $1,342 (12.5 hours * $107.38). Therefore, we estimate that the total cost of reviewing this final rule is $1,342,000 ($1,342 * 1,000 reviewers).

Note that this analysis assumed one reader per contract. Some alternatives include assuming one reader per parent organization. Using parent organizations instead of contracts will reduce the number of reviewers to approximately 500 (assuming approximately 250 parent organizations), and this will cut the total cost of reviewing in half. However, we believe it is likely that reviewing will be performed by contract. The argument for this is that a parent organization may have local reviewers assessing potential region-specific effects from this final rule.

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget (OMB).

We received no comments on our estimates of impact on small businesses and other items mentioned in the Overall Impact section. Therefore, we are finalizing this section as without modification.

C. Anticipated Effects

1. Requirements for Medicare Advantage Plans Offering Additional Telehealth Benefits (§§ 422.100, 422.135, 422.252, 422.254, and 422.264)

As described in section II.A.1. of this final rule, section 50323 of the Bipartisan Budget Act of 2018 allows MA plans the ability to provide MA additional telehealth benefits to enrollees starting in plan year 2020 and treat them as basic benefits. In this rule, we are finalizing—with slight modifications—most proposed requirements at § 422.135, which will authorize and set standards for MA plans to offer MA additional telehealth benefits. Section 422.135(a) defines these benefits as Part B services that have been identified by the MA plan for the applicable year as clinically appropriate to furnish through electronic exchange when the physician (as defined in section 1861(r) of the Act) or practitioner (described in section 1842(b)(18)(C) of the Act) providing the service is not in the same location as the enrollee. We are revising our proposed impact estimates based on stakeholder feedback. In the proposed rule, we set forth the following impacts.

There are two primary aspects of the MA additional telehealth benefits provision that could affect the cost and utilization of MA basic benefits, with a corresponding impact on Medicare program expenditures. The most direct effect is the reclassification of certain telehealth services covered by MA plans pre-Bipartisan Budget Act of 2018 from MA supplemental telehealth benefits to basic benefits. This change will lead to higher basic benefit bids, as the cost of MA additional telehealth benefits will be included in the basic benefit bid. The impact on the basic benefit bid may be muted due to the exclusion from the bid of capital and infrastructure costs related to MA additional telehealth benefits.

Prior to estimating the impact on the bid, we point out several other sources of impact. Many studies have argued that telehealth will increase utilization of medical services by making them more accessible. However, the increased utilization could lead to increased savings or cost. The increased utilization could lead to significant savings due to prevention of future illness. Alternatively, the increased utilization could lead to increased costs if enrollees start seeing doctors for complaints on which they did not traditionally seek medical advice. We cite studies for each possibility. Additionally, if there are more telehealth visits, providers may request more in-person visits to protect themselves from liability.

Consequently, there are four potential impacts of this provision, which we discuss in more detail later in this section. The four areas are as follows:

- Impact on the Medicare Trust Fund
- Savings for Enrollees due to Decreased Travel Time to Providers
- Savings from Illness Prevention due to Increased Access to Services
- Increased Costs if Unnecessary Medical Visits Increase

The final rule allows for differential cost sharing. We expect that enrollees would incur lower cost sharing from telehealth services than they would from in-person visits. This would result in enrollee savings. However, we have no way of estimating this savings because we lack any data experience with this differential cost sharing. Therefore, we are scoring this as a qualitative savings.

Because of the wide variability in potential impact, in the proposed rule we solicited comments on best practices in telehealth and the resulting savings. In the following sections, we summarize and respond to these comments.

a. Impact on the Medicare Trust Fund

Superficially, there appears to be no program change since the provision simply reclassifies certain benefits as basic instead of MA supplemental. Thus, the same benefits are provided. However, a closer look at the language and assumptions of the provision show that, while collectively MA additional telehealth benefits will yield a negligible change in program spending, there is a small transfer of costs (estimated to be 0.002 percent of the MA baseline) from enrollees to the Medicare Trust Fund, associated with reclassifying these benefits from MA supplemental benefits to basic benefits. MA supplemental benefits are generally paid with rebates while basic benefits are paid by a capitation rate, calculated with reference to the bid. For MA plans to provide benefits using rebates requires additional funding since the amount of rebates provided by the Medicare Trust Fund averages only $0.66 on the dollar. Thus, the effect of the rebate aspect is that the enrollee either pays a lower supplemental premium or receives richer MA supplemental benefits. In either case, whether the enrollee saves or receives richer MA supplemental benefits, the Medicare Trust Fund incurs a cost. It follows that this provision creates a cost transfer from the Medicare Trust Fund to enrollees. The direction of the cost is classified by whether the Medicare Trust Fund loses or gains. In this case, since the Medicare Trust Fund loses money, we classify the transfer as a cost. However, the transfer results in a savings to enrollees. After accounting for the exclusion of capital and infrastructure costs, and backing out the Part B premium, the extra cost to the Medicare Trust Fund is projected to be $80 million over 10 years. The calculations for these 10 years are presented in Table 7 and discussed in the narrative.

In order to estimate the 10-year impact (2020 through 2029) of the MA additional telehealth benefits provision on the Medicare Trust Fund, we considered the following six factors.

- First, we estimated the costs of MA additional telehealth benefits that are to be transferred from MA supplemental telehealth benefits to basic benefits. Using the 2019 submitted bid information, we estimated that $0.09 per member per month (PMPM) will be transferred. We computed $0.09 by examining and averaging the largest organizations' MA supplemental telehealth benefits, particularly under the category ''Web and Phone Based Technology.'' The reason for basing estimates on the largest organizations is that in past years, only the largest organizations included the category ''Web and Phone Based Technology'' as a separate line item in their bids; by contrast, the other organizations combined multiple, non-telehealth benefits in the same line as the MA supplemental telehealth benefits, and so we were not able to distinguish the costs between telehealth and non-telehealth for the smaller organizations. Information from the 2018 Medicare Trustees Report [48] shows that the applicable medical-inflation trend that should be applied to the $0.09 PMPM is 5.2 percent per year; the average trend can be derived from information in Table IV.C3 of this report.
- We applied the PMPM amounts to the projected MA enrollment for the years 2020 through 2029. The source of the projected MA enrollment is Table IV.C1 of the 2018 Medicare Trustees Report.
- We assumed that 15 percent of the MA additional telehealth benefits will be considered capital and infrastructure costs. As discussed in section II.A.1. of this final rule, these costs are excluded from the Medicare Trust Fund payments for MA additional telehealth benefits. We obtained the 15 percent assumption by subtracting the 85 percent required medical loss ratio (MLR) from 100 percent. We used the MLR as a proxy for the medical share of provider payments.
- We applied the average rebate percentage of 66 percent, which is based on the expected submitted bid information, including expected enrollment and expected average Star Ratings.
- We applied a factor of 86 percent to the calculation, which represents the exclusion or the backing out of the Part B premium.
- However, per OMB guidance, ordinary inflation should be carved out of estimates, while medical inflation, which outpaces ordinary inflation (as well as enrollment growth), may be retained. The source of the ordinary inflation is Table IV.D1 of the 2018 Medicare Trustees Report. It is 2.6 percent per year for each of the years 2020 through 2029.

TABLE 7—CALCULATIONS OF NET COSTS PER YEAR TO THE MEDICARE TRUST FUND FOR MA ADDITIONAL TELEHEALTH BENEFITS

Year	MA enrollment (in thousands)	PMPM cost	Number of months per year	Gross amount ($ in millions) (A)	Capital and infrastructure costs (%) (B)	Average rebate percentage (%) (C)	Backing out of Part B premium (%) (D)	Net cost ($ in millions) (A * (1 – B) * (1 – C) * (D)) (E)	Ordinary inflation (%) (F)	Net costs ($ in millions) (E)/(1 + (F)) ^ (year-2019)
2020	21,995	0.09	12	25.0	15	66	86	6.2	2.6	6.1
2021	22,873	0.10	12	27.3	15	66	86	6.8	2.6	6.5
2022	23,739	0.10	12	29.8	15	66	86	7.4	2.6	6.9
2023	24,584	0.11	12	32.5	15	66	86	8.1	2.6	7.3
2024	25,395	0.12	12	35.3	15	66	86	8.8	2.6	7.7
2025	26,198	0.12	12	38.4	15	66	86	9.5	2.6	8.2
2026	26,986	0.13	12	41.6	15	66	85	10.2	2.6	8.5
2027	27,737	0.14	12	44.9	15	66	85	11.0	2.6	9.0
2028	28,455	0.14	12	48.5	15	66	85	11.9	2.6	9.5
2029	29,101	0.15	12	52.2	15	66	85	12.8	2.6	9.9
Raw Total										79.6

Combining these six factors, we calculated the net costs to the Medicare Trust Fund to be $6.1 million in 2020, $6.5 million in 2021, $6.9 million in 2022, $7.3 million in 2023, and $7.7 million in 2024. We calculated the net costs to the Medicare Trust Fund for years 2025 through 2029 to be $8.2 million, $8.5 million, $9.0 million, $9.5

[48] *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2018.pdf.*

million, and $9.9 million, respectively. The calculations of impact for years 2020 through 2029 are summarized in Table 7. The total cost for all 10 years is found in the right-most column of Table 7, titled ''Net Costs.''

b. Savings for Enrollees Due to Decreased Travel Time to Providers

MA additional telehealth benefits will save enrollees the cost of traveling to and from providers. Currently, Medicare telehealth services are used to bring healthcare services to MA enrollees, including those in rural locations. In their comments on the proposed rule, as well as in response to specific inquiries we made in the proposed rule related to telehealth, stakeholders have informed CMS that MA enrollees benefit from the use of telehealth services to reduce travel times and have greater access to providers that may not otherwise be available. Several commenters provided specific details from their own experiences on the nature of these savings.

(1) Assumptions

Prior to our actual estimation of the savings for enrollees due to decreased travel time to providers, we discuss seven assumptions underlying our calculations.

(a) Current MA Supplemental Telehealth Benefits' Usage

Under the current MA program, MA plans may offer MA supplemental telehealth benefits in the form of telemonitoring and remote access technologies (including nursing hotlines).[49] However, the plan benefit package software does not have sufficient granularity to identify which types of MA supplemental telehealth benefits are being offered. Analyzing supporting documentation for the plan bids, the Office of the Actuary (OACT) has found an average spending of $0.09 PMPM for MA supplemental telehealth benefits among the large MA plans (smaller plans do not provide this data). OACT estimates that in 2019 there will be an average rebate of $110 PMPM. Of this $110, on average, 44 percent is applied to reduction in cost sharing (compared to cost sharing in original Medicare for Part A and B benefits), and 32 percent is applied to buying down the Part B and Part D premiums, leaving 24 percent or $27 PMPM with which to fund additional services. It follows that large MA plans use only 0.33 percent ($0.09/$27) of available rebate resources to fund MA supplemental telehealth benefits. It is reasonable that the $0.09 PMPM average for large MA plans is even less for smaller plans who may not have the resources to be as aggressive in their MA supplemental telehealth benefit designs.

These considerations—coupled with a discussion of how CMS and stakeholders expect telehealth to be used—suggest that while current MA policy theoretically allows MA supplemental telehealth benefits, they are not being significantly offered. The arguments for this are as follows:

- Telehealth Specialties and Telemonitoring: In response to our discussion and request for comments in the proposed rule, commenters enthusiastically supported the MA additional telehealth benefits proposal as a saver precisely because both telemonitoring and certain specialties—especially dermatology, cardiology, and psychiatry—will be used significantly more often under these new benefits. Commenters pointed out that there are not enough dermatologists, cardiologists, and psychiatrists to provide all needed services in rural areas. The availability of MA additional telehealth benefits will remedy a lack of access based on this lack of resources. Some commenters related their personal experience and the savings they expected to accrue. No commenter dissented whether this provision would significantly save. The tone of the comments seem to imply that these commenters believed that the final rule would allow these MA additional telehealth benefits or greatly facilitate their offering.
- Current Allowed MA Supplemental Telehealth Benefits: As discussed previously in the estimates of impact on the Medicare Trust Fund, we found that approximately $0.09 PMPM was being used for current MA supplemental telehealth benefits (telemonitoring and remote access technologies). Telehealth services are not low-cost (though they cost less than in-person visits). This $0.09 must pay for the provider review and assessment. Hence, this $0.09 reflects a significantly low utilization. The following simple hypothetical example illustrates this. Suppose in a plan, once a month, 30 enrollees in a plan with 8,300 total enrollees are using MA supplemental telehealth benefits, which costs $100/hr and takes 15 minutes to review. Then the cost to the plan is 30 enrollees $\times$ $100/hr $\times$ 0.25 hr = $750. However, the cost per enrollee is $750/8,300 = $0.09. This illustrative example with hypothetical numbers clarifies why we are inferring from the $0.09 that plan utilization is extremely low.

Although this $0.09 reflects the cost to the plan, it is legitimate to use this to estimate savings to enrollees. The logic behind this is as follows. The low cost of $0.09 indicates low utilization, and it is the low utilization which drives our assumption that few enrollees are spending travel time currently. For example, in our simple hypothetical example above, without MA additional telehealth benefits, only 30 enrollees would have to travel back and forth to a provider once a month. We are estimating that, under this final rule, there would be more usage of telehealth; we expect more than 30 enrollees to use this and we expect it to be used more than once a month. Without MA additional telehealth benefits, this would necessitate the cost of travel, while with MA additional telehealth benefits, there is no travel; hence, the estimate of savings is justified. Tables 8 and 9 indicate the frequency of utilization we expect over the next 10 years.

Despite the previous arguments, we must concede that currently some telehealth benefits are being offered as MA supplemental telehealth benefits. In the absence of further data, we are making an assumption that less than 50 percent of the telehealth services that will be furnished under this final rule are currently available. This assumption has intuitive appeal. If only $0.09 out of $27 is being used for MA supplemental telehealth benefits, while the remaining $26.91 is being used to fund non-telehealth benefits, it is very reasonable to assume that current utilization is less than 50 percent of what it is expected to become under the final rule when plans can fund these benefits from the Medicare Trust Fund without using their rebate dollars.

(b) Possible Overutilization

In the proposed rule, although we did estimate the potential savings to enrollees from reduced travel time to and from providers arising from MA additional telehealth benefits, we did not include this estimate in the summary and accounting tables (Tables 16 and 17) because there was a concern that telehealth would possibly lead to overutilization of provider visits, thus offsetting the savings. We address this concern in the following points:

- Only one article raised this concern, and the article itself listed several drawbacks to its conclusion.[50] More specifically, the article—

[49] Chapter 4 of the Managed Care Manual, Section 30.3 *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf.*

[50] J. Ashwood, A. Mehrotra, D. Cowling, and L. Uscher-Pines, ''Direct to Consumer Telehealth May

++ Used data from only one telehealth company;

++ Used data on only specific medical conditions;

++ Referenced a population study that had a ''low uptake of telehealth;'' and

++ Was from an early period in telehealth.

Despite low uptake of telehealth in 2013, we have seen a significant increase in telehealth usage over the past few years. Furthermore, one article on telehealth points to the importance of patient buy-in, which is more common today.[51]

• To better understand the concern regarding overutilization, we solicited comments in the proposed rule on whether MA additional telehealth benefits would save enrollees due to reduced travel time. We received numerous comments from several sources, and the commenters were overwhelmingly supportive. The comments were not subjective but evidence-based, reflecting MA plans' first-hand experience with telehealth in some of their existing products. Some commenters specifically addressed the travel time issue. For example, a commenter indicated that virtual visits can not only reduce patient travel time, but can also potentially supplant nursing and in-home visits. In addition, the commenter referenced a virtual care experience in one particular plan which spoke to both clinician and patient time-in-transit savings. Other commenters simply echoed the travel time estimates in the proposed rule. However, many commenters discussed increased usage of telehealth services particularly in specialties such as cardiology, psychiatry, and dermatology, and especially in rural areas where there is a shortage of specialists.

Based on the previous discussion, we are including our estimates of travel savings in the summary and accounting tables (Tables 16 and 17). In making these estimates, we are assuming that the number of visits will remain the same overall but that a certain percentage of the in-person visits will be replaced by visits through electronic exchange from MA additional telehealth benefits.

(c) Telehealth Provider Utilization by Age

The available statistics discuss telehealth without adequate distinction based on age. It is very likely that a breakout by age would give more precise estimates, but unfortunately we do not have such data.

(d) Avoiding Overestimation of Telehealth Growth

In creating a 10-year estimate, there are several conflicting sources with the growth of telehealth visits. To avoid problems of overestimation, we adopted the lower growth rate estimates. We present numerical details of this approach in the section containing the actual estimates.

(e) Enrollee Savings Versus Medicare Trust Fund Impact

We explicitly clarify that the $80 million cost over 10 years, estimated in Table 7, is a cost incurred by the Medicare Trust Fund and represents a transfer from the government to enrollees, because the rebate dollars that formerly paid for MA supplemental telehealth benefits are now being freed, possibly, for additional benefits to enrollees either in the form of MA supplemental benefits or reduced cost sharing. However, the savings described are savings to enrollees.

(f) Internet Access in the 65+ Population

Our estimates of impact include a trend factor for increased general use of telehealth over the next few years. This trend factor is for the entire population. We therefore clarify that we do not believe that access to telehealth will be lower in the 65+ population because of the following:

• Telehealth does not exclusively require broadband internet capability; for example, telehealth access may also be provided through cell phones providing internet access.

• Many seniors have children or other members of their social support group who regularly visit them and could provide internet access through laptops, tablets, cell phones, or other internet-capable devices during their visits.

• There is now a large market for internet access, possibly without computers, offered by major manufacturers and targeted specifically for seniors. Current products include smart televisions allowing access without a computer, laptops specifically designed for seniors, and free or low-cost laptops provided by a number of national and local organizations in an effort to specifically encourage senior computer use.

• There are a variety of free online courses specifically targeted to seniors to facilitate familiarity with internet usage.

Therefore, we believe that the uniformity of trend for telehealth access is not an issue.

(g) Healthcare Savings

Although we are including in our impact analysis the savings to enrollees arising from reduced travel time, we are not including a quantification of healthcare savings. The commenters overwhelmingly supported the idea that telehealth would reduce healthcare spending due to increased preventive measures, consequent reduced readmissions and reduced initial hospitalizations, and greater access to certain specialties where access is currently low, such as cardiology, psychiatry, and dermatology. Furthermore, in the proposed rule, we had provided references, estimating in specific (typically one-time) settings, and the healthcare savings per inpatient enrollee. We have omitted mention of these studies in this final rule because MA additional telehealth benefits only apply to Part B services, not to inpatient services. However, commenters merged comments about savings from both inpatient telehealth and specialty telehealth such as tele-cardiology, tele-dermatology, and tele-psychiatry. In general, the commenters were enthusiastic about all aspects of telehealth saving money for both Part B and Part A services. Many of the commenters cited similar studies or their own experience. These articles and comments point to a quantitative savings in health care. Although, as mentioned previously, in the early years of telehealth there was concern for overutilization which would raise costs, this does not seem to be major issue today.

However, we are not quantifying the healthcare savings since each dollar of healthcare savings does not automatically become a dollar reduction in Medicare Trust Fund expenditures paying for plan bid estimates. As a simple example, some savings may translate to higher administrative margins (increased profits). Similarly, a portion of the healthcare savings may be allocated to increased benefits, for example, preventive benefits. We do not have a basis for quantifying these factors. Therefore, we are leaving the healthcare savings as a qualitative impact without further quantification.

Increase Access to Care but Does not Decrease Spending,'' Health Affairs 36(3), 2017, accessible at *https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.1130.*

[51] Harry Wang, Director Health and Mobile Product Research, Parks Associates ''Virtual Health Care will revolutionize the Industry If we let it'', Forbes, 2014, accessible at *https://www.forbes.com/sites/ciocentral/2014/04/03/virtual-health-care-visits-will-revolutionize-the-industry-if-we-let-it/#4ee9a9e97c25; https://www.forbes.com/sites/ciocentral/2014/04/03/virtual-health-care-visits-will-revolutionize-the-industry-if-we-let-it/#4ee9a9e97c25.*

(2) Actual Estimation

Having completed our discussion of assumptions, we next turn to the actual estimation. We require four component estimates to estimate aggregate savings for enrollees due to decreased travel time to providers. We provide these four component estimates as follows:

(a) Average Travel Time and Average Travel Distance per Visit

While it is difficult to estimate the savings in reduced travel time quantitatively, since distances from enrollees to providers vary significantly, to estimate the travel time to providers we use a former CMS standard that providers should be located within 30 minutes or 30 miles of each enrollee. While this standard has since been replaced by a more sophisticated measurement of access, we can use it as a proxy. The former CMS standard was used because it is formulated simply in terms of time (30 minutes) and mileage (30 miles) and does not differentiate among provider types. The current standards for access involve sophisticated algorithms, which involve more than two parameters (time and mileage) and additionally differ by geographic location and provider types. Therefore, the current standards were not suitable due to their complexity. We therefore assume that the midpoint, 15 minutes or 0.25 hour, represents the typical travel time to providers per enrollee visit. We note that our estimate of 30 minutes round-trip is close to the 37-minute estimate used in one article.[52] Similarly, we believe that 15 miles (one-half of 30 miles) is the average travel distance per provider visit.

In estimating the savings in wages due to reduced travel time, we first note that the group of individual respondents varies widely by respondent age, location, years of employment, educational attainment, and working status with many people over 65 retired. To deal with this variability, we follow the OMB guidance for estimating hourly wages for enrollees using the occupational title ''All Occupations'' (occupation code 00–0000 on the BLS website), with a mean wage of $24.34/hour. This guidance reflects the OMB approach that all time should have a dollar value. However, since we believe most MA enrollees are not working, we are not adding 100 percent for overtime and fringe benefits. In other words, we are scoring the wages as $24.34/hour.

Thus, the net impact per enrollee per telehealth visit to providers would be $18.17 (15 miles * 2 (round trip) * $0.20 per mile (cost of gasoline for medical transportation [53]) + 0.25 hours travel time * 2 (round trip) * $24.34/hr). The $0.20 per mile for cost of gasoline for medical transportation reflects updated numbers by the Internal Revenue Service (IRS) for 2019. As discussed previously, we assume that at most 50 percent of expected telehealth visits are currently being offered. Therefore, we save at most $9.09 ($0.5 \times \$18.17$) per enrollee per telehealth visit. The actual percentage saved may be significantly more than 50 percent. This is summarized in Table 8.

(b) Average Number of Visits per Enrollee

In 2014, the Centers for Disease Control and Prevention (CDC) estimated that persons 65 years of age and older average 5.89 visits per person per year.[54]

(c) Number of MA Enrollees

Table IV.C1 of the 2018 Medicare Trustees Report provides the projected MA enrollment.

(d) Percent, per Year, of Provider Visits That Are Telehealth

Ideally, we would like an estimate on the number of total visits and telehealth visits for 65-year-olds. However, these data are not available. Therefore, we use the best available proportions. We proceed as follows.

The CDC website cited earlier estimates 885 million provider visits in 2014. This is an aggregate number over all age groups; the 885 million was not broken out further by age group.

Absent information on the proportion of telehealth visits among total visits by 65-year-olds to providers, we use general averages (across all age groups) with the understanding that some accuracy is lost. The Statista website suggests 22 million telehealth visits in 2014.[55] This implies that 2.49 percent (22/885) of all physician visits were telehealth visits.

Inferring growth rates from the numbers on the Statista website, the projected low and high growth rates for telehealth services are 8.9 percent and 22 percent respectively. Other websites give similar ranges. For example, Becker gives three estimates for telehealth growth rates of 14.3 percent, 16.5 percent, and 27.5 percent.[56] Because of this variability, we use the lower estimate for projected telehealth growth, which is about 8.9 percent. These numbers can be used to estimate the proportion of provider visits that will be telehealth in future years. For example, in 2015, we assume 1.089 (growth rate) * 2.49 percent (proportion of provider visits that are telehealth in 2014) = 2.71 percent of provider visits will be telehealth visits.

Multiplying these four component estimates together—average savings per visit ($9.09) * visits per enrollee (5.89) * number of MA enrollees * percent of provider visits that are telehealth (2.49 percent * 1.089 per year)—we arrive at a conservative aggregate savings estimate of $30 million, growing to $50 million in 2024, and $88 million in 2029. Had we used the higher projected visits, we would have obtained $30 million, growing to $280 million. The aggregate savings over 10 years is $557 million. The results are summarized in Table 9.

[52] J. Ashwood, A. Mehrotra, D. Cowling, and L. Uscher-Pines, ''Direct to Consumer Telehealth May Increase Access to Care but Does not Decrease Spending,'' Health Affairs 36(3), 2017, accessible at *https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.1130.*

[53] *https://www.irs.gov/newsroom/irs-issues-standard-mileage-rates-for-2019.*

[54] *https://www.cdc.gov/nchs/products/databriefs/db292.htm; https://www.cdc.gov/nchs/products/databriefs/db292.htm.*

[55] *https://www.statista.com/statistics/820756/number-of-telehealth-visits-in-us/; https://www.statista.com/statistics/820756/number-of-telehealth-visits-in-us/.*

[56] See *https://www.beckershospitalreview.com/healthcare-information-technology/telemedicine-to-attract-7m-patient-users-by-2018-12-statistics-on-the-thriving-market.html; https://www.beckershospitalreview.com/telehealth/global-telemedicine-market-to-experience-16-5-annual-growth-rate-through-2023.html; https://www.beckershospitalreview.com/healthcare-information-technology/the-growth-of-telehealth-20-things-to-know.html; https://www.beckershospitalreview.com/telehealth/global-telemedicine-market-to-experience-16-5-annual-growth-rate-through-2023.html.*

TABLE 8—TRAVEL SAVINGS PER PROVIDER VISIT, TELEHEALTH

Label	Item	Amount	Source
(A)	One way travel to provider	0.25 hours	Prior CMS standard of provider availability within 30 minutes or 30 miles. We use the midpoint of 30 and 0 minutes, or 15 minutes/0.25 hours. An alternative approach uses the Health Affairs article of 37 minutes total.
(B)	Travel to and from provider	2	
(C)	Wages for enrollee per hour	$24.34	OMB guidance, use of occupational code 00–0000 on BLS website. OMB provided further guidance that, although it supports the idea of dollar value of time, since many enrollees are retirees, the wage estimate should not be doubled to reflect overhead and benefits.
(D)	Mileage cost per mile for medical travel	$0.20	IRS website.
(E)	Mileage	15 miles	Prior CMS standard of provider availability within 30 minutes or 30 miles. We use the midpoint of 30 and 0 miles, or 15 miles.
(F)	Wage savings per provider visit	$12.17	(A) * (B) * (C).
(G)	Mileage savings per provider visit	$6.00	(E) * (B) * (D).
(H)	Factor to be applied for current telehealth usage.	0.50	Currently, only 0.3% of rebate dollars available for supplemental benefits are spent on telehealth services. This small percentage suggests that, at most, half of all expected telehealth services are currently being offered.
	Total savings per visit	$9.09	0.5 × [(F) + (G)]

Notes: This table reflects savings based on the following two assumptions: The value of enrollee time is $24.34/hr and at most 50% of expected telehealth is being offered.

TABLE 9—TRAVEL SAVINGS PER YEAR, TELEHEALTH

Year	Total travel savings ($ in thousands) to enrollees from telehealth	MA enrollment (in thousands)	Savings per telehealth visit	Provider visits per enrollee	Percent of provider visits that use telehealth (percent)
2020	$30,903.7	23,181	$9.09	5.89	2.49
2021	34,912.4	24,062	9.09	5.89	2.71
2022	39,441.6	24,972	9.09	5.89	2.95
2023	44,440.5	25,858	9.09	5.89	3.21
2024	50,048.2	26,708	9.09	5.89	3.50
2025	56,218.7	27,549	9.09	5.89	3.81
2026	63,057.8	28,375	9.09	5.89	4.15
2027	70,572.1	29,161	9.09	5.89	4.52
2028	78,981.9	29,969	9.09	5.89	4.92
2029	88,393.9	30,799	9.09	5.89	5.36
Raw Total	556,970.9	.....	.....	.....	.....

c. Savings From Illness Prevention Due to Increased Access to Services

Telehealth savings due to preventive telemonitoring may arise from easier or increased access to Part B services. The MA additional telehealth benefits to be included in the MA basic benefit bid stem from the Bipartisan Budget Act of 2018 amendment of section 1852 of the Act, and will likely represent a mix of replacement of pre-Bipartisan Budget Act of 2018 in-person visits and additional Part B services. We believe that increased coverage of the MA additional telehealth benefits will generally result in an aggregate reduction in use of emergency room visits and inpatient admissions because the relative increased ease of receiving healthcare services should improve health outcomes and reduce avoidable utilization that results from untreated conditions that exacerbate illness. Several studies predict that telehealth can significantly reduce illness through prevention. We mention two situations where Part B services could be provided by a physician or practitioner via MA additional telehealth benefits: (1) Comprehensive medication reviews and (2) post-discharge transitional care programs.

(1) Comprehensive Medication Reviews [57]

Telehealth can help significantly with patients who need multiple medications. Remote medication management can reduce the multiple patient visits that are often necessary to get the appropriate mix of medications. One recent meta-study on medication reviews summarizes seven studies, showing that using comprehensive medication reviews reduced hospitalizations, readmissions, drugs, and mortality.[58]

(2) Post-Discharge Transitional Care Programs

Telehealth has been used to provide transitional care for discharged hospital patients. One study found a savings of $1,333 per beneficiary, half of which

[57] Our current MA program allows telemonitoring, hospital readmission prevention programs, and post-discharge in home medication reconciliation.

[58] Evan A. DeZeeuw, PharmD; Ashley M. Coleman, PharmD; and Milap C. Nahata, PharmD, MS, ''Impact of Telephonic Comprehensive Medication Reviews on Patient Outcomes'', Am J Manag Care. 2018;24(2):e54–e58.

was due to reduced inpatient follow-up care.[59]

In the proposed rule, we solicited comments on potential savings. Numerous commenters were overwhelmingly supportive of CMS's projected savings. Furthermore, they backed their support with quantifiable details from their own experiences in their various products. Commenters particularly emphasized healthcare savings due to increased preventive care, significantly reduced hospital admissions, and increased access to specialties with insufficient providers to meet current demands (for example, tele-cardiology, tele-psychiatry, and tele-dermatology).

d. Increased Costs if Unnecessary Medical Visits Increase

We have moved the content in this section of the proposed rule to the previous section ''Possible Overutilization.'' We noted that we received overwhelming support from commenters that there should be no concern about overutilization, and the one article citing this concern is an old article in a very specific setting (the article itself cast doubt on its own findings).

We are finalizing our requirement that MA plans must advise enrollees that they may receive the specified Part B service(s) either through an in-person visit or through electronic exchange (§ 422.135(c)(2)). As discussed in section II.A.1. of this final rule, based on public comments, we are not finalizing the portion of proposed § 422.135(c)(2) that referenced the Evidence of Coverage (EOC) document as the required vehicle for this notification. Instead, we intend to address the EOC in future subregulatory guidance.

We received the following comments, and our responses follow.

Comment: In response to CMS's request for comments in the proposed rule on whether there would be savings to enrollees arising from reduced travel time to and from providers, several commenters expressed overwhelming support. More specifically, there were no dissenting comments that overutilization of services would reduce these enrollee savings.

Response: We appreciate the commenters' support. Although there will be no change in policy, based on these comments, we are confident in including the savings due to reduced enrollee travel time to and from providers in the summary and accounting tables (Tables 16 and 17). This will result in a $557 million savings over 10 years, making this final rule economically significant.

Comment: In response to CMS's request for comments in the proposed rule on whether telehealth would significantly reduce medical spending, a variety of commenters also expressed overwhelming support. Commenters pointed out that savings would arise from increased prevention, reduced hospital readmissions, and increased access in such areas as tele-dermatology and tele-psychiatry. Commenters frequently provided statistics based on their own experience.

Response: We thank the commenters for their support. Although it is clear that telehealth will result in healthcare savings, we do not have enough information to estimate the impact on reductions of Medicare Trust Fund payments. Consequently, we are scoring this as a qualitative savings in this final rule.

We received several comments on our estimated impacts for MA additional telehealth benefits. The comments were overwhelmingly supportive with no one dissenting to our impact estimates. After careful consideration of all comments received, and for the reasons set forth in our responses to the related comments summarized earlier, we are finalizing our impact analysis for this provision with the following modification. We are revising our proposed impact of this rule. The final rule is now expected to be an economically significant rule that will save enrollees $557 million over 10 years. The savings to enrollees are due to the MA additional telehealth benefits provision, which will reduce enrollee travel time to and from providers.

2. Integration Requirements for Dual Eligible Special Needs Plans (§§ 422.2, 422.60, 422.102, 422.107, 422.111, and 422.752)

As stated in the earlier in the preamble of this final rule, starting in 2021, section 50311(b) of the Bipartisan Budget Act of 2018 establishes new Medicare and Medicaid integration standards for MA organizations seeking to offer D–SNPs and enrollment sanctions for those MA organizations that fail to comply with the new standards. We proposed to add a revised definition for ''D–SNP'' at § 422.2 and establish at § 422.107 revisions to the existing minimum state Medicaid agency contracting requirement for D–SNPs other than FIDE SNPs and HIDE SNPs, which are also defined at § 422.2.

As noted in the preamble of the proposed rule and at section II.A.2.a. of this final rule, many of the changes we proposed would unify and streamline existing requirements, which should reduce burden and are therefore not expected to have impact. For example—

- *Passive enrollment:* The reference to the definition of a HIDE SNP at § 422.2 will not materially change the plan types that are eligible for passive enrollment; rather, the existing rule simply refers to them as the D–SNPs that meet a high standard of integration under the supplemental benefit authority at § 422.102(e); and
- *Enhanced Supplemental Benefits:* We are also clarifying at § 422.102(e) that not only are HIDE SNPs that meet minimum quality and performance standards eligible to offer supplemental benefits, but FIDE SNPs that similarly meet minimum quality and performance standards may do so as well. While this amendment does not change what has occurred in practice, we believe it clarifies the types of plans that are eligible to offer enhanced supplemental benefits.

The impacts were presented in section III.B.2. of this final rule. However, the COI reduced the cost to state Medicaid agencies by 50 percent, reflecting a 50 percent Federal Financial Participation (FFP) rate; consequently, the RIA must include this 50 percent FFP rate as a cost to the federal government. Table 10 repeats the analysis summarized in Table 4 and includes transfers to the federal government. The narrative accompanying Table 4 presents our assumptions in reaching this impact as well as our assumption that there are no costs in subsequent years. As noted in section III.B.2. of this final rule, wage estimates and occupational titles were updated to reflect greater specificity as well as the latest BLS wage data.

As detailed in this section, the total first year cost is $3.9 million ($3.4 million to plans + $0.25 million to State Medicaid Agencies and $0.25 million to the federal government). The $3.9 million represents a true cost since it pays for the services of lawyers, software developers and programmers, and business operation specialists. Of this $3.9 million, $3.4 million is a cost to plans, while $0.5 million is a cost to the state Medicaid agencies which transfers $0.25 million to the federal government.

[59] Keith Kranker, Ph.D.; Linda M. Barterian, MPP; Rumin Sarwar, MS; G. Greg Peterson, Ph.D.; Boyd Gilman, Ph.D.; Laura Blue, Ph.D.; Kate Allison Stewart, Ph.D.; Sheila D. Hoag, MA; Timothy J. Day, MSHP; and Lorenzo Moreno, Ph.D. ''Rural Hospital Transitional Care Program Reduces Medicare Spending'', Am J Manag Care. 2018;24(5):256–260.

TABLE 10—FIRST YEAR COSTS OF D–SNP INTEGRATION REQUIREMENTS

Item	Number of respondents	Hours per respondent	Total hours	Cost per hour ($)	Cost to D–SNPs ($)	Cost to state Medicaid agencies ($)	Transfers to federal government ($)
Initial update by state Medicaid agency of its contracts with D–SNPs.	44 (states)	24	1,056	136.44		72,040	72,040
Initial establishment of system for notification of hospital and SNF admissions by state Medicaid agency.	13	160	2,080	98.54		102,482	102,482
	13	160	2,080	72.84		75,754	75,754
Initial update by D–SNPs of their contracts with state Medicaid agency.	190 (D–SNPs)	8	1,520	136.44	207,389		
Initial notification of hospital and SNF admissions by D–SNPs to state Medicaid agency.	116	160	18,560	98.54	1,828,902		
	116	160	18,560	72.84	111,351,910		
Total by Stakeholder					3,388,201	250,276	250,276

We received no comments on our impact estimates related to these provisions and therefore are finalizing our estimates as proposed, with modifications to reflect the omission of estimates for the impact of the contract modification at §§ 422.107(c)(1) through (3) and 422.107(c)(9) in the proposed rule, minor modifications to the occupational codes, and the corresponding adjusted hourly wages previously mentioned in this section.

3. Unified Grievance and Appeals Procedures for Dual Eligible Special Needs Plans and Medicaid Managed Care Plans at the Plan Level (§§ 422.560 Through 422.562, 422.566, 422.629 Through 422.634, 438.210, 438.400, and 438.402)

The addition of the appeals and grievances provisions at §§ 422.629 through 422.634 focus on creating MA and Medicaid appeal and grievances processes that are unified for D–SNPs that also have comprehensive Medicaid managed care contracts (or are the subsidiary of a parent organization or share a parent organization with the entity with a comprehensive Medicaid managed care contract) and have exclusively aligned enrollment. The final rule addresses appeals at the plan level. Currently, Medicaid and MA appeals and grievance processes differ in several key ways. These differences hinder a streamlined grievance and appeals process across Medicare and Medicaid managed care sectors and create unnecessary administrative complexity for plans that cover dual eligible individuals for both Medicare and Medicaid services. These new regulations will allow enrollees in a D–SNP that is also a Medicaid managed care plan through which the enrollees get Medicaid coverage to better understand the grievance and appeals processes and generally receive a resolution of their grievances and appeals more quickly.

There are four areas where this provision will have an impact, listed here and discussed in further detail later in this section.

- Furnishing Medicare Parts A and B Services during the pendency of appeals (that is, through the integrated reconsideration);
- Updating plan grievance policies and procedures and consolidation of plan grievance notifications and reviews;
- Updating applicable integrated plan appeals policies and procedures; and
- Sending appeal files to enrollees who request them.

Following are details on these four areas of impact.

a. Furnishing Medicare Parts A and B Services During the Pendency of Appeals

One of the provisions related to appeals integration may marginally impact the ways MA sponsors bid for their D–SNPs, which could impact Medicare spending. We are finalizing as proposed that the existing standards for continuation of benefits at § 438.420 apply to applicable integrated plans for Medicare benefits under Parts A and B and Medicaid benefits in the new integrated appeals requirements at § 422.632. Under our final rule, and as is applicable to Medicaid managed care plans currently, if an applicable integrated plan decides to stop or reduce a benefit that the enrollee is currently authorized to receive, the enrollee could request that the benefit continue to be provided at the currently authorized level while the enrollee's appeal is pending through the integrated reconsideration. Currently, MA plans generally are not required to provide benefits pending appeal, whereas in Medicaid it has been a long-standing feature.

We expect that the new integrated appeals provisions will result in an increase in expenditures by applicable integrated plans for Medicare Parts A and Part B covered services because they will be required to continue coverage for services during the pendency of the reconsideration request, or first-level appeal under our final rule.

The estimate of impact of this continuation is based on calendar year 2016 appeal metrics, which are then trended to calendar year 2021. The assumptions, sources and calculations are summarized in Tables 11 and 12 in this rule and further clarified as follows.

The first step in this estimation is to determine the number of integrated reconsiderations per 1,000 beneficiaries enrolled in applicable integrated plans affected by this provision. Given the similarity of population characteristics, the reconsideration experience for the Medicare-Medicaid Plans (MMPs) participating in the Financial Alignment Initiative was used as a proxy for the applicable integrated plans. In 2016, MMP enrollees were impacted by 1,232 reconsiderations for services which were resolved adversely or partially favorably to the beneficiary. The corresponding MMP enrollment in 2016 was 368,841, which implies a rate of 3.3 reconsiderations per 1,000 in 2016.

We projected D–SNP enrollment impacted by the unified procedures to grow from 150,000 in 2018 to 172,000 (150,000 * 1.145) in 2021 based on the estimated enrollment growth for all D–SNPs during the period of 14.5 percent. Applying the MMP reconsideration rate of 3.3 per 1,000 to the projected 2021 enrollment in applicable integrated plans of 172,000 results in an estimated 568 (172,000 * 3.3/1,000) service reconsiderations for applicable integrated plans in 2020.

The next step is to determine the average level of benefit subject to the appeals. Table 1 in the report Medicare Part C QIC Reconsideration Data for

2016 [60] contains data on the number and benefit amounts by service category for the second level appeals filed in 2016. Analysis of these data resulted in an estimated per-appeal benefit value of $737 for 2016. The determination of this value took into account that some services would not be subject to the regulatory extension of coverage due to the existence of immediate review rights (inpatient hospital, skilled nursing facility, and home health), other benefits would likely have been rendered already (emergency room, and ambulance), and other services are not covered as a D–SNP basic benefit (hospice and non-Medicare benefits). Accounting for 19.5 percent inflation in per-capita Medicare spending between 2016 and 2021, and carving out the 13.38 percent consumer price index inflation in years 2016–2020 inclusive, results in an estimated per-appeal benefit value of $774 (that is, $737 * 1.195/1.1338) for 2021.

[60] *https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/IRE.html.*

Taking the product of the number of applicable integrated plan service reconsiderations in 2021 (568) and average benefit value in 2021 ($774) yields an estimated cost in 2021 of $439,632 (that is, 568 * $774) due to an increase in Medicare expenditures stemming from the unified appeals procedures for applicable integrated plans. We believe that this figure represents an upper bound of the cost given that not all applicable services will be rendered during the extended period of benefit continuation in this regulation. These calculations are summarized in Table 11.

Using the 2021 estimates as a basis, estimates for 2021 through 2029 are presented in Table 12. The following assumptions were used in creating Table 12:

- As described earlier in this section, the numbers in the row for 2021 come from Table 11.
- The projected FIDE SNP enrollment for 2022 through 2029 was obtained by multiplying the estimated 2021 FIDE SNP enrollment of 172,000, using SNP enrollment growth factors inferred from Table IV.C1 in the 2018 Medicare Trustees Report.
- The projected cost per appeal for 2022 through 2029 was obtained by first multiplying the estimated 2021 cost per appeal of $774 by FFS per capita growth rates obtained from internal documentation for the Table of FFS USPCC, non-ESRD estimates in attachment II of the 2019 Rate Announcement and Call Letter (*https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf*).

As summarized in Table 12, there is an estimated true cost (reflecting purchase of goods and services) of $0.4 million in 2021 and $0.5 million in 2022 through 2025, modestly increasing to $0.6 and $0.7 million in 2026 through 2029. Eighty-six percent of this cost is transferred from the plans to the Medicare Trust Fund; the remainder of this cost is born by beneficiary cost sharing.

TABLE 11: IMPACT OF INTEGRATED APPEALS PROVISION OF FIDE SNPS

Row ID	Item Description	Number	Data Source
	MMP Appeals: 2016		
(A)	Appeals	1,232	2016 Parts C and D Reporting Requirements PUF (not incl. Part D MTM data) from https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartCDDataValidation.html. Sum of service reconsiderations partially favorable and adverse for organization type "Demo"
(B)	Enrollment	368,841	2016 Parts C and D Reporting Requirements PUF (not incl. Part D MTM data) from https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartCDDataValidation.html. Sum of enrollment for organization type "Demo"
(C)	MMP appeals per 1000	3.3	(C) =(A) / (B) * 1000
	FIDE SNP Appeals 2021		
(D)	Enrollment 2018	150,000	Internal CMS enrollment extract in HPMS data system for July 2018
(E)	D-SNP enrollment growth: '18-'21	14.5%	Table IV.C1, "Private Health Enrollment" in 2018 Medicare Trustees Report, accessible at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2018.pdf
(F)	Enrollment 2021	172,000	(F) = (D)*(1+(E))
(G)	MMP Appeals per 1000 in 2016	3.3	Row (C)
(H)	FIDE SNP appeals 2021	568	(H) = (F)/1000 * (G)
	Cost of FIDE SNP Appeals: 2021		
(I)	Average benefit per appeal (2016)	$737	Data obtained from CMS Appeal & Grievance Contractor
(J)	Inflation: 2016 – 2021	19.5%	Ratio of 2021 and 2016 entries in table "Comparison of Current and Previous Estimates of the FFS USPCC - Non ESRD" in the 2019 Rate Announcement and Call letter accessible at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf
(K)	Carving out Ordinary Inflation 2016-2021	13.80%	Product of the urban consumer price index (CPI-U) increase factors for 2016-2020 inclusive. Data were obtained from Table V.B2 in the 2017 Medicare Trustees Report accessible at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2017.pdf
(L)	Average benefit per appeal (2021)	$774	(L) = (I) * (1 + (J)) / (1+(K))
(M)	Aggregate amount of appeal (2021)	$440,000	(M) = (L) * (H)

TABLE 12—NET COST PER YEAR TO THE MEDICARE TRUST FUND FOR INTEGRATED PLAN APPEALS

Contract year	Affected FIDE SNP enrollment (A)	Appeals per 1,000 affected enrollees (B)	Number of affected appeals per year (C) = (A)/ 1000 * (B)	Cost per appeal (D)	Gross cost of appeals ($ in millions) (E) = (D) * (C)/ 1,000,000	Share of cost funded by medicare trust fund (%) (F)	Net cost of appeals to medicare trust fund ($ in millions) (F) * (E)	Net cost of appeals to beneficiaries ($ in millions) (1–F) * (E)
2021	172,000	3.3	568	$774	0.4	86%	0.4	
2022	179,000	3.3	591	791	0.5	86	0.4	0.1
2023	185,000	3.3	611	808	0.5	86	0.4	0.1
2024	191,000	3.3	630	828	0.5	86	0.4	0.1
2025	197,000	3.3	650	842	0.5	86	0.5	0.1
2026	203,000	3.3	670	861	0.6	85	0.5	0.1
2027	209,000	3.3	690	883	0.6	85	0.5	0.1
2028	215,000	3.3	710	903	0.6	85	0.5	0.1
2029	220,000	3.3	726	920	0.7	85	0.6	0.1

b. Updating Plan Grievance Policies and Procedures and Consolidation of Plan Grievance Notifications and Reviews

As detailed in section III.B.3. of this final rule, there are only 34 contracts representing 37 D–SNPs that we currently believe will be classified as a HIDE SNP or FIDE SNP and operate in states that have policies requiring exclusively aligned enrollment across MA and Medicaid managed care plans. In addition to the costs estimated in section III.B.3. of this final rule, we estimate the following impacts: (1) Sending a notice of acknowledgement; (2) sending a notice of resolution; and (3) review of integrated grievances.

(1) Sending a Notice of Acknowledgement

Under § 422.629(g), applicable integrated plans must send a notice of acknowledgment for all grievances, both those submitted orally and in writing. Medicaid managed care organizations are currently required to send this notice under § 438.406(b)(1), whereas MA plans are not currently required to send this notice. Under this final rule, applicable integrated plans must now send this notice for all grievances, not only those pertaining to Medicaid issues. In the absence of data on the types of grievances submitted, we assume half the grievances currently made to an applicable integrated plan are related to Medicare issues and half are related to Medicaid issues.

Estimates of impacts for this notice take into account overlapping Medicare and Medicaid benefits. As we do not have data on grievances for overlapping Medicare and Medicaid benefits, we assume 25 percent of all grievances are related to overlapping Medicare and Medicaid benefits. This 25 percent estimate reflects our belief that there is some (more than 0 percent) overlap, but that the majority of grievances (more than 50 percent) do not overlap. The average of 0 percent and 50 percent results in the 25 percent assumption we have made. We use the following 6 estimates to estimate the costs associated with this provision:

- As detailed in section IV.B.3.a of this final rule, we estimate that the aggregate number of enrollees in applicable integrated plans in Contract Year 2021 is 172,000. We used an average of the following two estimates for the percentage of enrollees expected to file a grievance:

++ The May 2016 Medicaid Managed Care final rule estimate of a 2 percent filing rate; and

++ The currently approved burden under OMB control number 0938–0753 (CMS–R–267) estimate of a 6.8 percent filing rate.

Thus we estimate that 4.4 percent (½ × (6.8 percent + 2 percent) of all enrollees file a grievance.

- As indicated previously, we estimate that 50 percent of all grievances are related to Medicare coverage issues and half are related to Medicaid coverage issues.
- As indicated previously, we estimate 25 percent of all grievances for applicable integrated plans are regarding overlapping Medicare and Medicaid benefits issues.
- We estimate that the time for mailing an acknowledgment notice using a standard form is 1 minute, or 1/60th of an hour.
- A business operations specialist would perform this task at an hourly wage of $72.84/hr.
- Therefore, we estimate there are 7,568 grievances (172,000 enrollees × 4.4 percent who file a grievance), of which 3,784 (7,568 grievances × 50 percent) are related to enrollees' Medicare coverage and 3,784 are related to their Medicaid coverage. We estimate that 1,892 grievances (7,568 grievances × 25 percent of grievances for overlapping benefits) are made with respect to overlapping Medicare and Medicaid issues and currently only require acknowledgment notices under Medicaid rules. It follows that the new burden arising from this provision applies to 1,892 grievances (3,784 grievances related to Medicare coverage minus the 1,892 grievances that would have resulted in notices of acknowledgement because they related to Medicaid coverage).

Thus the aggregate annual burden across all plans from this provision is 32 hours (1,892 grievances × 1/60 hr) at a cost of $2,297 (1,892 grievances × 1/60 hr × $72.84/hr).

(2) Sending a Notice of Resolution

Section 422.630(e) requires that applicable integrated plans issue a notice upon resolution of the integrated grievance, unless the grievance was made orally and: (1) Was not regarding quality of care; and (2) the enrollee did not request a written response. To estimate the savings from the reduction in the number of grievance resolution notices due to unification of grievance processes for applicable integrated plans, we first estimate the total cost of issuing such notices and then multiply by 25 percent (the estimated number of grievances that are regarding overlapping Medicare and Medicaid benefits). The resulting amount is the cost of the eliminated duplicative grievance notices under the unified procedures. We used the following 7 estimates in our calculation:

- As previously discussed regarding sending the notice of acknowledgement, we estimate that the aggregate number of enrollees in applicable integrated plans in Contract Year 2021 is 172,000.
- As previously discussed regarding sending the notice of acknowledgement, we estimate that 4.4 percent of all enrollees file a grievance.
- The currently approved burden under OMB control number 0938–0753 (CMS–R–267) estimates that 60 percent

of all those who file a grievance will file orally.

- We estimate that of those who file orally, 10 percent will request a follow up written response.
- We estimate 9.5 percent of those who file a grievance, file on quality matters.[61]
- We estimate that it will take one-quarter of an hour to prepare a written response to a grievance, reflecting the current time estimate under OMB control number 0938–0753 (CMS–R–267).
- A business operations specialist would perform this task at an hourly wage of $72.84/hr.

We use these 7 estimates to derive the following:

- We estimate there will be 7,568 grievances (172,000 enrollees × 4.4 percent who file a grievance)
- 51.13 percent of those who file a grievance require written responses, either because the grievance was on a quality issue, was submitted in writing, or was orally submitted (but not on quality issues) and the enrollee requested a written response. The 51.13 percent estimate is based on the following assumptions:

++ 9.5 percent of all grievances are on quality matters, all of which require written response;

++ 36.2 percent of all grievances are submitted in writing and not on quality issues (90.5 percent of grievances that are not on quality issues × 40 percent (100 percent − 60 percent of grievances submitted orally));

++ 5.43 percent of all grievances are orally submitted (but not on quality issues), and the enrollee requested a written response (90.5 percent of grievances that are not on quality issues × 60 percent of grievances are filed orally × 10 percent of all oral grievances request a written response).

It therefore follows that 51.13 percent of grievances (9.5 percent + 36.20 percent + 5.43 percent) require written response.

Thus, the aggregate burden associated with responding in writing to grievances is 967 hours (7,568 grievances × 51.13 percent of grievances requiring a written response × 0.25 hr to write a response) at a cost of $70,436 (967 hours × $72.84/hour wage of a business operations specialist). It follows that the savings due to reduction of duplicative notices is 242 hours (967 hours × 0.25 grievances involving an overlap of Medicare and Medicaid benefits) at an annual savings of $17,616 (172,000 enrollees × 4.4 percent of enrollees who file grievances × 51.13 percent of grievances requiring a written response × one quarter of grievances eliminated due to overlap of Medicare and Medicaid × one quarter hour × $72.84/hour).

(3) Review of Grievances

We estimate a burden adjustment from grievance reviews detailed under § 422.629(k)(2) in a manner similar to the estimates for sending notices of acknowledgement and resolution. We first estimate total cost and then estimate the savings as 25 percent of that total cost due to the elimination of duplicative grievance reviews for Medicare and Medicaid overlap issues. We assume that the review of each grievance will be done by a business operations specialist working at $72.84/hr. Based on the May 2016 Medicaid Managed Care final rule (81 FR 21498), we assume the average grievance takes 30 minutes for a business operations specialist to resolve. We estimate the aggregate annual cost for grievance review is 3,784 hours (172,000 enrollees × 0.044 × 0.5 hr) at a cost of $275,627 (3,784 hr × $72.84/hr). Therefore, the reduction in grievance reviews is 946 hours (3,784 hr × 25 percent), at an annual savings of $68,907 (3,784/h4 × $72.84).

Thus, the total annual savings associated with consolidation of applicable integrated plans' grievance notifications and reviews is $84,226 per year [($17,616 (notice of resolution) + $68,907 (grievance review) − $2,297 (notice of acknowledgement).]

Section III.B.3. of this final rule estimates a one-time cost of $29,864 ($19,812 for updating policies and procedures + $10,051 for recordkeeping). Thus, the total impact arising from updating policies and procedures and consolidation of grievance notices and reviews is a savings of $54,362 ($88,820 − $29,864) in the first year and savings of $84,226 in subsequent years.

c. Updating Applicable Integrated Plan Appeals Policies and Procedures

Applicable integrated plans' internal appeals policies and procedures must be updated to comply with the unified appeals requirements. In terms of updates, we see no reason to differentiate between the work required for grievances and appeals. Therefore, as indicated in section IV.B.3.b. of this final rule, we estimated a one-time cost of $29,864 for updating applicable integrated plans' appeals policies and procedures.

d. Sending Appeal Files to Enrollees Who Request Them

Medicaid managed care regulations under § 438.406(b)(5) currently require plans to send, for free, appeal case files to enrollees who appeal while, in contrast, the Parts C & D Enrollee Grievance, Organization/Coverage Determinations, and Appeals Guidance, § 50.5.2, requires MA plans to send such files at a reasonable cost.[62] Our final rule requires the applicable integrated plans to send such files for free. To estimate this cost, we must first estimate the cost of sending such a file.

Livanta, a Quality Improvement Organization, estimates the cost per case file as $40–$100.[63] This can be justified independently with a stricter range as follows: Assuming a typical case file has 100 pages, it would weigh about 1 pound at 6 pages per ounce. The cost of mailing a 1-pound case file by FedEx (to assure security) is $10. The cost of photocopying 100 pages at a minimum rate of $0.05 per page is $5. The $0.05 per page is likely to be an overestimate for plans that own their own photocopying equipment. Thus, the total cost of photocopying and mailing would be about $15. We assume a correspondence clerk, BLS occupation code 43–4021,[64] would take 1 hour of work, at $36.64 per hour (including 100 percent for overtime and fringe benefits) to retrieve the file, photocopy it, and prepare it for mailing. Thus we estimate the total cost at $36.64 + $10 + $5 = $51.64.

We need further estimates to complete the calculation. We assume 43.5 total appeals (favorable and unfavorable) per 1,000.[65] Based on our experience, we assume that 10 percent of all appeals would require a file sent. Finally, as indicated in section III.B.3. of this final rule, there are 37 applicable integrated plans in 34 contracts with 150,000 enrollees in 2018 projected to grow to 172,000 enrollees in 2021. Thus we estimate the total annual cost of mailing files to enrollees as $38,637 (that is, 172,000 enrollees * 4.35 percent appeals * 10 percent requesting files * $51.64 cost).

The various impacts of unified grievances and appeals are summarized in Table 13. The aggregate impact is a cost $0.4 to $0.6 million per year for the

[61] This percent estimate comes from the total percent of grievances relating to quality of care as reported by MA plans for calendar Year 2017 Medicare Part C Reporting Requirements Data.

[62] See *https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf.*

[63] See *https://bfccqioareal.com/recordrequests.html.*

[64] *https://www.bls.gov/oes/current/oes_nat.htm.*

[65] *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartCDDataValidation.html.*

next 10 years. This impact reflects both costs to the Medicare Trust Fund, costs to enrollees, costs related to first-year updates to policies and procedures, and savings due to consolidation of notifications to enrollees as a result of unified grievance procedures.

TABLE 13—SUMMARY OF COSTS FOR GRIEVANCE INTEGRATION PROVISION ($ IN MILLIONS)

[Negative numbers indicate savings]

Item	Cost to Medicare Trust Fund	Cost sharing for MA enrollees	Updating policies and procedures and consolidation of grievance notices and reviews	Updating appeal policies and procedures	Sending files to enrollees who request them	Total impact
Subsection in this Unified Grievance Section	(a)	(a)	(b)	(c)	(d)	
2020	n/a	n/a	n/a	n/a	n/a	n/a
2021	0.38	0.06	(0.05)	0.03	0.038	0.5
2022	0.4	0.07	(0.08)	0	0.038	0.4
2023	0.42	0.07	(0.08)	0	0.038	0.4
2024	0.45	0.07	(0.08)	0	0.038	0.5
2025	0.47	0.08	(0.08)	0	0.038	0.5
2026	0.49	0.09	(0.08)	0	0.038	0.5
2027	0.52	0.09	(0.08)	0	0.038	0.6
2028	0.54	0.1	(0.08)	0	0.038	0.6
2029	0.57	0.1	(0.08)	0	0.038	0.6

We note that these costs and savings are true costs and savings since they reflect payment for additional or fewer economic resources (reduced notifications and increased cost of appeals). The increased appeals costs are a cost to MA plans, which transfer this cost to enrollees and the Medicare Trust Fund (the government).

We received no comments on our estimates and therefore are finalizing them with modifications to reflect the omission of the impact associated with sending the notice of acknowledgement and to the occupational codes and corresponding adjusted hourly wages as previously mentioned in this section.

4. Proposal for Prescription Drug Plan Sponsors' Access to Medicare Parts A and B Claims Data Extracts (§ 423.153)

As described in section II.A.3. of this final rule, section 50354 of the Bipartisan Budget Act of 2018 requires the establishment of a process under which the sponsor of a PDP that provides prescription drug benefits under Medicare Part D may request, beginning in plan year 2020, that the Secretary provide on a periodic basis and in an electronic format standardized extracts of Medicare claims data about its plan enrollees. In the proposed rule, we proposed to add a new § 423.153(g) to implement the process for requesting these data.

To estimate the impact we required a model of operationalizing this provision, without however committing to a particular operationalizing process. We outlined a process which—

- Meets all regulatory requirements; and
- Requires as little burden as possible to make and grant requests.

We solicited comments from stakeholders on this proposed operationalization.

Electronic request and transfers are superior (have less burden) than paper processes. We could therefore add functionalities to the CMS HPMS system (or other CMS systems) which would allow the following functions:

- Request of claims data for the current and future quarters for enrollees of the PDP requesting the data.
- Request to no longer receive data.
- Attestation that all regulatory requirements will be complied with. The attestation would be in the form of a screen listing all regulatory requirements; the authorized PDP HPMS user would have to electronically attest by clicking a button.

Such a process would combine request and attestation. The receipt of the submission would verify completeness of request. Furthermore, there would be no burden in request (under 1 minute of work).

The HPMS contractors estimated that there would be a one-time update costing approximately $200,000.

Besides requesting the data, data must be transmitted to the requesting sponsor. Ideally, data would be transmitted electronically but we do not yet have such an API. Instead, we would treat requested data like data requested for research. Typically, such data is downloaded onto encrypted external hard drives and mailed to requestors.

The data could come from the Chronic Condition Warehouse (CCW). We asked our contractors the cost of downloading quarterly such data and sending it out. The cost varies by sponsor size. Currently, based on CMS public data, there are 63 PDP sponsors. Their size and the quarterly cost per sponsor of providing them with data, should they request it, is summarized in Table 14.

TABLE 14—COST PER PDP SPONSOR PER QUARTER FOR TRANSMITTING CLAIMS DATA

PDP size in enrollees	Number of sponsors	Cost per quarter per sponsor for transmission of claims data
Above 5 million	1	$26,500
1 million–5 million	6	17,500
100,000–1 million	11	10,500

TABLE 14—COST PER PDP SPONSOR PER QUARTER FOR TRANSMITTING CLAIMS DATA—Continued

PDP size in enrollees	Number of sponsors	Cost per quarter per sponsor for transmission of claims data
Under 100,000	45	10,500

To complete the annual impact analysis we needed an estimate of proportions for each plan size that would request data. For example, we are certain that the 1 PDP sponsor with over 5 million enrollees will request data. Thus the annual burden for that plan size is 1 * 4 quarters × $26,500 per quarter = $106,000. Similarly, if we assume that all six PDP sponsors with enrollments between 1 and 5 million would request data then the annual burden is 6 sponsors * 4 quarters * $17,500 per quarter per sponsor = $420,000. If we assume that only three-quarters of these six sponsors request data then the annual burden would be 0.75 * $420,000 = $315,000. In the absence of any other basis for the decision, it is reasonable to assume that the proportion goes down as the size goes down. In the absence of data, we could use a descent of simple fractions (1, three-fourths, one-half, one-fourth). Note, that 50 percent of plans with under 100,000 enrollees have under 10,000 enrollees. It is very unlikely that such plans would have the resources to use the data. Thus an assumption that only 50 percent of plans under 100,000 request data is reasonable. However, we considered multiple scenarios. Table 15 presents for a variety of scenarios of proportions and their total impact. The average of the five scenarios is $1.5 million while the median is $1.3 million. The range of impacts is $0.8 million to $2.9 million. For purposes of Executive Order 13771 accounting we listed the impact as $1.5 million annually, with a $0.2 million one-time cost in the first year. We did not trend this estimate by year since the number of PDP sponsors has remained at 63 since 2015.

TABLE 15—ANNUAL BURDEN OF PROVIDING CLAIMS DATA TO PDP SPONSORS

Scenario label	Proportion of sponsors with over 5 million enrollees requesting data (%)	Proportion of sponsors with 1–5 million enrollees requesting data (%)	Proportion of sponsors with 100,000 to 1 million enrollees requesting data (%)	Proportion of sponsors with less than 100,000 enrollees requesting data (%)	Aggregate annual burden based on costs provided in Table 14 ($ in millions)
A	100	75	50	33	1.3
B	100	100	75	50	1.8
C	100	50	33	25	0.9
D	100	100	100	100	2.9
E	100	100	50	0	0.8

We did not anticipate any further burden. It is most likely that the PDP sponsor would exclusively use the data. In the event that downstream entities are shared any data they are already bound in their contracts by all Medicare regulations including the regulations of this provision.

We received no comments on this proposal and therefore are finalizing this provision without modification.

5. Medicare Advantage and Part D Prescription Drug Plan Quality Rating System (§§ 422.162(a) and 423.182(a), §§ 422.166(a) and 423.186(a), §§ 422.164 and 423.184, and §§ 422.166(i)(1) and 423.186(i)(1))

We proposed some measure specification updates. These type of changes are routine and do not have an impact on the highest ratings of contracts (that is, overall rating for MA–PDs, Part C summary rating for MA-only contracts, and Part D summary rating for stand-alone prescription drug plans). Hence, there will be no, or negligible, impact on the Medicare Trust Fund.

We also proposed some adjustments to MA and Part D Star Ratings for extreme and uncontrollable circumstances. The proposed policy will make adjustments to take into account the potential impact on contracts when there are extreme and uncontrollable circumstances affecting them. This policy is in response to the multiple disasters in 2017 and 2018, including several hurricanes and wildfires. We proposed a policy to permit an adjustment to Star Ratings when extreme and uncontrollable circumstances occur during the performance period or measurement period for MA and Part D plans.

We also proposed enhancements to the current methodology to set Star Ratings cut points. The intent of the changes is to increase the stability and predictability of cut points from year to year. This proposal is consistent with the CMS goal to increase transparency. We believe this provision would also have minimal impact on the highest ratings of contracts. Specifically, simulations of the proposed changes to the Star Ratings methodology using the 2018 Star Ratings data show that the impact on the MA Quality Bonus Payment (QBP) ratings is minimal with the QBP ratings overall increasing for less than 1 percent of MA enrollees.

We received no comments on our proposed RIA statement and, therefore, are finalizing this provision without modification.

6. Improving Clarity of the Exceptions Timeframes for Part D Drugs (§§ 423.568, 423.570, and 423.572)

We proposed to limit the amount of time an exceptions request can be held open to 14 calendar days, meaning that there will be an outside limit to how long the request is in a pending status while the Part D plan sponsor attempts to obtain the prescribing physician's or other prescriber's supporting statement. Under current manual guidance, plan sponsors are instructed that an exceptions request should only be held open for a reasonable period of time if a supporting statement is needed. We believe that no more than 14 calendar

days is a reasonable period of time to have an exceptions request open and this rule seeks to codify that standard. Based on comments received, we are modifying the proposed approach to clearly account for circumstances where a prescriber's supporting statement is received late or not received at all within the 14 calendar day timeframe. Under this final rule, if a supporting statement is not received by the end of 14 calendar days from receipt of the exceptions request, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours (24 hours for an expedited request) from the end of 14 calendar days from receipt of the exceptions request. We do not expect this to have any new impact on the number of pending appeals or pose a potential burden to plan sponsors, as we expect plans are already making and notifying enrollees of decisions on exceptions requests under a similar reasonable timeframe. Based on findings from plan sponsor audits, this approach is generally consistent with how plans sponsors have operationalized the current guidance that cases only be held open for a reasonable period of time pending receipt of a prescriber's supporting statement. Therefore, we do not expect that plan sponsors would need to hire more staff or adjust their operations in a manner that would affect costs. Consequently, we expect the impact of this final rule to be negligible.

We received no comments on our proposed RIA statement and therefore are finalizing this provision of the RIA statement without modification.

7. Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in MA, Cost Plans, and PACE (§§ 422.222 and 423.120(c)(6))

We do not anticipate any additional cost or savings associated with our preclusion list provisions. As we indicated in section II.C.1 of this final rule, said provisions will not involve activities for plan sponsors and MA organizations outside of those described in the previously mentioned April 2018 final rule. The provisions are, generally speaking, clarifications of our intended policy and do not constitute new requirements. Hence, the expected impact is negligible.

We received no comments on our proposed RIA statement and are therefore finalizing it without modification.

D. Alternatives Considered

1. Requirements for Medicare Advantage Plans Offering Additional Telehealth Benefits (§§ 422.100, 422.135, 422.252, 422.254, and 422.264)

Section 1852(m)(2)(A)(i) of the Act, as added by the Bipartisan Budget Act of 2018, defines MA additional telehealth benefits as services that are identified for the applicable year as clinically appropriate to furnish using electronic information and telecommunications technology when a physician (as defined in section 1861(r) of the Act) or practitioner (described in section 1842(b)(18)(C) of the Act) providing the service is not at the same location as the plan enrollee (which we refer to as ''through electronic exchange''). We considered various alternative definitions of ''clinically appropriate'' but decided not to finalize specific regulation text defining the term. We are finalizing our proposal to implement the statutory requirement for MA additional telehealth benefits to be provided only when ''clinically appropriate'' to align with existing CMS rules for contract provisions at § 422.504(a)(3)(iii), which requires each MA organization to agree to provide all benefits covered by Medicare ''in a manner consistent with professionally recognized standards of health care.''

The statute does not specify who or what entity identifies the services for the year. We considered various alternatives, including retaining the authority as an agency to specify what services are clinically appropriate to furnish each year. MA plans could have been required to comply with an annual list of clinically appropriate services identified by CMS. However, we rejected this alternative as too restrictive; we believe MA plans are in the best position and it is in their own interest to stay abreast of professional standards necessary to determine which services are clinically appropriate. MA plans have a vested interest in staying abreast of the current professionally recognized standards of health care. Healthcare standards and technology continuously develop as a result of new advancements in modern medicine. As healthcare standards change over time and differ from practice area to practice area, we believe our approach is flexible enough to allow plans to take those changes and differences into account. We believe that failing to allow this flexibility will result in the need for another regulation that addresses future technological changes in health care. We do not want to unduly burden MA plans with an unnecessary regulation or restrict their efforts to provide healthcare services. Thus, we are finalizing our proposal to interpret this provision broadly by not specifying the Part B services that an MA plan may offer as MA additional telehealth benefits for the applicable year, but instead allowing MA plans to independently determine which services each year are clinically appropriate to furnish in this manner. Our final definition of additional telehealth benefits at § 422.135(a)(2) provides that it is the MA plan (not CMS) that identifies the appropriate services for the applicable year.

We also considered alternatives to implement how telehealth benefits are provided through ''electronic exchange.'' CMS considered defining the specific means of ''electronic exchange.'' However, we decided to define ''electronic exchange'' at § 422.135(a) as ''electronic information and telecommunications technology,'' as the former is a concise term for the latter, which is the statutory description of the means used to provide the MA additional telehealth benefits. We did not propose specific regulation text that defines or provides examples of electronic information and telecommunications technology. We considered providing a complete list of means of providing electronic information and telecommunications technology. Although we provided examples of electronic information and telecommunications technology in the proposed rule, we did not provide a comprehensive list because the technology needed and used to provide MA additional telehealth benefits will vary based on the service being offered. CMS appreciates that health care is evolving. CMS's purpose in not providing specific regulation text that defines or provides examples of electronic information and telecommunications technology is to promote flexibility that allows plans to continue to develop methods of healthcare delivery. CMS cannot contemplate the various technological methods plans will use to deliver healthcare services. We do not believe plans will misuse this flexibility because it is in their best interest to provide healthcare services that meet the changing needs of enrollees. We also believe the more narrow approach of defining or providing examples of electronic information and telecommunications technology will cause the added burden of requiring another CMS rule.

We believe this broad approach will avoid tying the authority in the final rule to specific information formats or technologies that permit non-face-to-

face interactions for furnishing clinically appropriate services. This approach will also result in savings due to increased disease prevention among enrollees because plans will be able to develop technology that is less expensive, more predictive, and more accurate. We received no comments on our alternatives considered for this provision and are therefore finalizing our explanation of them without modification.

2. Integration Requirements for Dual Eligible Special Needs Plans (§§ 422.2, 422.60, 422.102, 422.107, 422.111, and 422.752)

This final rule requires D–SNPs that—(1) do not meet the HIDE SNP or FIDE SNP integration standard; and (2) do not have a parent organization assuming clinical and financial responsibility for Medicare and Medicaid benefits to notify the state Medicaid agency or its designee when a high-risk full-benefit dual eligible individual has a hospital or skilled nursing facility admission. We considered several alternatives to this proposal, as explained in section II.A.2.a.(2). of the proposed rule, including examples provided in the Bipartisan Budget Act of 2018: Notifying the state in a timely manner of enrollees' emergency room visits and hospital or nursing home discharges; assigning each enrollee a primary care provider; and data sharing that benefits the coordination of items and services under Medicare and Medicaid. However, we believe our final rule is preferable to the alternatives when considering the degree to which it meets our criteria for establishing minimum contract criteria discussed in section II.A.2.a.(2) of the proposed and final rules. While we lack experience and data to quantify cost, these alternatives would impact a larger number of D–SNP enrollees and require additional state data-sharing infrastructure than the notification requirement we are finalizing in this rule, which we believe would result in increased administrative burden and implementation costs. We received no comments on this discussion of alternatives to the proposed rule and therefore are finalizing our discussion without modification.

3. Unified Grievance and Appeals Procedures for Dual Eligible Special Needs Plans and Medicaid Managed Care Plans at the Plan Level (§§ 422.560, 422.562, 422.566, 422.629 Through 422.634, 438.210, 438.400, and 438.402)

We are creating unified grievance and appeals procedures for certain D–SNPs (FIDE SNPs and HIDE SNPs) with exclusively aligned enrollment, which we define as occurring when such a D–SNP limits enrollment to full-benefit dual eligible individuals whose Medicaid benefits are covered by the D–SNP itself, or by a Medicaid managed care organization that is the same organization, the D–SNP's parent organization, or another entity that is owned and controlled by the D–SNP's parent organization. Because most D–SNP enrollees are not enrolled in D–SNPs with exclusively aligned enrollment, we considered the feasibility of broadening the scope of these unified procedures to apply to more D–SNPs—that is, to D–SNPs without exclusively aligned enrollment. However, in most states, the majority of D–SNP enrollees have Medicaid coverage either through a different organization's Medicaid MCO, in a prepaid ambulatory or inpatient health plan (PAHP or PIHP), or through a state's Medicaid fee-for-service system. In these circumstances, the D–SNP has no control over the Medicaid grievance and appeals process. Even a D–SNP that has a Medicaid managed care organization operated by such plan's parent organization available to its enrollees, but whose members may instead enroll in other Medicaid plans, can only unify the procedures for Medicaid appeals and grievances of those enrollees who are also simultaneously enrolled in the Medicaid managed care organization controlled by such plan's parent organization. We lack experience and data to quantify the cost of this alternative due to the uncertainty involved in calculating the additional levels of administrative burden and cost associated with unifying grievance and appeals processes when D–SNPs and Medicaid managed care plans that do not have the same enrollees, or where the organizations offering the D–SNPs and Medicaid plans are unaffiliated or even competitors. We received no comments on this proposal and therefore are finalizing our discussion here without modification.

E. Accounting Statement and Table

The following table summarizes costs, savings, and transfers by provision.

As required by OMB Circular A–4 (available at *https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/*), in Table 16, we have prepared an accounting statement showing the savings, costs, and transfers associated with the provisions of this final rule for calendar years 2020 through 2029. Table 16 is based on Tables 17A, B, and C which lists savings, costs, and transfers by provision.

BILLING CODE 4120–01–P

The following Table 17 summarizes savings, costs, and transfers by provision and forms a basis for the accounting table. For reasons of space, Table 17 is broken into Table 17A (2020 through 2023), Table 17B (2024 through 2027), and Table 17C (2028, 2029, and totals). In these tables, all numbers are positive; positive numbers in the savings columns indicate actual dollars saved while positive numbers in the cost columns indicate actual dollars spent; and the aggregate row indicates savings less costs and does not include transfers. The transfer numbers are expressed as negative numbers to reflect the fact that the Medicare Trust Fund incurs a cost while enrollees experience a cost savings. All numbers are in millions. Tables 17A, 17B, and 17C form the basis for Table 16 and for the

TABLE 16: ACCOUNTING STATEMENT - CLASSIFICATIONS OF ESTIMATED SAVINGS, COSTS, AND TRANSFERS

For Calendar Years 2020 To 2029 ($ in millions)	Savings			Whom is Saving, Spending, or Transferring
	Discount Rate		Period	
	7%	3%	Covered	
Net Savings Per Year	49.76	51.75	2020-2029	See itemization in rows below.
Savings Per Year	52.27	54.21	2020-2029	MA enrollees save from reduced travel times to and from providers.
Costs Per Year	2.51	2.45	2020-2029	MA enrollees (cost sharing) and MA plans (that pass costs to the Medicare Trust Fund), Contractors (for claims processing), State Medicaid Agencies that transfer 50% of costs to the federal government.
Transfers Per Year	(7.73)	(7.86)	2020-2029	Medicare Trust Fund and MA enrollees (enrollees save while Medicare Trust Fund incurs cost of telehealth as a basic vs. supplemental benefit; hence the amount is listed as negative, reflecting Medicare Trust Fund cost)

calculation to the infinite horizon discounted to 2016, mentioned in the conclusion.

TABLE 17A: AGGREGATE SAVINGS, COSTS, AND TRANSFERS IN MILLIONS BY PROVISION AND YEAR FROM 2020 TO 2023

	2020 Savings	2020 Costs	2020 Transfers	2021 Savings	2021 Costs	2021 Transfers	2022 Savings	2022 Costs	2022 Transfers	2023 Savings	2023 Costs	2023 Transfers
Total Savings	30.9			35.0			39.5			44.5		
Total Costs		5.6			1.9			2.0			2.0	
Aggregate Total	25.3			33.0			37.6			42.5		
Total Transfers			(6.1)			(6.5)			(6.9)			(7.3)
Telehealth Enrollees	30.9			34.9			39.4			44.4		
Telehealth Government			(6.1)			(6.5)			(6.9)			(7.3)
D-SNP Integration, MA Plans		3.4										
D-SNP Integration, State Medicaid Agencies		0.5										
D-SNP Grievance & Appeals, Paperwork Reduction				0.1			0.1			0.1		
D-SNP Grievance & Appeals, Enrollees		0.0			0.1			0.1			0.1	
D-SNP Grievance & Appeals, Medicare Trust Fund		0.0			0.4			0.4			0.4	
Claims Data		1.7			1.5			1.5			1.5	
Star Ratings				0.0			0.0			0.0		
Preclusion				0.0			0.0			0.0		

TABLE 17B: AGGREGATE SAVINGS, COSTS, AND TRANSFERS IN MILLIONS BY PROVISION AND YEAR FROM 2024 TO 2027

	2024 Savings	2024 Costs	2024 Transfers	2025 Savings	2025 Costs	2025 Transfers	2026 Savings	2026 Costs	2026 Transfers	2027 Savings	2027 Costs	2027 Transfers
Total Savings	50.1			56.3			63.1			70.7		
Total Costs		2.0			2.1			2.1			2.1	
Aggregate Total	48.1			54.3			61.1			68.5		
Total Transfers			(7.7)			(8.2)			(8.5)			(9.0)
Telehealth Enrollees	50.0			56.2			63.1			70.6		
Telehealth Government			(7.7)			(8.2)			(8.5)			(9.0)
D-SNP Integration, MA Plans												
D-SNP Integration, State Medicaid Agencies												
D-SNP Grievance & Appeals, Paperwork Reduction	0.1			0.1			0.1			0.1		
D-SNP Grievance & Appeals, Enrollees		0.1			0.1			0.1			0.1	
D-SNP Grievance & Appeals, Medicare Trust Fund		0.5			0.5			0.5			0.5	
Claims Data		1.5			1.5			1.5			1.5	
Star Ratings	0.0			0.0			0.0			0.0		
Preclusion	0.0			0.0			0.0			0.0		

BILLING CODE 4120–01–C

TABLE 17C: AGGREGATE SAVINGS, COSTS, AND TRANSFERS IN MILLIONS BY PROVISION AND YEAR FROM 2028 TO 2029, AND TOTALS COLUMNS

	2028 Savings	2028 Costs	2028 Transfers	2029 Savings	2029 Costs	2029 Transfers	Raw Totals Savings	Raw Totals Costs	Raw Totals, Transfers, Costs to Medicare Trust Fund
Total Savings	79.1			88.5			557.7		
Total Costs		2.1			2.2			24.1	
Aggregate Total	76.9			86.3			533.6		
Total Transfers			(9.5)			(9.9)			(79.6)
Telehealth Enrollees	79.0			88.4			557.0		
Telehealth Government			(9.5)			(9.9)			
D-SNP Integration, MA Plans								3.4	
D-SNP Integration, State Medicaid Agencies								0.5	
D-SNP Grievance & Appeals, Paperwork Reduction	0.1			0.1			0.7		
D-SNP Grievance & Appeals, Enrollees		0.1			0.1			0.7	
D-SNP Grievance & Appeals, Medicare Trust Fund		0.5			0.6			4.2	
Claims Data		1.5			1.5			15.2	
Star Ratings							0.0		
Preclusion	0.0			0.0			0.0		

F. Conclusion

As indicated in Tables 17A through C, we estimate that this final rule generates annual cost savings of approximately $25 to $86 million per year over 2020 through 2029. The raw total net savings over 10 years is $534 million.

G. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771 requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the

elimination of existing costs associated with at least two prior regulations.'' In line with Executive Order 13771, in Table 18 we estimate present and annualized values of costs and cost savings over an infinite time horizon. Both costs and savings are presented as positive numbers; net savings equals savings minus costs and is positive. As shown, this final rule generates level annual cost savings of $55.80 million in 2016 dollars over an infinite time horizon, discounted at 7 percent. Based on these cost savings, this final rule would be considered a deregulatory action under Executive Order 13771. Details on estimated savings is found in the preceding analyses.

TABLE 18—EXECUTIVE ORDER 13771 SUMMARY TABLE IN 2016 DOLLARS OVER AN INFINITE TIME HORIZON

[$ In millions]

Item	Primary (7%)	Primary (3%)
Present Value of Costs	27.27	68.39
Present Value of Cost Savings	824.36	2,431.69
Present Value of Net Costs	797.09	2,363.30
Annualized Costs	1.91	2.05
Annualized Cost Savings	57.71	72.95
Annualized Net Savings	55.80	70.90

List of Subjects

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, and Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, and Reporting and recordkeeping requirements.

42 CFR Part 438

Grant programs-health, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 498

Administrative practice and procedure, Health facilities, Health professions, Medicare, and Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 1. The authority citation for part 422 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 2. Section 422.2 is amended—

■ a. By adding definitions of ''Aligned enrollment'' and ''Dual eligible special needs plan'' in alphabetical order;

■ b. By revising the definition of ''Fully integrated dual eligible special needs plan'';

■ c. By adding the definition of ''Highly integrated dual eligible special needs plan'' in alphabetical order; and

■ d. In the definition of ''Preclusion list'' by revising the introductory text and paragraphs (1)(i), (2)(i), (2)(ii)(C) and adding paragraph (3).

The additions and revisions read as follows:

§ 422.2 Definitions.

* * * * *

Aligned enrollment refers to the enrollment in a dual eligible special needs plan of full-benefit dual eligible individuals whose Medicaid benefits are covered under a Medicaid managed care organization contract under section 1903(m) of the Act between the applicable State and: the dual eligible special needs plan's (D–SNP's) MA organization, the D–SNP's parent organization, or another entity that is owned and controlled by the D–SNP's parent organization. When State policy limits a D–SNP's membership to individuals with aligned enrollment, this condition is referred to as exclusively aligned enrollment.

* * * * *

Dual eligible special needs plan or D–SNP means a specialized MA plan for special needs individuals who are entitled to medical assistance under a State plan under title XIX of the Act that—

(1) Coordinates the delivery of Medicare and Medicaid services for individuals who are eligible for such services;

(2) May provide coverage of Medicaid services, including long-term services and supports and behavioral health services for individuals eligible for such services;

(3) Has a contract with the State Medicaid agency consistent with § 422.107 that meets the minimum requirements in paragraph (c) of such section; and

(4) Beginning January 1, 2021, satisfies one or more of the following criteria for the integration of Medicare and Medicaid benefits:

(i) Meets the additional requirement specified in § 422.107(d) in its contract with the State Medicaid agency.

(ii) Is a highly integrated dual eligible special needs plan.

(iii) Is a fully integrated dual eligible special needs plan.

* * * * *

Fully integrated dual eligible special needs plan means a dual eligible special needs plan—

(1) That provides dual eligible individuals access to Medicare and Medicaid benefits under a single entity that holds both an MA contract with CMS and a Medicaid managed care organization contract under section 1903(m) of the Act with the applicable State;

(2) Whose capitated contract with the State Medicaid agency provides coverage, consistent with State policy, of specified primary care, acute care, behavioral health, and long-term services and supports, and provides coverage of nursing facility services for a period of at least 180 days during the plan year;

(3) That coordinates the delivery of covered Medicare and Medicaid services using aligned care management and specialty care network methods for high-risk beneficiaries; and

(4) That employs policies and procedures approved by CMS and the State to coordinate or integrate beneficiary communication materials, enrollment, communications, grievance and appeals, and quality improvement.

* * * * *

Highly integrated dual eligible special needs plan means a dual eligible special needs plan offered by an MA organization that provides coverage, consistent with State policy, of long-term services and supports, behavioral health services, or both, under a capitated contract that meets one of the following arrangements—

(1) The capitated contract is between the MA organization and the Medicaid agency; or

(2) The capitated contract is between the MA organization's parent organization (or another entity that is owned and controlled by its parent organization) and the Medicaid agency.

* * * * *

Preclusion list means a CMS compiled list of individuals and entities that—

(1) * * *

(i) The individual or entity is currently revoked from Medicare for a reason other than that stated in § 424.535(a)(3) of this chapter.

* * * * *

(2) * * *

(i) The individual or entity has engaged in behavior, other than that

described in § 424.535(a)(3) of this chapter, for which CMS could have revoked the individual or entity to the extent applicable had they been enrolled in Medicare.

(ii) * * *

(C) Any other evidence that CMS deems relevant to its determination; or

(3) The individual or entity, regardless of whether they are or were enrolled in Medicare, has been convicted of a felony under Federal or State law within the previous 10 years that CMS deems detrimental to the best interests of the Medicare program. Factors that CMS considers in making such a determination under this paragraph (3) are—

(i) The severity of the offense;

(ii) When the offense occurred; and

(iii) Any other information that CMS deems relevant to its determination.

* * * * *

■ 3. Section 422.60 is amended by revising paragraph (g)(2)(i) to read as follows:

§ 422.60 Election process.

* * * * *

(g) * * *

(2) * * *

(i) Operate as a fully integrated dual eligible special needs plan or highly integrated dual eligible special needs plan.

* * * * *

■ 4. Section 422.100 is amended by revising paragraphs (a) and (c)(1) to read as follows:

§ 422.100 General requirements.

(a) *Basic rule.* Subject to the conditions and limitations set forth in this subpart, an MA organization offering an MA plan must provide enrollees in that plan with coverage of the basic benefits described in paragraph (c)(1) of this section (except that additional telehealth benefits may be, but are not required to be, offered by the MA plan) and, to the extent applicable, supplemental benefits as described in paragraph (c)(2) of this section, by furnishing the benefits directly or through arrangements, or by paying for the benefits. CMS reviews these benefits subject to the requirements of this section and the requirements in subpart G of this part.

* * * * *

(c) * * *

(1) Basic benefits are all items and services (other than hospice care or coverage for organ acquisitions for kidney transplants) for which benefits are available under parts A and B of Medicare, including additional telehealth benefits offered consistent with the requirements at § 422.135.

* * * * *

■ 5. Section 422.102 is amended by revising paragraph (e) introductory text to read as follows:

§ 422.102 Supplemental benefits.

* * * * *

(e) *Supplemental benefits for certain dual eligible special needs plans.* Subject to CMS approval, fully integrated dual eligible special needs plans and highly integrated dual eligible special needs plans that meet minimum performance and quality-based standards may offer additional supplemental benefits, consistent with the requirements of this part, where CMS finds that the offering of such benefits could better integrate care for the dual eligible population provided that the special needs plan—

* * * * *

■ 6. Section 422.107 is amended by—

■ a. Revising the section heading;

■ b. By revising paragraphs (a), (b), (c)(1), (c)(2), and (c)(3);

■ c. By redesignating paragraph (d) as paragraph (e); and

■ d. Reserving paragraph (d).

The revisions and additions read as follows:

§ 422.107 Special needs plans and dual eligibles: Contract with State Medicaid Agency.

(a) *Definition.* For the purpose of this section, a contract with a State Medicaid agency means a formal written agreement between an MA organization and the State Medicaid agency documenting each entity's roles and responsibilities with regard to dual eligible individuals.

(b) *General rule.* MA organizations seeking to offer a dual eligible special needs plan must have a contract consistent with this section with the State Medicaid agency.

(c) * * *

(1) The MA organization's responsibility to—

(i) Coordinate the delivery of Medicaid benefits for individuals who are eligible for such services; and

(ii) If applicable, provide coverage of Medicaid services, including long-term services and supports and behavioral health services, for individuals eligible for such services.

(2) The category(ies) and criteria for eligibility for dual eligible individuals to be enrolled under the SNP, including as described in sections 1902(a), 1902(f), 1902(p), and 1905 of the Act.

(3) The Medicaid benefits covered under a capitated contract between the State Medicaid agency and the MA organization offering the SNP, the SNP's parent organization, or another entity that is owned and controlled by the SNP's parent organization.

* * * * *

(d) [Reserved]

■ 7. Effective January 1, 2021, § 422.107 is further amended by adding paragraphs (c)(9), (d), and (e)(2) to read as follows:

§ 422.107 Special needs plans and dual eligibles: Contract with State Medicaid Agency.

(c) * * *

* * * * *

(9) For each dual eligible special needs plan that is an applicable integrated plan as defined in § 422.561, a requirement for the use of the unified appeals and grievance procedures under §§ 422.629 through 422.634, 438.210, 438.400, and 438.402.

* * * * *

(d) *Additional minimum contract requirement.* For any dual eligible special needs plan that is not a fully integrated or highly integrated dual eligible special needs plan, the contract must also stipulate that, for the purpose of coordinating Medicare and Medicaid-covered services between settings of care, the SNP notifies, or arrange for another entity or entities to notify, the State Medicaid agency, individuals or entities designated by the State Medicaid agency, or both, of hospital and skilled nursing facility admissions for at least one group of high-risk full-benefit dual eligible individuals, identified by the State Medicaid agency. The State Medicaid agency must establish the timeframe(s) and method(s) by which notice is provided. In the event that a SNP authorizes another entity or entities to perform this notification, the SNP must retain responsibility for complying with this requirement.

(e) * * *

(2) MA organizations offering a dual eligible SNP must comply with paragraphs (c)(9) and (d) of this section beginning January 1, 2021.

* * * * *

■ 8. Section 422.111 is amended by revising paragraph (b)(2)(iii) to read as follows:

§ 422.111 Disclosure requirements.

* * * * *

(b) * * *

(2) * * *

(iii) By a dual eligible special needs plan, prior to enrollment, for each prospective enrollee, a comprehensive written statement describing cost

sharing protections and benefits that the individual is entitled to under title XVIII and the State Medicaid program under title XIX.

* * * * *

■ 9. Section 422.135 is added to subpart C to read as follows:

§ 422.135 Additional telehealth benefits.

(a) *Definitions.* For purposes of this section, the following definitions apply:

Additional telehealth benefits means services:

(1) For which benefits are available under Medicare Part B but which are not payable under section 1834(m) of the Act; and

(2) That have been identified by the MA plan for the applicable year as clinically appropriate to furnish through electronic exchange when the physician (as defined in section 1861(r) of the Act) or practitioner (described in section 1842(b)(18)(C) of the Act) providing the service is not in the same location as the enrollee.

Electronic exchange means electronic information and telecommunications technology.

(b) *General rule.* An MA plan may treat additional telehealth benefits as basic benefits covered under the original Medicare fee-for-service program for purposes of this part 422 provided that the requirements of this section are met. If the MA plan fails to comply with the requirements of this section, then the MA plan may not treat the benefits provided through electronic exchange as additional telehealth benefits, but may treat them as supplemental benefits as described in § 422.102, subject to CMS approval.

(c) *Requirements.* An MA plan furnishing additional telehealth benefits must:

(1) Furnish in-person access to the specified Part B service(s) at the election of the enrollee.

(2) Advise each enrollee that the enrollee may receive the specified Part B service(s) through an in-person visit or through electronic exchange.

(3) Comply with the provider selection and credentialing requirements provided in § 422.204, and, when providing additional telehealth benefits, ensure through its contract with the provider that the provider meet and comply with applicable State licensing requirements and other applicable laws for the State in which the enrollee is located and receiving the service.

(4) Make information about coverage of additional telehealth benefits available to CMS upon request. Information may include, but is not limited to, statistics on use or cost, manner(s) or method of electronic exchange, evaluations of effectiveness, and demonstration of compliance with the requirements of this section.

(d) *Requirement to use contracted providers.* An MA plan furnishing additional telehealth benefits may only do so using contracted providers. Coverage of benefits furnished by a non-contracted provider through electronic exchange may only be covered as a supplemental benefit.

(e) *Bidding.* An MA plan that fully complies with this section may include additional telehealth benefits in its bid for basic benefits in accordance with § 422.254.

(f) *Cost sharing.* MA plans offering additional telehealth benefits may maintain different cost sharing for the specified Part B service(s) furnished through an in-person visit and the specified Part B service(s) furnished through electronic exchange.

§ 422.156 [Amended]

■ 10. Section 422.156 is amended in paragraph (b)(1) by removing the phrase ''the quality improvement projects (QIPs) and''.

■ 11. Section 422.162 (a) is amended by adding the definitions ''Absolute percentage cap'', ''Cut point cap'', ''Guardrail'', ''Mean resampling'', ''Restricted range'', and ''Restricted range cap'' in alphabetical order to read as follows:

§ 422.162 Medicare Advantage Quality Rating System.

(a) * * *

Absolute percentage cap is a cap applied to non-CAHPS measures that are on a 0 to 100 scale that restricts movement of the current year's measure-threshold-specific cut point to no more than the stated percentage as compared to the prior year's cut point.

* * * * *

Cut point cap is a restriction on the change in the amount of movement a measure-threshold-specific cut point can make as compared to the prior year's measure-threshold-specific cut point. A cut point cap can restrict upward movement, downward movement, or both.

* * * * *

Guardrail is a bidirectional cap that restricts both upward and downward movement of a measure-threshold-specific cut point for the current year's measure-level Star Ratings as compared to the prior year's measure-threshold-specific cut point.

* * * * *

Mean resampling refers to a technique where measure-specific scores for the current year's Star Ratings are randomly separated into 10 equal-sized groups. The hierarchal clustering algorithm is done 10 times, each time leaving one of the 10 groups out. By leaving out one of the 10 groups for each run, 9 of the 10 groups, which is 90 percent of the applicable measure scores, are used for each run of the clustering algorithm. The method results in 10 sets of measure-specific cut points. The mean cut point for each threshold per measure is calculated using the 10 values.

* * * * *

Restricted range is the difference between the maximum and minimum measure score values using the prior year measure scores excluding outer fence outliers (first quartile −3*Interquartile Range (IQR) and third quartile + 3*IQR).

Restricted range cap is a cap applied to non-CAHPS measures that restricts movement of the current year's measure-threshold-specific cut point to no more than the stated percentage of the restricted range of a measure calculated using the prior year's measure score distribution.

* * * * *

■ 12. Section 422.164 is amended by adding paragraphs (f)(1)(v), (g)(1)(iii)(O), and (h) to read as follows:

§ 422.164 Adding, updating, and removing measures.

* * * * *

(f) * * *

(1) * * *

(v) CMS excludes any measure that receives a measure-level Star Rating reduction for data integrity concerns for either the current or prior year from the improvement measure(s).

* * * * *

(g) * * *

(1) * * *

(iii) * * *

(O) CMS reduces the measure rating to 1 star for the applicable appeals measure(s) if a contract fails to submit Timeliness Monitoring Project data for CMS's review to ensure the completeness of the contract's IRE data.

* * * * *

(h) *Review of sponsors' data.* (1) An MA organization may request that CMS or the IRE review its' contract's appeals data provided that the request is received by the annual deadline set by CMS.

(2) An MA organization may request that CMS review its' contract's Complaints Tracking Module (CTM) data provided that the request is received by the annual deadline set by CMS for the applicable Star Ratings year.

■ 13. Section 422.166 is amended by revising paragraph (a)(2)(i) and adding paragraph (i) to read as follows:

§ 422.166 Calculation of Star Ratings.

(a) * * *

(2) * * *

(i) The method maximizes differences across the star categories and minimizes the differences within star categories using mean resampling with the hierarchal clustering of the current year's data, and a guardrail so that the measure-threshold-specific cut points for non-CAHPS measures do not increase or decrease more than the value of the cap from one year to the next. The cap is equal to 5 percentage points for measures having a 0 to 100 scale (absolute percentage cap) or 5 percent of the restricted range for measures not having a 0 to 100 scale (restricted range cap). New measures that have been in the Part C and D Star Rating program for three years or less use the hierarchal clustering methodology with mean resampling with no guardrail for the first three years in the program.

* * * * *

(i) *Extreme and uncontrollable circumstances.* In the event of extreme and uncontrollable circumstances that may negatively impact operational and clinical systems and contracts' abilities to conduct surveys needed for accurate performance measurement, CMS calculates the Star Ratings as specified in paragraphs (i)(2) through (10) of this section for each contract that is an affected contract during the performance period for the applicable measures. We use the start date of the incident period to determine which year of Star Ratings could be affected, regardless of whether the incident period lasts until another calendar year.

(1) *Identification of affected contracts.* A contract that meets all of the following criteria is an affected contract:

(i) The contract's service area is within an ''emergency area'' during an ''emergency period'' as defined in section 1135(g) of the Act.

(ii) The contract's service area is within a county, parish, U.S. territory or tribal area designated in a major disaster declaration under the Stafford Act and the Secretary exercised authority under section 1135 of the Act based on the same triggering event(s).

(iii) As specified in paragraphs (i)(2) through (10) of this section, a certain minimum percentage (25 percent or 60 percent) of the enrollees under the contract must reside in a Federal Emergency Management Agency (FEMA)-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance.

(2) *CAHPS adjustments.* (i) A contract, even if an affected contract, must administer the CAHPS survey unless exempt under paragraph (i)(2)(ii) of this section.

(ii) An affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance is exempt from administering the CAHPS survey if the contract completes both of the following:

(A) Demonstrates to CMS that the required sample for the survey cannot be contacted because a substantial number of the contract's enrollees are displaced due to the FEMA-designated disaster identified in paragraph (i)(1)(iii) of this section in the prior calendar year.

(B) Requests and receives a CMS approved exemption.

(iii) An affected contract with an exemption described in paragraph (i)(2)(ii) of this section receives the contract's CAHPS measure stars and corresponding measure scores from the prior year.

(iv) For an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance, the contract receives the higher of the previous year's Star Rating or the current year's Star Rating (and corresponding measure score) for each CAHPS measure.

(v) When a contract is an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance with regard to separate extreme and uncontrollable circumstances that begin in successive years, it is a multiple year-affected contract. A multiple year-affected contract receives the higher of the current year's Star Rating or what the previous year's Star Rating would have been in the absence of any adjustments that took into account the effects of the previous year's disaster for each measure (using the corresponding measure score for the Star Ratings year selected).

(3) *HOS adjustments.* (i) An affected contract must administer the HOS survey unless exempt under paragraph (i)(3)(ii) of this section.

(ii) An affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance is exempt from administering the HOS survey if the contract completes the following:

(A) Demonstrates to CMS that the required sample for the survey cannot be contacted because a substantial number of the contract's enrollees are displaced due to the FEMA-designated disaster identified in paragraph (i)(1)(iii) of this section during the measurement period.

(B) Requests and receives a CMS approved exemption.

(iii) Affected contracts with an exemption described in paragraph (i)(3)(ii) of this section receive the prior year's HOS and Healthcare Effectiveness Data and Information Set (HEDIS)-HOS measure stars and corresponding measure scores.

(iv) For an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance, the affected contract receives the higher of the previous year's Star Rating or the current year's Star Rating (and corresponding measure score) for each HOS and HEDIS–HOS measure.

(v) When a contract is an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance with regard to separate extreme and uncontrollable circumstances that begin in successive years, it is a multiple year-affected contract. A multiple year-affected contract receives the higher of the current year's Star Rating or what the previous year's Star Rating would have been in the absence of any adjustments that took into account the effects of the previous year's disaster for each measure (using the corresponding measure score for the Star Ratings year selected).

(4) *HEDIS adjustments.* (i) An affected contract must report HEDIS data unless exempted under paragraph (i)(4)(ii) of this section.

(ii) An affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance is exempt from reporting HEDIS data if the contract completes the following:

(A) Demonstrates an inability to obtain both administrative and medical record data that are required for reporting HEDIS measures due to a FEMA-designated disaster in the prior calendar year.

(B) Requests and receives a CMS approved exemption.

(iii) Affected contracts with an exemption described in paragraph

(i)(4)(ii) of this section receive the prior year's HEDIS measure stars and corresponding measure scores.

(iv) Contracts that do not have an exemption defined in paragraph (i)(4)(ii) of this section may contact National Committee for Quality Assurance (NCQA) to request modifications to the samples for measures that require medical record review.

(v) For an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance, the affected contract receives the higher of the previous year's Star Rating or the current year's Star Rating (and corresponding measure score) for each HEDIS measure.

(vi) When a contract is an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance with regard to separate extreme and uncontrollable circumstances that begin in successive years, it is a multiple year-affected contract. A multiple year-affected contract receives the higher of the current year's Star Rating or what the previous year's Star Rating would have been in the absence of any adjustments that took into account the effects of the previous year's disaster for each measure (using the corresponding measure score for the Star Ratings year selected).

(5) *New measure adjustments.* For affected contracts with at least 25 percent of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance, CMS holds the affected contract harmless by using the higher of the contract's summary or overall rating or both with and without including all of the applicable new measures.

(6) *Other Star Ratings measure adjustments.* (i) For all other measures except those measures identified in this paragraph (i)(6)(ii) of this section, affected contracts with at least 25 percent of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance receive the higher of the previous or current year's measure Star Rating (and corresponding measure score).

(ii) CMS does not adjust the scores or Star Ratings for the following measures, unless the exemption in paragraph (i)(6)(iii) of this section applies.

(A) Part C Call Center—Foreign Language Interpreter and TTY Availability.

(B) Part D Call Center—Foreign Language Interpreter and TTY Availability.

(iii) CMS adjusts the measures listed in paragraph (i)(6)(ii) of this section using the adjustments listed in paragraph (i)(6)(i) of this section for contracts affected by extreme and uncontrollable circumstances where there are continuing communications issues related to loss of electricity and damage to infrastructure during the call center study.

(iv) When a contract is an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance with regard to separate extreme and uncontrollable circumstances that begin in successive years, it is a multiple year-affected contract. A multiple year-affected contract receives the higher of the current year's Star Rating or what the previous year's Star Rating would have been in the absence of any adjustments that took into account the effects of the previous year's disaster for each measure (using the corresponding measure score for the Star Ratings year selected).

(7) *Exclusion from improvement measures.* Any measure that reverts back to the data underlying the previous year's Star Rating due to the adjustments made in paragraph (i) of this section is excluded from both the count of measures and the applicable improvement measures for the current and next year's Star Ratings for the affected contract. Contracts affected by extreme and uncontrollable circumstances do not have the option of reverting to the prior year's improvement rating.

(8) *Missing data.* For an affected contract that has missing data in the current or previous year, the final measure rating comes from the current year unless any of the exemptions described in paragraphs (i)(2)(ii), (i)(3)(ii), and (i)(4)(ii) of this section apply.

(9) *Cut points for non-CAHPS measures.* (i) CMS excludes the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the clustering algorithms described in paragraph (a)(2) of this section.

(ii) The cut points calculated as described in paragraph (i)(9)(i) of this section are used to assess all affected contracts' measure Star Ratings.

(10) *Reward Factor.* (i) CMS excludes the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the determination of the performance summary and variance thresholds for the Reward Factor described in paragraph (f)(1) of this section.

(ii) All affected contracts are eligible for the Reward Factor based on the calculations described in paragraph (i)(10)(i) of this section.

■ 14. Effective June 17, 2019, § 422.222 is amended by revising paragraph (a)(2) to read as follows:

§ 422.222 Preclusion list.

(a) * * *

(2)(i) CMS sends written notice to the individual or entity via letter of their inclusion on the preclusion list. The notice must contain the reason for the inclusion and inform the individual or entity of their appeal rights. An individual or entity may appeal their inclusion on the preclusion list, defined in § 422.2, in accordance with part 498 of this chapter.

(ii) If the individual's or entity's inclusion on the preclusion list is based on a contemporaneous Medicare revocation under § 424.535 of this chapter:

(A) The notice described in paragraph (a)(2)(i) of this section must also include notice of the revocation, the reason(s) for the revocation, and a description of the individual's or entity's appeal rights concerning the revocation.

(B) The appeals of the individual's or entity's inclusion on the preclusion list and the individual's or entity's revocation must be filed jointly by the individual or entity and, as applicable, considered jointly under part 498 of this chapter.

■ 15. Section 422.222 is amended by revising the section heading and paragraph (a) to read as follows:

§ 422.222 Preclusion list for contracted and non-contracted individuals and entities.

(a)(1)(i) Except as provided in paragraph (a)(1)(ii) of this section, an MA organization must not make payment for a health care item, service, or drug that is furnished, ordered, or prescribed by an individual or entity that is included on the preclusion list, defined in § 422.2.

(ii) With respect to MA providers that have been added to an updated preclusion list but are not currently excluded by the OIG, the MA organization must do all of the following:

(A) No later than 30 days after the posting of this updated preclusion list,

must provide an advance written notice to any beneficiary who has received or been prescribed an MA service, item, or drug from or by the individual or entity added to the preclusion list in this update.

(B)(*1*) Subject to paragraph (a)(1)(ii)(B)(*2*) of this section, must ensure that reasonable efforts are made to notify the individual or entity described in paragraph (a)(1)(ii) of this section of a beneficiary who was sent a notice under paragraph (a)(1)(ii)(A) of this section.

(*2*) Paragraph (a)(1)(ii)(B)(*1*) of this section applies only upon receipt of a claim from a precluded provider in Medicare Part C when—

(*i*) The MA organization has enough information on file to either copy the provider on the notification previously sent to the beneficiary or send a new notice informing the provider that they may not see plan beneficiaries due to their preclusion status; and

(*ii*) The claim is received after the claim denial or reject date in the preclusion file.

(C) Must not deny payment for a service, item, or drug furnished, ordered, or prescribed by the newly added individual or entity, solely on the ground that they have been included in the updated preclusion list, in the 60-day period after the date it sent the notice described in paragraph (a)(1)(ii)(A) of this section.

(2)(i) CMS sends written notice to the individual or entity via letter of their inclusion on the preclusion list. The notice must contain the reason for the inclusion and inform the individual or entity of their appeal rights. An individual or entity may appeal their inclusion on the preclusion list, defined in § 422.2, in accordance with part 498 of this chapter.

(ii) If the individual's or entity's inclusion on the preclusion list is based on a contemporaneous Medicare revocation under § 424.535 of this chapter:

(A) The notice described in paragraph (a)(2)(i) of this section must also include notice of the revocation, the reason(s) for the revocation, and a description of the individual's or entity's appeal rights concerning the revocation.

(B) The appeals of the individual's or entity's inclusion on the preclusion list and the individual's or entity's revocation must be filed jointly by the individual or entity and, as applicable, considered jointly under part 498 of this chapter.

(3)(i) Except as provided in paragraph (a)(3)(ii) of this section, an individual or entity will only be included on the preclusion list after the expiration of either of the following:

(A) If the individual or entity does not file a reconsideration request under § 498.5(n)(1) of this chapter, the individual or entity will be added to the preclusion list upon the expiration of the 60-day period in which the individual or entity may request a reconsideration; or

(B) If the individual or entity files a reconsideration request under § 498.5(n)(1) of this chapter, the individual or entity will be added to the preclusion list effective on the date on which CMS, if applicable, denies the individual's or entity's reconsideration.

(ii) An OIG excluded individual or entity is added to the preclusion list effective on the date of the exclusion.

(4) Payment denials based upon an individual's or entity's inclusion on the preclusion list are not appealable by beneficiaries.

(5)(i) Except as provided in paragraphs (a)(5)(iii) and (iv) of this section, an individual or entity that is revoked under § 424.535 of this chapter will be included on the preclusion list for the same length of time as the individual's or entity's reenrollment bar.

(ii) Except as provided in paragraphs (a)(5)(iii) and (iv) of this section, an individual or entity that is not enrolled in Medicare will be included on the preclusion list for the same length of time as the reenrollment bar that CMS could have imposed on the individual or entity had they been enrolled and then revoked.

(iii) Except as provided in paragraph (a)(5)(iv) of this section, an individual or entity, regardless of whether they are or were enrolled in Medicare, that is included on the preclusion list because of a felony conviction will remain on the preclusion list for a 10-year period, beginning on the date of the felony conviction, unless CMS determines that a shorter length of time is warranted. Factors that CMS considers in making such a determination are as follows:—

(A) The severity of the offense.

(B) When the offense occurred.

(C) Any other information that CMS deems relevant to its determination.

(iv) In cases where an individual or entity is excluded by the OIG, the individual or entity must remain on the preclusion list until the expiration of the CMS-imposed preclusion list period or reinstatement by the OIG, whichever occurs later.

(6) CMS has the discretion not to include a particular individual or entity on (or if warranted, remove the individual or entity from) the preclusion list should it determine that exceptional circumstances exist regarding beneficiary access to MA items, services, or drugs. In making a determination as to whether such circumstances exist, CMS takes into account:

(i) The degree to which beneficiary access to MA items, services, or drugs would be impaired; and

(ii) Any other evidence that CMS deems relevant to its determination.

* * * * *

■ 16. Section 422.252 is amended by revising the definition of ''MA monthly basic beneficiary premium'', ''MA monthly MSA premium'', ''Monthly aggregate bid amount'', ''Plan basic cost sharing'', and ''Unadjusted MA statutory non-drug monthly bid amount'' to read as follows:

§ 422.252 Terminology.

* * * * *

MA monthly basic beneficiary premium means the premium amount (if any) an MA plan (except an MSA plan) charges an enrollee for basic benefits as defined in § 422.100(c)(1), and is calculated as described at § 422.262.

MA monthly MSA premium means the amount of the plan premium for coverage of basic benefits as defined in § 422.100(c)(1) through an MSA plan, as set forth at § 422.254(e).

* * * * *

Monthly aggregate bid amount means the total monthly plan bid amount for coverage of an MA eligible beneficiary with a nationally average risk profile for the factors described in § 422.308(c), and this amount is comprised of the following:

(1) The unadjusted MA statutory non-drug monthly bid amount for coverage of basic benefits as defined in § 422.100(c)(1).

(2) The amount for coverage of basic prescription drug benefits under Part D (if any).

(3) The amount for provision of supplemental health care benefits (if any).

* * * * *

Plan basic cost sharing means cost sharing that would be charged by a plan for basic benefits as defined in § 422.100(c)(1) before any reductions resulting from mandatory supplemental benefits.

* * * * *

Unadjusted MA statutory non-drug monthly bid amount means a plan's estimate of its average monthly required revenue to provide coverage of basic benefits as defined in § 422.100(c)(1) to an MA eligible beneficiary with a nationally average risk profile for the

risk factors CMS applies to payment calculations as set forth at § 422.308(c).

■ 17. Section 422.254 is amended by—
■ a. Revising paragraph (b)(1)(i);
■ b. Adding paragraph (b)(3)(i);
■ c. Reserving paragraph (b)(3)(ii); and
■ d. Revising paragraphs (b)(4), (c)(3)(i), and (e)(2).

The revisions and addition read as follows:

§ 422.254 Submission of bids.

* * * * *

(b) * * *

(1) * * *

(i) The unadjusted MA statutory non-drug monthly bid amount, which is the MA plan's estimated average monthly required revenue for providing basic benefits as defined in § 422.100(c)(1).

* * * * *

(3) * * *

(i) MA plans offering additional telehealth benefits as defined in § 422.135(a) must exclude any capital and infrastructure costs and investments directly incurred or paid by the MA plan relating to such benefits from their bid submission for the unadjusted MA statutory non-drug monthly bid amount.

(ii) [Reserved]

(4) The bid amount is for plan payments only but must be based on plan assumptions about the amount of revenue required from enrollee cost-sharing. The estimate of plan cost-sharing for the unadjusted MA statutory non-drug monthly bid amount for coverage of basic benefits as defined in § 422.100(c)(1) must reflect the requirement that the level of cost sharing MA plans charge to enrollees must be actuarially equivalent to the level of cost sharing (deductible, copayments, or coinsurance) charged to beneficiaries under the original Medicare fee-for-service program option. The actuarially equivalent level of cost sharing reflected in a regional plan's unadjusted MA statutory non-drug monthly bid amount does not include cost sharing for out-of-network Medicare benefits, as described at § 422.101(d).

* * * * *

(c) * * *

(3) * * *

(i) The provision of basic benefits as defined in § 422.100(c)(1);

* * * * *

(e) * * *

(2) The amount of the MA monthly MSA premium for basic benefits (as defined in § 422.252);

* * * * *

■ 18. Section 422.264 is amended by revising paragraph (a) to read as follows:

§ 422.264 Calculation of savings.

(a) *Computation of risk adjusted bids and benchmarks*—(1) *The risk adjusted MA statutory non-drug monthly bid amount* is the unadjusted MA statutory non-drug monthly bid amount (defined at § 422.254(b)(1)(i)), adjusted using the factors described in paragraph (c) of this section for local plans and paragraph (e) of this section for regional plans.

(2) The *risk adjusted MA area-specific non-drug monthly benchmark amount* is the unadjusted benchmark amount for coverage of basic benefits defined in § 422.100(c)(1) by a local MA plan, adjusted using the factors described in paragraph (c) of this section.

(3) The *risk adjusted MA region-specific non-drug monthly benchmark amount* is the unadjusted benchmark amount for coverage of basic benefits defined in § 422.100(c)(1) by a regional MA plan, adjusted using the factors described in paragraph (e) of this section.

* * * * *

■ 19. Section 422.504 is amended by adding paragraphs (g)(1)(iv) and (v) to read as follows:

§ 422.504 Contract provisions.

* * * * *

(g) * * *

(1) * * *

(iv) Ensure that the enrollee does not have any financial liability for services, items, or drugs furnished, ordered, or prescribed to the enrollee by an MA contracted individual or entity on the preclusion list, as defined in § 422.2 and as described in § 422.222.

(v) Ensure that the plan's provider agreement contains a provision stating that after the expiration of the 60-day period specified in § 422.222:

(A) The provider will no longer be eligible for payment from the plan and will be prohibited from pursuing payment from the beneficiary as stipulated by the terms of the contract between CMS and the plan per § 422.504(g)(1)(iv); and

(B) The provider will hold financial liability for services, items, and drugs that are furnished, ordered, or prescribed after this 60-day period, at which point the provider and the beneficiary will have already received notification of the preclusion.

* * * * *

■ 20. Effective January 1, 2021, § 422.560 is amended by adding paragraphs (a)(4) and (b)(5) to read as follows:

§ 422.560 Basis and scope.

(a) * * *

(4) Section 1859(f)(8) of the Act provides for, to the extent feasible, unifying grievances and appeals procedures under sections 1852(f), 1852(g), 1902(a)(3), 1902(a)(5), and 1932(b)(4) of the Act for Medicare and Medicaid covered items and services provided by specialized MA plans for special needs individuals described in subsection 1859(b)(6)(B)(ii) of the Act for individuals who are eligible under titles XVIII and XIX of the Act. Beginning January 1, 2021, procedures established under section 1859(f)(8) of the Act apply in place of otherwise applicable grievances and appeals procedures with respect to Medicare and Medicaid covered items and services provided by applicable integrated plans.

(b) * * *

(5) Requirements for applicable integrated plans with respect to procedures for integrated grievances, integrated organization determinations, and integrated reconsiderations.

* * * * *

■ 21. Section 422.561 is amended by adding the definitions ''Applicable integrated plans'', ''Integrated appeal'', ''Integrated grievance'', ''Integrated organization determination'', and ''Integrated reconsideration'' in alphabetical order to read as follows:

§ 422.561 Definitions.

* * * * *

Applicable integrated plan means:

(1) A fully integrated dual eligible special needs plan with exclusively aligned enrollment or a highly integrated dual eligible special needs plan with exclusively aligned enrollment, and

(2) The Medicaid managed care organization, as defined in section 1903(m) of the Act, through which such dual eligible special needs plan, its parent organization, or another entity that is owned and controlled by its parent organization covers Medicaid services for dually eligible individuals enrolled in such dual eligible special needs plan and such Medicaid managed care organization.

* * * * *

Integrated appeal means any of the procedures that deal with, or result from, adverse integrated organization determinations by an applicable integrated plan on the health care services the enrollee believes he or she is entitled to receive, including delay in providing, arranging for, or approving the health care services (such that a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for a service. Integrated appeals cover procedures that would otherwise be defined and

covered, for non-applicable integrated plans, as an appeal defined in § 422.561 or the procedures required for appeals in accordance with §§ 438.400 through 438.424 of this chapter. Such procedures include integrated reconsiderations.

Integrated grievance means a dispute or compliant that would be defined and covered, for grievances filed by an enrollee in non-applicable integrated plans, under § 422.564 or §§ 438.400 through 438.416 of this chapter. Integrated grievances do not include appeals procedures and QIO complaints, as described in § 422.564(b) and (c). An integrated grievance made by an enrollee in an applicable integrated plan is subject to the integrated grievance procedures in §§ 422.629 and 422.630.

Integrated organization determination means an organization determination that would otherwise be defined and covered, for a non-applicable integrated plan, as an organization determination under § 422.566, an adverse benefit determination under § 438.400(b), or an action under § 431.201 of this chapter. An integrated organization determination is made by an applicable integrated plan and is subject to the integrated organization determination procedures in §§ 422.629, 422.631, and 422.634.

Integrated reconsideration means a reconsideration that would otherwise be defined and covered, for a non-applicable integrated plan, as a reconsideration under § 422.580 and appeal under § 438.400(b) of this chapter. An integrated reconsideration is made by an applicable integrated plan and is subject to the integrated reconsideration procedures in §§ 422.629 and 422.632 through 422.634.

* * * * *

■ 22. Section 422.562 is amended by—
■ a. Revising paragraph (a)(1)(i);
■ b. By adding paragraph (a)(5); and
■ c. By revising paragraphs (b)(1), (b)(2), (b)(3), (b)(4)(i), and (b)(4)(ii).

The revisions and addition read as follows:

§ 422.562 General provisions.

(a) * * *

(1) * * *

(i) A grievance procedure as described in § 422.564 or, beginning January 1, 2021, § 422.630 as applicable, for addressing issues that do not involve organization determinations;

* * * * *

(5) An MA organization that offers a dual eligible special needs plan has the following additional responsibilities:

(i) The dual eligible special needs plan must offer to assist an enrollee in that dual eligible special needs plan with obtaining Medicaid covered services and resolving grievances, including requesting authorization of Medicaid services, as applicable, and navigating Medicaid appeals and grievances in connection with the enrollee's own Medicaid coverage, regardless of whether such coverage is in Medicaid fee-for-service or a Medicaid managed care plan, such as a Medicaid MCO, PIHP, or PAHP as defined in § 438.2 of this chapter. If the enrollee accepts the offer of assistance, the plan must provide the assistance. Examples of such assistance include the following:

(A) Explaining to an enrollee how to make a request for Medicaid authorization of a service and how to file appeal following an adverse benefit determination, such as—

(*1*) Assisting the enrollee in identifying the enrollee's specific Medicaid managed care plan or fee-for-service point of contact;

(*2*) Providing specific instructions for contacting the appropriate agency in a fee-for-service setting or for contacting the enrollee's Medicaid managed care plan, regardless of whether the Medicaid managed care plan is affiliated with the enrollee's dual eligible special needs plan; and

(*3*) Assisting the enrollee in making contact with the enrollee's fee-for-service contact or Medicaid managed care plan.

(B) Assisting a beneficiary in filing a Medicaid grievance or a Medicaid appeal.

(C) Assisting an enrollee in obtaining documentation to support a request for authorization of Medicaid services or a Medicaid appeal.

(ii) The dual eligible special needs plan must offer to provide the assistance described in paragraph (a)(5)(i) of this section whenever it becomes aware of an enrollee's need for a Medicaid-covered service. Offering such assistance is not dependent on an enrollee's specific request.

(iii) The dual eligible special needs plan must offer to provide and actually provide assistance as required by paragraph (a)(5)(i) of this section using multiple methods.

(A) When an enrollee accepts the offer of assistance described in paragraph (a)(5)(i) of this section, the dual eligible special needs plan may coach the enrollee on how to self-advocate.

(B) The dual eligible special needs plan must also provide an enrollee reasonable assistance in completing forms and taking procedural steps related to Medicaid grievances and appeals.

(iv) The dual eligible special needs plan must, upon request from CMS, provide documentation demonstrating its compliance with this paragraph (a)(5).

(v) The obligation to provide assistance under paragraph (a)(5)(i) of this section does not create an obligation for a dual eligible special needs plan to represent an enrollee in a Medicaid appeal.

(b) * * *

(1) The right to have grievances between the enrollee and the MA organization heard and resolved, as described in § 422.564 or, beginning January 1, 2021, § 422.630, as applicable.

(2) The right to a timely organization determination, as provided under § 422.566 or, beginning January 1, 2021, § 422.631, as applicable.

(3) The right to request an expedited organization determination, as provided under §§ 422.570 or, beginning January 1, 2021, § 422.631(e), as applicable.

(4) * * *

(i) The right to a reconsideration of the adverse organization determination by the MA organization, as provided under § 422.578 or, beginning January 1, 2021, § 422.633, as applicable.

(ii) The right to request an expedited reconsideration, as provided under § 422.584 or, beginning January 1, 2021, § 422.633(f), as applicable.

* * * * *

■ 23. Effective January 1, 2021, § 422.566 is amended by revising paragraph (a) to read as follows:

§ 422.566 Organization determinations.

(a) *Responsibilities of the MA organization.* Each MA organization must have a procedure for making timely organization determinations (in accordance with the requirements of this subpart) regarding the benefits an enrollee is entitled to receive under an MA plan, including basic benefits as described under § 422.100(c)(1) and mandatory and optional supplemental benefits as described under § 422.102, and the amount, if any, that the enrollee is required to pay for a health service. The MA organization must have a standard procedure for making determinations, in accordance with § 422.568, and an expedited procedure for situations in which applying the standard procedure could seriously jeopardize the enrollee's life, health, or ability to regain maximum function, in accordance with §§ 422.570 and 422.572. For an applicable integrated plan, beginning January 1, 2021, the MA

organization must comply with §§ 422.629 through 422.634 in lieu of §§ 422.566(c) and (d), 422.568, 422.570 and 422.572 with regard to the procedures for making determinations, including integrated organization determinations and integrated reconsiderations, on a standard and expedited basis.

* * * * *

■ 24. Effective January 1, 2021, add an undesignated center heading and §§ 422.629 through 422.634 to Subpart M to read as follows:

Subpart M—Grievances, Organization Determinations and Appeals

* * * * *

Requirements Applicable to Certain Integrated Dual Eligible Special Needs Plans

Sec.

422.629 General requirements for applicable integrated plans.
422.630 Integrated grievances.
422.631 Integrated organization determinations.
422.632 Continuation of benefits while the applicable integrated plan reconsideration is pending.
422.633 Integrated reconsideration.
422.634 Effect.

Requirements Applicable to Certain Integrated Dual Eligible Special Needs Plans

§ 422.629 General requirements for applicable integrated plans.

(a) *Scope.* The provisions in this section and in §§ 422.630 through 422.634 set forth requirements for unified appeals and grievance processes with which applicable integrated plans must comply. Beginning January 1, 2021, these provisions apply to an applicable integrated plan in lieu of §§ 422.564, 422.566(c) and (d), and 422.568 through 422.590, and 422.618(a) and §§ 438.404 through 438.424 of this chapter.

(b) *General process.* An applicable integrated plan must create integrated processes for enrollees for integrated grievances, integrated organization determinations, and integrated reconsiderations.

(c) *State flexibilities.* A State may, at its discretion, implement standards for timeframes or notice requirements that are more protective for the enrollee than required by this section and §§ 422.630 through 422.634. The contract under § 422.107 must include any standards that differ from the standards set forth in this section.

(d) *Evidence.* The applicable integrated plan must provide the enrollee a reasonable opportunity, in person and in writing, to present evidence and testimony and make legal and factual arguments for integrated grievances, and integrated reconsiderations. The applicable integrated plan must inform the enrollee of the limited time available for presenting evidence sufficiently in advance of the resolution timeframe for appeals as specified in this section if the case is being considered under an expedited timeframe for the integrated grievance or integrated reconsideration.

(e) *Assistance.* In addition to the requirements in § 422.562(a)(5), the applicable integrated plan must provide an enrollee reasonable assistance in completing forms and taking other procedural steps related to integrated grievances and integrated appeals.

(f) *Applicable requirements.* The requirements in §§ 422.560, 422.561, 422.562, 422.566, and 422.592 through 422.626 apply to an applicable integrated plan unless otherwise provided in this section or in §§ 422.630 through 422.634.

(g) *Acknowledgement.* The applicable integrated plan must send to the enrollee written acknowledgement of integrated grievances and integrated reconsiderations upon receiving the request.

(h) *Recordkeeping.* (1) The applicable integrated plan must maintain records of integrated grievances and integrated appeals. Each applicable integrated plan that is a Medicaid managed care organization must review the Medicaid-related information as part of its ongoing monitoring procedures, as well as for updates and revisions to the State quality strategy.

(2) The record of each integrated grievance or integrated appeal must contain, at a minimum:

(i) A general description of the reason for the integrated appeal or integrated grievance.

(ii) The date of receipt.

(iii) The date of each review or, if applicable, review meeting.

(iv) Resolution at each level of the integrated appeal or integrated grievance, if applicable.

(v) Date of resolution at each level, if applicable.

(vi) Name of the enrollee for whom the integrated appeal or integrated grievance was filed.

(vii) Date the applicable integrated plan notified the enrollee of the resolution.

(3) The record of each integrated grievance or integrated appeal must be accurately maintained in a manner accessible to the State and available upon request to CMS.

(i) *Prohibition on punitive action.* Each applicable integrated plan must ensure that no punitive action is taken against a provider that requests an integrated organization determination or integrated reconsideration, or supports an enrollee's request for these actions.

(j) *Information to providers and subcontractors.* The applicable integrated plan must provide information about the integrated grievance and integrated appeal system to all providers and subcontractors at the time they enter into a contract including, at minimum, information on integrated grievance, integrated reconsideration, and fair hearing procedures and timeframes as applicable. Such information must include the following:

(1) The right to file an integrated grievance and integrated reconsideration.

(2) The requirements and timeframes for filing an integrated grievance or integrated reconsideration.

(3) The availability of assistance in the filing process.

(k) *Review decision-making requirements*—(1) *General rules.* Individuals making decisions on integrated appeals and grievances must take into account all comments, documents, records, and other information submitted by the enrollee or their representative without regard to whether such information was submitted or considered in the initial adverse integrated organization determination.

(2) *Integrated grievances.* Individuals making decisions on integrated grievances must be individuals who—

(i) Were neither involved in any previous level of review or decision-making nor a subordinate of any such individual; and

(ii) If deciding any of the following, have the appropriate clinical expertise in treating the enrollee's condition or disease:

(A) A grievance regarding denial of expedited resolution of an appeal.

(B) A grievance that involves clinical issues.

(3) *Integrated organization determinations.* If the applicable integrated plan expects to issue a partially or fully adverse medical necessity (or any substantively equivalent term used to describe the concept of medical necessity) decision based on the initial review of the request, the integrated organization determination must be reviewed by a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare and Medicaid

coverage criteria, before the applicable integrated plan issues the integrated organization determination. Any physician or other health care professional who reviews an integrated organization determination must have a current and unrestricted license to practice within the scope of his or her profession.

(4) *Integrated reconsideration determinations.* Individuals making an integrated reconsideration determination must be individuals who—

(i) Were neither involved in any previous level of review or decision-making nor a subordinate of any such individual; and

(ii) If deciding an appeal of a denial that is based on lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), are a physician or other appropriate health care professional who have the appropriate clinical expertise, in treating the enrollee's condition or disease, and knowledge of Medicare coverage criteria, before the MA organization issues the organization determination decision.

(l) *Parties.* (1) The following individuals or entities can request an integrated grievance, integrated organization determination, and integrated reconsideration, and are parties to the case:

(i) The enrollee or his or her representative;

(ii) An assignee of the enrollee (that is, a physician or other provider who has furnished or intends to furnish a service to the enrollee and formally agrees to waive any right to payment from the enrollee for that service), or any other provider or entity (other than the applicable integrated plan) who has an appealable interest in the proceeding;

(iii) The legal representative of a deceased enrollee's estate; or

(iv) Subject to paragraph (l)(3) of this section, any provider that furnishes, or intends to furnish, services to the enrollee. If the provider requests that the benefits continue while the appeal is pending, pursuant to § 422.632 and consistent with State law, the provider must obtain the written consent of the enrollee to request the appeal on behalf of the enrollee.

(2) When the term ''enrollee'' is used throughout §§ 422.629 through 422.634, it includes providers that file a request and authorized representatives consistent with this paragraph, unless otherwise specified.

(3) A provider who is providing treatment to the enrollee may, upon providing notice to the enrollee, request a standard or expedited pre-service integrated reconsideration on behalf of an enrollee.

§ 422.630 Integrated grievances.

(a) *General rule.* In lieu of complying with § 422.564, and the grievance requirements of §§ 438.402, 438.406, 438.408, 438.414, and 438.416 of this chapter, each applicable integrated plan must comply with this section. Each applicable integrated plan must provide meaningful procedures for timely hearing and resolving integrated grievances between enrollees and the applicable integrated plan or any other entity or individual through which the applicable integrated plan provides covered items and services.

(b) *Timing.* An enrollee may file an integrated grievance at any time with the applicable integrated plan.

(c) *Filing.* An enrollee may file an integrated grievance orally or in writing with the applicable integrated plan, or with the State for an integrated grievance related to a Medicaid benefit, if the State has a process for accepting Medicaid grievances.

(d) *Expedited grievances.* An applicable integrated plan must respond to an enrollee's grievance within 24 hours if the complaint involves the applicable integrated plan's—

(1) Decision to invoke an extension relating to an integrated organization determination or integrated reconsideration; or

(2) Refusal to grant an enrollee's request for an expedited integrated organization determination under § 422.631 or expedited integrated reconsideration under § 422.633.

(e) *Resolution and notice.* (1) The applicable integrated plan must resolve standard integrated grievances as expeditiously as the case requires, based on the enrollee's health status, but no later than 30 calendar days from the date it receives the integrated grievance.

(i) All integrated grievances submitted in writing must be responded to in writing.

(ii) Integrated grievances submitted orally may be responded to either orally or in writing, unless the enrollee requests a written response.

(iii) All integrated grievances related to quality of care, regardless of how the integrated grievance is filed, must be responded to in writing. The response must include a description of the enrollee's right to file a written complaint with the QIO with regard to Medicare covered services. For any complaint submitted to a QIO, the applicable integrated plan must cooperate with the QIO in resolving the complaint.

(2) The timeframe for resolving the integrated grievance may be extended by 14 calendar days if the enrollee requests an extension or if the applicable integrated plan justifies the need for additional information and documents how the delay is in the interest of the enrollee. When the applicable integrated plan extends the timeframe, it must—

(i) Make reasonable efforts to promptly notify the enrollee orally of the reasons for the delay; and

(ii) Send written notice to the enrollee of the reasons for the delay immediately, but no later than within 2 calendar days of making the decision to extend the timeframe to resolve the integrated grievance. This notice must explain the right to file an integrated grievance if the enrollee disagrees with the decision to delay.

§ 422.631 Integrated organization determinations.

(a) *General rule.* An applicable integrated plan must adopt and implement a process for enrollees to request that the plan make an integrated organization determination. The process for requesting that the applicable integrated plan make an integrated organization determination must be the same for all covered benefits.

(b) *Requests.* The enrollee, or a provider on behalf of an enrollee, may request an integrated organization determination orally or in writing, except for requests for payment, which must be in writing (unless the applicable integrated plan or entity responsible for making the determination has implemented a voluntary policy of accepting verbal payment requests).

(c) *Expedited integrated organization determinations.* (1) An enrollee, or a provider on behalf of an enrollee, may request an expedited integrated organization determination.

(2) The request can be oral or in writing.

(3) The applicable integrated plan must complete an expedited integrated organization determination when the applicable integrated plan determines (based on a request from the enrollee or on its own) or the provider indicates (in making the request on the enrollee's behalf or supporting the enrollee's request) that taking the time for a standard resolution could seriously jeopardize the enrollee's life, physical or mental health, or ability to attain, maintain, or regain maximum function.

(d) *Timeframes and notice*—(1) *Integrated organization determination notice.* (i) The applicable integrated plan must send an enrollee a written

notice of any adverse decision on an integrated organization determination (including a determination to authorize a service or item in an amount, duration, or scope that is less than the amount previously requested or authorized for an ongoing course of treatment) within the timeframes set forth in this section.

(ii) For an integrated organization determination not reached within the timeframes specified in this section (which constitutes a denial and is thus an adverse decision), the applicable integrated plan must send a notice on the date that the timeframes expire. Such notice must describe all applicable Medicare and Medicaid appeal rights.

(iii) Integrated organization determination notices must be written in plain language, be available in a language and format that is accessible to the enrollee, and explain the following:

(A) The applicable integrated plan's determination.

(B) The date the determination was made.

(C) The date the determination will take effect.

(D) The reasons for the determination.

(E) The enrollee's right to file an integrated reconsideration and the ability for someone else to file an appeal on the enrollee's behalf.

(F) Procedures for exercising enrollee's rights to an integrated reconsideration.

(G) Circumstances under which expedited resolution is available and how to request it.

(H) If applicable, the enrollee's rights to have benefits continue pending the resolution of the integrated appeal process.

(2) *Timing of notice*—(i) *Standard integrated organization determinations.* (A) The applicable integrated plan must send a notice of its integrated organization determination at least 10 days before the date of action (that is, before the date on which a termination, suspension, or reduction becomes effective), in cases where a previously approved service is being reduced, suspended, or terminated, except in circumstances where an exception is permitted under §§ 431.213 and 431.214 of this chapter.

(B) For other integrated organization determinations that are not expedited integrated organization determinations, the applicable integrated plan must send a notice of its integrated organization determination as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days from when it receives the request for the integrated organization determination.

(ii) *Extensions.* The applicable integrated plan may extend the timeframe for a standard or expedited integrated organization determination by up to 14 calendar days if—

(A) The enrollee or provider requests the extension; or

(B) The applicable integrated plan can show that—

(*1*) The extension is in the enrollee's interest; and

(*2*) There is need for additional information and there is a reasonable likelihood that receipt of such information would lead to approval of the request, if received.

(iii) *Notices in cases of extension.* (A) When the applicable integrated plan extends the timeframe, it must notify the enrollee in writing of the reasons for the delay as expeditiously as the enrollee's health condition requires but no later than upon expiration of the extension, and inform the enrollee of the right to file an expedited integrated grievance if he or she disagrees with the applicable integrated plan's decision to grant an extension.

(B) If the applicable integrated plan extends the timeframe for making its integrated organization determination, it must send the notice of its determination as expeditiously as the enrollee's health condition requires and no later than the date the extension expires.

(iv) *Expedited integrated organization determinations.* (A) The applicable integrated plan must provide notice of its expedited integrated organization determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request.

(B) If the applicable integrated plan denies the request for an expedited integrated organization determination, it must:

(*1*) Automatically transfer a request to the standard timeframe and make the determination within the 14-day timeframe established in this paragraph for a standard integrated organization determination. The 14-day period begins with the day the applicable integrated plan receives the request for expedited integrated organization determination.

(*2*) Give the enrollee prompt oral notice of the denial and transfer and subsequently deliver, within 3 calendar days, a written letter that—

(*i*) Explains that the applicable integrated plan will process the request using the 14-day timeframe for standard integrated organization determinations;

(*ii*) Informs the enrollee of the right to file an expedited integrated grievance if he or she disagrees with the applicable integrated plan's decision not to expedite;

(*iii*) Informs the enrollee of the right to resubmit a request for an expedited integrated organization determination with any physician's support; and

(*iv*) Provides instructions about the integrated grievance process and its timeframes.

(C) If the applicable integrated plan must receive medical information from noncontract providers, the applicable integrated plan must request the necessary information from the noncontract provider within 24 hours of the initial request for an expedited integrated organization determination. Noncontract providers must make reasonable and diligent efforts to expeditiously gather and forward all necessary information to assist the applicable integrated plan in meeting the required timeframe. Regardless of whether the applicable integrated plan must request information from noncontract providers, the applicable integrated plan is responsible for meeting the timeframe and notice requirements of this section.

§ 422.632 Continuation of benefits while the applicable integrated plan reconsideration is pending.

(a) *Definition.* As used in this section, timely files means files for continuation of benefits on or before the later of the following:

(1) Within 10 calendar days of the applicable integrated plan sending the notice of adverse integrated organization determination.

(2) The intended effective date of the applicable integrated plan's proposed adverse integrated organization determination.

(b) *Continuation of benefits.* The applicable integrated plan must continue the enrollee's benefits under Parts A and B of title XVIII and title XIX if all of the following occur:

(1) The enrollee files the request for an integrated appeal timely in accordance with § 422.633(e);

(2) The integrated appeal involves the termination, suspension, or reduction of previously authorized services;

(3) The services were ordered by an authorized provider;

(4) The period covered by the original authorization has not expired; and

(5) The enrollee timely files for continuation of benefits.

(c) *Duration of continued or reinstated benefits.* If, at the enrollee's request, the applicable integrated plan continues or reinstates the enrollee's benefits, as described in paragraph (b) of this section, while the integrated reconsideration is pending, the benefits must be continued until—

(1) The enrollee withdraws the request for an integrated reconsideration;

(2) The applicable integrated plan issues an integrated reconsideration that is unfavorable to the enrollee related to the benefit that has been continued;

(3) For an appeal involving Medicaid benefits—

(i) The enrollee fails to file a request for a State fair hearing and continuation of benefits, within 10 calendar days after the applicable integrated plan sends the notice of the integrated reconsideration;

(ii) The enrollee withdraws the appeal or request for a State fair hearing; or

(iii) A State fair hearing office issues a hearing decision adverse to the enrollee.

(d) *Recovery of costs.* In the event the appeal or State fair hearing is adverse to the enrollee—

(1) The applicable integrated plan or State agency may not pursue recovery for costs of services furnished by the applicable integrated plan pending the integrated reconsideration, to the extent that the services were furnished solely under of the requirements of this section.

(2) If, after the integrated reconsideration decision is final, an enrollee requests that Medicaid services continue through a State fair hearing, state rules on recovery of costs, in accordance with the requirements of § 438.420(d) of this chapter, apply for costs incurred for services furnished pending appeal subsequent to the date of the integrated reconsideration decision.

§ 422.633 Integrated reconsideration.

(a) *General rule.* An applicable integrated plan may only have one level of integrated reconsideration for an enrollee.

(b) *External medical reviews.* If a State has established an external medical review process, the requirements of § 438.402(c)(1)(i)(B) of this chapter apply to each applicable integrated plan that is a Medicaid managed care organization, as defined in section 1903 of the Act.

(c) *Case file.* Upon request of the enrollee or his or her representative, the applicable integrated plan must provide the enrollee and his or her representative the enrollee's case file, including medical records, other documents and records, and any new or additional evidence considered, relied upon, or generated by the applicable integrated plan (or at the direction of the applicable integrated plan) in connection with the appeal of the integrated organization determination. This information must be provided free of charge and sufficiently in advance of the resolution timeframe for the integrated reconsideration, or subsequent appeal, as specified in this section.

(d) *Timing.* (1) *Timeframe for filing*—An enrollee has 60 calendar days from the date on the adverse organization determination notice to file a request for an integrated reconsideration with the applicable integrated plan.

(2) *Oral inquires*—Oral inquires seeking to appeal an adverse integrated organization determination must be treated as a request for an integrated reconsideration (to establish the earliest possible filing date for the appeal).

(3) *Extending the time for filing a request*—(i) *General rule.* If a party or physician acting on behalf of an enrollee shows good cause, the applicable integrated plan may extend the timeframe for filing a request for an integrated reconsideration.

(ii) *How to request an extension of timeframe.* If the 60-day period in which to file a request for an integrated reconsideration has expired, a party to the integrated organization determination or a physician acting on behalf of an enrollee may file a request for integrated reconsideration with the applicable integrated plan. The request for integrated reconsideration and to extend the timeframe must—

(A) Be in writing; and

(B) State why the request for integrated reconsideration was not filed on time.

(e) *Expedited integrated reconsiderations.* (1) An enrollee may request, or a provider may request on behalf of an enrollee, an expedited review of the integrated reconsideration.

(2) The request can be oral or in writing.

(3) The applicable integrated plan must grant the request to expedite the integrated reconsideration when it determines (for a request from the enrollee), or the provider indicates (in making the request on the enrollee's behalf or supporting the enrollee's request), that taking the time for a standard resolution could seriously jeopardize the enrollee's life, physical or mental health, or ability to attain, maintain, or regain maximum function.

(4) If an applicable integrated plan denies an enrollee's request for an expedited integrated reconsideration, it must automatically transfer a request to the standard timeframe and make the determination within the 30-day timeframe established in paragraph (f)(1) of this section for a standard integrated reconsideration. The 30-day period begins with the day the applicable integrated plan receives the request for expedited integrated reconsideration. The applicable integrated plan must give the enrollee prompt oral notice of the decision, and give the enrollee written notice within 2 calendar days. The written notice must do all of the following:

(i) Include the reason for the denial.

(ii) Inform the enrollee of the right to file a grievance if the enrollee disagrees with the decision not to expedite, including timeframes and procedures for filing a grievance.

(iii) Inform the enrollee of the right to resubmit a request for an expedited determination with any physician's support.

(5) If the applicable integrated plan must receive medical information from noncontract providers, the applicable integrated plan must request the necessary information from the noncontract provider within 24 hours of the initial request for an expedited integrated reconsideration. Noncontract providers must make reasonable and diligent efforts to expeditiously gather and forward all necessary information to assist the applicable integrated plan in meeting the required timeframe. Regardless of whether the applicable integrated plan must request information from noncontract providers, the applicable integrated plan is responsible for meeting the timeframe and notice requirements of this section.

(f) *Resolution and notification.* The applicable integrated plan must make integrated reconsidered determinations as expeditiously as the enrollee's health condition requires but no later than the timeframes established in this section.

(1) *Standard integrated reconsiderations.* The applicable integrated plan must resolve integrated reconsiderations as expeditiously as the enrollee's health condition requires but no longer than 30 calendar days from the date of receipt of the request for the integrated reconsideration. This timeframe may be extended as described in paragraph (f)(3) of this section.

(2) *Expedited integrated reconsiderations.* The applicable integrated plan must resolve expedited integrated reconsiderations as expeditiously as the enrollee's health condition requires but no later than within 72 hours of receipt for the integrated reconsideration. This timeframe may be extended as described in paragraph (f)(3) of this section. In addition to the written notice required under paragraph (f)(4) of this section, the applicable integrated plan must make reasonable efforts to provide prompt oral notice of the expedited resolution to the enrollee.

(3) *Extensions.* (i) The applicable integrated plan may extend the timeframe for resolving integrated reconsiderations by 14 calendar days if—

(A) The enrollee requests the extension; or

(B) The applicable integrated plan can show that—

(*1*) The extension is in the enrollee's interest; and

(*2*) There is need for additional information and there is a reasonable likelihood that receipt of such information would lead to approval of the request, if received.

(ii) If the applicable integrated plan extends the timeframe for resolving the integrated reconsideration, it must make reasonable efforts to give the enrollee prompt oral notice of the delay, and give the enrollee written notice within 2 calendar days of making the decision to extend the timeframe to resolve the integrated reconsideration. The notice must include the reason for the delay and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the decision to grant an extension.

(4) *Notice of resolution.* The applicable integrated plan must send a written notice to enrollees that includes the integrated reconsidered determination, within the resolution timeframes set forth in this section. The notice of determination must be written in plain language and available in a language and format that is accessible to the enrollee and must explain the following:

(i) The resolution of and basis for the integrated reconsideration and the date it was completed.

(ii) For integrated reconsiderations not resolved wholly in favor of the enrollee:

(A) An explanation of the next level of appeal available under the Medicare and Medicaid programs, and what steps the enrollee must take to pursue the next level of appeal under each program, and how the enrollee can obtain assistance in pursuing the next level of appeal under each program; and

(B) The right to request and receive Medicaid-covered benefits while the next level of appeal is pending, if applicable.

§ 422.634 Effect.

(a) *Failure of the applicable integrated plan to send timely notice of a determination.* If the applicable integrated plan fails to adhere to the notice and timing for an integrated organization determination or integrated reconsideration, this failure constitutes an adverse determination for the enrollee.

(1) For an integrated organization determination, this means that the enrollee may request an integrated reconsideration.

(2) For integrated reconsiderations of Medicare benefits, this means the applicable integrated plan must forward the case to the independent review entity, in accordance with the timeframes under paragraph (b) of this section and § 422.592. For integrated reconsiderations of Medicaid benefits, this means that an enrollee or other party may file for a State fair hearing in accordance with § 438.408(f) of this chapter, or if applicable, a State external medical review in accordance with § 438.402(c) of this chapter.

(b) *Adverse integrated reconsiderations.* (1) Subject to paragraph (b)(2) of this section, when the applicable integrated plan affirms, in whole or in part, its adverse integrated organization determination involving a Medicare benefit—

(i) The issues that remain in dispute must be reviewed and resolved by an independent, outside entity that contracts with CMS, in accordance with §§ 422.592 and 422.594 through 422.619;

(ii) For standard integrated reconsiderations, the applicable integrated plan must prepare a written explanation and send the case file to the independent review entity contracted by CMS, as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date it receives the request (or no later than the expiration of an extension described in § 422.633(f)(3)). The applicable integrated plan must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity; and

(iii) For expedited integrated reconsiderations, the applicable integrated plan must prepare a written explanation and send the case file to the independent review entity contracted by CMS as expeditiously as the enrollee's health condition requires, but no later than within 24 hours of its affirmation (or no later than the expiration of an extension described in § 422.633(f)(3)). The applicable integrated plan must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity.

(2) When the applicable integrated plan affirms, in whole or in part, its adverse integrated organization determination involving a Medicaid benefit, the enrollee or other party (that is not the applicable integrated plan) may initiate a State fair hearing in the timeframe specified in § 438.408(f)(2) following the integrated plan's notice of resolution. If a provider is filing for a State fair hearing on behalf of the enrollee as permitted by State law, the provider needs the written consent of the enrollee, if he or she has not already obtained such consent.

(c) *Final determination.* The reconsidered determination of the applicable integrated plan is binding on all parties unless it is appealed to the next applicable level. In the event that the enrollee pursues the appeal in multiple forums and receives conflicting decisions, the applicable integrated plan is bound by, and must act in accordance with, decisions favorable to the enrollee.

(d) *Services not furnished while the appeal is pending.* If an applicable integrated plan reverses its decision, or, for a Medicaid benefit, a State fair hearing reverses an applicable plan's integrated reconsideration decision, to deny, limit, or delay services that were not furnished while the appeal was pending, the applicable integrated plan must authorize or provide the disputed services promptly and as expeditiously as the enrollee's health condition requires but no later than 72 hours from the date it receives notice reversing the determination in lieu of the timeframes described in § 422.618(a). Reversals by the Part C independent review entity, an administrative law judge or attorney adjudicator at the Office of Medicare Hearings and Appeals, or the Medicare Appeals Council must be effectuated under same timelines applicable to other MA plans as specified in §§ 422.618 and 422.619.

(e) *Services furnished while the appeal is pending.* If the applicable integrated plan or the State fair hearing officer reverses a decision to deny, limit, or delay Medicaid-covered benefits, and the enrollee received the disputed services while the integrated reconsideration was pending, the applicable integrated plan or the State must pay for those services, in accordance with State policy and regulations. If the applicable integrated plan reverses a decision to deny, limit, or delay Medicare-covered benefits, and the enrollee received the disputed services while the integrated reconsideration was pending, the applicable integrated plan must pay for those services.

■ 25. Effective January 1, 2021, § 422.752 is amended by adding paragraph (d) to read as follows:

§ 422.752 Basis for imposing intermediate sanctions and civil money penalties.

* * * * *

(d) *Special rule for non-compliant dual eligible special needs plans.* Notwithstanding any other provision of this section, CMS must impose during plan years 2021 through 2025 intermediate sanctions specified at § 422.750(a) on an MA organization with a contract to operate a dual eligible special needs plan if CMS determines that the dual eligible special needs plan fails to comply with at least one of the criteria for the integration of Medicare and Medicaid benefits provided in the definition of a dual eligible special needs plan at § 422.2. If CMS imposes such an intermediate sanction, the MA organization must submit to CMS a corrective action plan in a form, manner, and timeframe established by CMS. The procedures outlined in § 422.756 apply to the imposition of the intermediate sanction under this provision.

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 26. The authority citation for part 423 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1395w–101 through 1395w–152, and 1395hh.

■ 27. In 423.100, in the definition of ''Preclusion list'', revise paragraphs (1)(i), (2)(i), (2)(ii)(C) and add paragraph (3) to read as follows:

§ 423.100 Definitions.

* * * * *

Preclusion list * * *

(1) * * *

(i) The prescriber is currently revoked from Medicare for a reason other than that stated in § 424.535(a)(3) of this chapter.

* * * * *

(2) * * *

(i) The prescriber has engaged in behavior, other than that described in § 424.535(a)(3) of this chapter, for which CMS could have revoked the individual to the extent applicable had he or she been enrolled in Medicare.

(ii) * * *

(C) Any other evidence that CMS deems relevant to its determination; or

(3) The prescriber, regardless of whether he or she is or was enrolled in Medicare, has been convicted of a felony under Federal or State law within the previous 10 years that CMS deems detrimental to the best interests of the Medicare program. Factors that CMS considers in making such a determination under this paragraph are as follows:

(i) The severity of the offense.

(ii) When the offense occurred.

(iii) Any other information that CMS deems relevant to its determination.

* * * * *

■ 28. Effective June 17, 2019, § 423.120 is amended by revising paragraphs (c)(6)(iv) to read as follows:

§ 423.120 Access to covered Part D drugs.

* * * * *

(c) * * *

(6) * * *

(iv) With respect to Part D prescribers who have been added to an updated preclusion list but are not currently excluded by the OIG, the Part D plan sponsor must do all of the following:

(A) Subject to all other Part D rules and plan coverage requirements, and no later than 30 days after the posting of this updated preclusion list, must provide an advance written notice to any beneficiary who has received a Part D drug prescribed by an individual added to the preclusion list in this update and whom the plan sponsor has identified during the applicable 30-day period.

(B)(*1*) Subject to paragraph (c)(6)(iv)(B)(*2*) of this section, must ensure that reasonable efforts are made to notify the individual described in paragraph (c)(6)(iv) of this section of a beneficiary who was sent a notice under paragraph (c)(6)(iv)(A) of this section.

(*2*) Paragraph (c)(6)(iv)(B)(*1*) of this section applies only upon a prescriber writing a prescription in Medicare Part D when:

(*i*) The plan sponsor has enough information on file to either copy the prescriber on the notification previously sent to the beneficiary or send a new notice informing the prescriber that they may not see plan beneficiaries due to their preclusion status; and

(*ii*) The claim is received after the claim denial or reject date in the preclusion file.

(C) Must not reject a pharmacy claim or deny a beneficiary request for reimbursement for a Part D drug prescribed by the prescriber, solely on the ground that they have been included in the updated preclusion list, in the 60-day period after the date it sent the notice described in paragraph (c)(6)(iv)(A) of this section.

■ 29. Section 423.120 is further amended by—

■ a. Revising paragraphs (c)(6)(v); and

■ b. Adding paragraphs (c)(6)(vii) and (viii).

The revision and additions read as follows:

§ 423.120 Access to covered Part D drugs.

* * * * *

(c) * * *

(6) * * *

(v)(A) CMS sends written notice to the prescriber via letter of his or her inclusion on the preclusion list. The notice must contain the reason for the inclusion on the preclusion list and inform the prescriber of his or her appeal rights. A prescriber may appeal his or her inclusion on the preclusion list under this section in accordance with part 498 of this chapter.

(B) If the prescriber's inclusion on the preclusion list is based on a contemporaneous Medicare revocation under § 424.535 of this chapter:

(*1*) The notice described in paragraph (c)(6)(v)(A) of this section must also include notice of the revocation, the reason(s) for the revocation, and a description of the prescriber's appeal rights concerning the revocation.

(*2*) The appeals of the prescriber's inclusion on the preclusion list and the prescriber's revocation must be filed jointly by the prescriber and, as applicable, considered jointly under part 498 of this chapter.

(C)(*1*) Except as provided in paragraph (c)(6)(v)(C)(*2*) of this section, a prescriber will only be included on the preclusion list after the expiration of either of the following:

(*i*) If the prescriber does not file a reconsideration request under § 498.5(n)(1) of this chapter, the prescriber will be added to the preclusion list upon the expiration of the 60-day period in which the prescriber may request a reconsideration.

(ii) If the prescriber files a reconsideration request under § 498.5(n)(1) of this chapter, the prescriber will be added to the preclusion list effective on the date on which CMS, if applicable, denies the prescriber's reconsideration.

(2) An OIG excluded prescriber is added to the preclusion list effective on the date of the exclusion.

* * * * *

(vii)(A) Except as provided in paragraphs (c)(6)(vii)(C) and (D) of this section, a prescriber who is revoked under § 424.535 of this chapter will be included on the preclusion list for the same length of time as the prescriber's reenrollment bar.

(B) Except as provided in paragraphs (c)(6)(vii)(C) and (D) of this section, a prescriber who is not enrolled in Medicare will be included on the preclusion list for the same length of time as the reenrollment bar that CMS could have imposed on the prescriber had the prescriber been enrolled and then revoked.

(C) Except as provided in paragraph (c)(6)(vii)(D) of this section, an

individual, regardless of whether the individual is or was enrolled in Medicare, that is included on the preclusion list because of a felony conviction will remain on the preclusion list for a 10-year period, beginning on the date of the felony conviction, unless CMS determines that a shorter length of time is warranted. Factors that CMS considers in making such a determination are—

(*1*) The severity of the offense;

(*2*) When the offense occurred; and

(*3*) Any other information that CMS deems relevant to its determination.

(D) In cases where an individual is excluded by the OIG, the individual must remain on the preclusion list until the expiration of the CMS-imposed preclusion list period or reinstatement by the OIG, whichever occurs later.

(viii) Payment denials under paragraph (c)(6) of this section that are based upon the prescriber's inclusion on the preclusion list are not appealable by beneficiaries.

* * * * *

■ 30. Section 423.153 is amended by revising the section heading and adding paragraph (g) to read as follows:

§ 423.153 Prescription drug plan sponsors' access to Medicare Parts A and B claims data extracts.

* * * * *

(g) *Parts A and B claims data extracts*—(1) *General rule.* (i) Beginning in plan year 2020, a PDP sponsor may submit a request to CMS for the data described in paragraph (g)(2) of this section about enrollees in its prescription drug plans.

(ii) CMS makes the data requested in paragraph (g)(1)(i) of this section available to eligible PDP sponsors, in accordance with all applicable laws. The data is provided at least quarterly on a specified release date, and in an electronic format to be determined by CMS.

(iii) If CMS determines or has a reasonable belief that the PDP sponsor has violated the requirements of this paragraph (g) or that unauthorized uses, reuses, or disclosures of the Medicare claims data have taken place, at CMS' sole discretion, the PDP sponsor may be denied further access to the data described in paragraph (g)(2) of this section.

(2) *Data described.* The data that may be requested under paragraph (g)(1) of this section are standardized extracts of claims data under Medicare parts A and B for items and services furnished under such parts to beneficiaries who are enrolled in a plan offered by the PDP sponsor at the time of the disclosure.

(3) *Purposes.* A PDP sponsor must comply with all laws that may be applicable to data received under this provision, including State and Federal privacy and security laws, and, furthermore subject to the limitations in paragraph (g)(4) of this section may only use or disclose the data provided by CMS under paragraph (g)(1) of this section for the following purposes:

(i) To optimize therapeutic outcomes through improved medication use, as such phrase is used in paragraph (d)(1)(i) of this section.

(ii) To improve care coordination so as to prevent adverse health outcomes, such as preventable emergency department visits and hospital readmissions.

(iii) For activities falling under paragraph (1) of the definition of ''health care operations'' under 45 CFR 164.501.

(iv) For activities falling under paragraph (2) of the definition of ''health care operations'' under 45 CFR 164.501.

(v) For ''fraud and abuse detection or compliance activities'' under 45 CFR 164.506(c)(4)(ii).

(vi) For disclosures that qualify as ''required by law'' disclosures at 45 CFR 164.103.

(4) *Limitations.* A PDP sponsor must comply with the following requirements regarding the data provided by CMS under this paragraph (g):

(i) The PDP sponsor will not use the data to inform coverage determinations under Part D.

(ii) The PDP sponsor will not use the data to conduct retroactive reviews of medically accepted indications determinations.

(iii) The PDP sponsor will not use the data to facilitate enrollment changes to a different prescription drug plan or an MA–PD plan offered by the same parent organization.

(iv) The PDP sponsor will not use the data to inform marketing of benefits.

(v) The PDP sponsor will contractually bind its contractors that have access to the Medicare claims data, and require their contractors to contractually bind any other potential downstream data recipients, to the terms and conditions imposed on the PDP sponsor under this paragraph (g).

(5) *Ensuring the privacy and security of data.* As a condition of receiving the requested data, the PDP sponsor must attest that it will adhere to the permitted uses and limitations on the use of the Medicare claims data listed in paragraphs (g)(3) and (4) of this section.

■ 31. Section 423.182(a) is amended by adding the definitions ''Absolute percentage cap'', ''Cut point cap'', ''Guardrail'', ''Mean resampling'', ''Restricted range'', and ''Restricted range cap'' in alphabetical order to read as follows:

§ 423.182 Part D Prescription Drug Plan Quality Rating System.

(a) * * *

Absolute percentage cap is a cap applied to non-CAHPS measures that are on a 0 to 100 scale that restricts movement of the current year's measure-threshold-specific cut point to no more than the stated percentage as compared to the prior year's cut point.

* * * * *

Cut point cap is a restriction on the change in the amount of movement a measure-threshold-specific cut point can make as compared to the prior year's measure-threshold-specific cut point. A cut point cap can restrict upward movement, downward movement, or both.

* * * * *

Guardrail is a bidirectional cap that restricts both upward and downward movement of a measure-threshold-specific cut point for the current year's measure-level Star Ratings as compared to the prior year's measure-threshold-specific cut point.

* * * * *

Mean resampling refers to a technique where measure-specific scores for the current year's Star Ratings are randomly separated into 10 equal-sized groups. The hierarchal clustering algorithm is done 10 times, each time leaving one of the 10 groups out. By leaving out one of the 10 groups for each run, 9 of the 10 groups, which is 90 percent of the applicable measure scores, are used for each run of the clustering algorithm. The method results in 10 sets of measure-specific cut points. The mean cut point for each threshold per measure is calculated using the 10 values.

* * * * *

Restricted range is the difference between the maximum and minimum measure score values using the prior year measure scores excluding outer fence outliers (first quartile −3*Interquartile Range (IQR) and third quartile + 3*IQR).

Restricted range cap is a cap applied to non-CAHPS measures that restricts movement of the current year's measure-threshold-specific cut point to no more than the stated percentage of the restricted range of a measure calculated using the prior year's measure score distribution.

* * * * *

■ 32. Section 423.184 is amended by adding paragraphs (f)(1)(iv), (g)(1)(ii)(M), and (h) to read as follows:

§ 423.184 Adding, updating, and removing measures.

* * * * *

(f) * * *

(1) * * *

(iv) CMS excludes any measure that receives a measure-level Star Rating reduction for data integrity concerns for either the current or prior year from the improvement measure(s).

* * * * *

(g) * * *

(1) * * *

(ii) * * *

(M) CMS reduces the measure rating to 1 star for the applicable appeals measure(s) if a contract fails to submit Timeliness Monitoring Project data for CMS's review to ensure the completeness of the contract's IRE data.

* * * * *

(h) *Review of sponsors' data.* (1) A Part D plan sponsor may request that CMS or the IRE review its' contract's appeals data provided that the request is received by the annual deadline set by CMS for the applicable Star Ratings year.

(2) A Part D plan sponsor may request that CMS review its' contract's Complaints Tracking Module (CTM) data provided that the request is received by the annual deadline set by CMS for the applicable Star Ratings year.

■ 33. Section 423.186 is amended by revising paragraph (a)(2)(i) and adding paragraph (i) to read as follows:

§ 423.186 Calculation of Star Ratings.

(a) * * *

(2) * * *

(i) The method maximizes differences across the star categories and minimizes the differences within star categories using mean resampling with the hierarchal clustering of the current year's data, and a guardrail so that the measure-threshold-specific cut points for non-CAHPS measures do not increase or decrease more than the value of the cap from one year to the next. The cap is equal to 5 percentage points for measures having a 0 to 100 scale (absolute percentage cap) or 5 percent of the restricted range for measures not having a 0 to 100 scale (restricted range cap). New measures that have been in the Part C and D Star Rating program for three years or less use the hierarchal clustering methodology with mean resampling with no guardrail for the first 3 years in the program.

* * * * *

(i) *Extreme and uncontrollable circumstances.* In the event of extreme and uncontrollable circumstances that may negatively impact operational and clinical systems and contracts' abilities to conduct surveys needed for accurate performance measurement, CMS calculates the Star Ratings as specified in paragraphs (i)(2) through (8) of this section for each contract that is an affected contract during the performance period for the applicable measures. We use the start date of the incident period to determine which year of Star Ratings could be affected, regardless of whether the incident period lasts until another calendar year.

(1) *Identification of affected contracts.* A contract that meets all of the following criteria is an affected contract:

(i) The contract's service area is within an ''emergency area'' during an ''emergency period'' as defined in section 1135(g) of the Act.

(ii) The contract's service area is within a county, parish, U.S. territory or tribal area designated in a major disaster declaration under the Stafford Act and the Secretary exercised authority under section 1135 of the Act based on the same triggering event(s).

(iii) As specified in paragraphs (i)(2) through (8) of this section, a certain minimum percentage (25 percent or 60 percent) of the enrollees under the contract must reside in a Federal Emergency Management Agency (FEMA)-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance.

(2) *CAHPS adjustments.* (i) A contract, even if an affected contract, must administer the CAHPS survey unless exempt under paragraph (i)(2)(ii) of this section.

(ii) An affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance is exempt from administering the CAHPS survey if the contract completes both of the following:

(A) Demonstrates to CMS that the required sample for the survey cannot be contacted because a substantial number of the contract's enrollees are displaced due to the FEMA-designated disaster identified in paragraph (i)(1)(iii) of this section in the prior calendar year.

(B) Requests and receives a CMS approved exemption.

(iii) An affected contract with an exemption described in paragraph (i)(2)(ii) of this section receives the contract's CAHPS measure stars and corresponding measure scores from the prior year.

(iv) For an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance, the contract receives the higher of the previous year's Star Rating or the current year's Star Rating (and corresponding measure score) for each CAHPS measure.

(v) When a contract is an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance with regard to separate extreme and uncontrollable circumstances that begin in successive years, it is a multiple year-affected contract. A multiple year-affected contract receives the higher of the current year's Star Rating or what the previous year's Star Rating would have been in the absence of any adjustments that took into account the effects of the previous year's disaster for each measure (using the corresponding measure score for the Star Ratings year selected).

(3) *New measure adjustments.* For affected contracts with at least 25 percent of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance, CMS holds the affected contract harmless by using the higher of the contract's summary or overall rating or both with and without including all of the applicable new measures.

(4) *Other Star Ratings measure adjustments.* (i) For all other Part D measures except those measures identified in this paragraph (i)(4)(ii) of this section, affected contracts with at least 25 percent of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance receive the higher of the previous or current year's measure Star Rating (and corresponding measure score).

(ii) CMS does not adjust the scores of the Star Ratings for the Part D Call Center—Foreign Language Interpreter and TTY Availability measure, unless the exemption listed in paragraph (i)(4)(iii) of this section applies.

(iii) CMS adjusts the measure listed in paragraph (i)(4)(ii) of this section using the adjustments listed in paragraph (i)(4)(i) of this section for contracts affected by extreme and uncontrollable circumstances where there are continuing communications issues related to loss of electricity and damage to infrastructure during the call center study.

(iv) When a contract is an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance with regard to separate extreme and uncontrollable circumstances that begin in successive years, it is a multiple year-affected contract. A multiple year-affected contract receives the higher of the current year's Star Rating or what the previous year's Star Rating would have been in the absence of any adjustments that took into account the effects of the previous year's disaster for each measure (using the corresponding measure score for the Star Ratings year selected).

(5) *Exclusion from improvement measures.* Any measure that reverts back to the data underlying the previous year's Star Rating due to the adjustments made in paragraph (i) of this section is excluded from both the count of measures and the applicable improvement measures for the current and next year's Star Ratings for the affected contract. Contracts affected by extreme and uncontrollable circumstances do not have the option of reverting to the prior year's improvement rating.

(6) *Missing data.* For an affected contract that has missing data in the current or previous year, the final measure rating comes from the current year unless an exemption described in paragraph (i)(2)(ii) of this section applies.

(7) *Cut points for non-CAHPS measures.* (i) CMS excludes the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the clustering algorithms described in paragraph (a)(2) of this section.

(ii) The cut points calculated as described in paragraph (i)(7)(i) of this section are used to assess all affected contracts' measure Star Ratings.

(8) *Reward factor.* (i) CMS excludes the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the determination of the performance summary and variance thresholds for the Reward Factor described in paragraph (f)(1) of this section.

(ii) All affected contracts are eligible for the Reward Factor based on the calculations described in paragraph (i)(8)(i) of this section.

■ 34. Section 423.568 is amended by revising paragraph (b) to read as follows:

§ 423.568 Standard timeframe and notice requirements for coverage determinations.

* * * * *

(b) *Timeframe for requests for drug benefits.* When a party makes a request for a drug benefit, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request. For an exceptions request, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the physician's or other prescriber's supporting statement. If a supporting statement is not received by the end of 14 calendar days from receipt of the exceptions request, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours from the end of 14 calendar days from receipt of the exceptions request.

* * * * *

■ 35. Section 423.570 is amended by revising paragraph (d)(1) to read as follows:

§ 423.570 Expediting certain coverage determinations.

* * * * *

(d) * * *

(1) Make the determination within the 72-hour timeframe established in § 423.568(b) for a standard determination. The 72-hour period begins on the day the Part D plan sponsor receives the request for expedited determination. For an exceptions request, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the physician's or other prescriber's supporting statement. If a supporting statement is not received by the end of 14 calendar days from receipt of the exceptions request, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours from the end of 14 calendar days from receipt of the exceptions request.

* * * * *

■ 36. Section 423.572 is amended by revising paragraph (a) to read as follows:

§ 423.572 Timeframes and notice requirements for expedited coverage determinations.

(a) *Timeframe for determination and notification.* Except as provided in paragraph (b) of this section, a Part D plan sponsor that approves a request for expedited determination must make its determination and notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its decision, whether adverse or favorable, as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receiving the request. For an exceptions request, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receipt of the physician's or other prescriber's supporting statement. If a supporting statement is not received by the end of 14 calendar days from receipt of the exceptions request, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 24 hours from the end of 14 calendar days from receipt of the exceptions request.

* * * * *

PART 438—MANAGED CARE

■ 37. The authority for part 438 is revised to read as follows:

Authority: 42 U.S.C. 1302.

■ 38. Effective January 1, 2021, § 438.210 is amended by—

■ a. Revising paragraph (c);

■ b. Adding paragraph (d)(4); and

■ c. Revising paragraph (f).

The addition and revisions read as follows:

§ 438.210 Coverage and authorization of services.

* * * * *

(c) *Notice of adverse benefit determination.* Each contract must provide for the MCO, PIHP, or PAHP to notify the requesting provider, and give the enrollee written notice of any decision by the MCO, PIHP, or PAHP to deny a service authorization request, or to authorize a service in an amount, duration, or scope that is less than

requested. For MCOs, PIHPs, and PAHPs, the enrollee's notice must meet the requirements of § 438.404. For Medicaid contracts with an applicable integrated plan, as defined in § 422.561 of this chapter, in lieu of the provisions in this paragraph governing notices of adverse benefit determinations, the provisions set forth in §§ 422.629 through 422.634 of this chapter apply to determinations affecting dually eligible individuals who are also enrolled in a dual eligible special needs plan with exclusively aligned enrollment, as defined in § 422.2 of this chapter.

(d) * * *

* * * * *

(4) For Medicaid contracts with an applicable integrated plan, as defined in § 422.561 of this chapter, timelines for decisions and notices must be compliant with the provisions set forth in §§ 422.629 through 422.634 of this chapter in lieu of §§ 438.404 through 438.424.

* * * * *

(f) *Applicability date.* (1) Subject to paragraph (f)(2) of this section, this section applies to the rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after July 1, 2017. Until that applicability date, States are required to continue to comply with § 438.210 contained in the 42 CFR parts 430 to 481, edition revised as of October 1, 2015.

(2) Provisions in this section affecting applicable integrated plans, as defined in § 422.561 of this chapter, are applicable no later than January 1, 2021.

■ 39. Effective January 1, 20121, § 438.400 is amendedby adding paragraph (a)(4) and revising paragraph (c) to read as follows:

§ 438.400 Statutory basis, definitions, and applicability.

(a) * * *

(4) Section 1859(f)(8)(B) of the Act requires that the Secretary, to the extent feasible, establish procedures unifying grievances and appeals procedures under sections 1852(f), 1852(g), 1902(a)(3), 1902(a)(5), and 1932(b)(4) of the Act for items and services provided, by specialized Medicare Advantage plans for special needs individuals described in section 1859(b)(6)(B)(ii), under Titles XVIII and XIX of the Act.

* * * * *

(c) *Applicability.* (1) Subject to paragraph (c)(2) of this section, this subpart applies to the rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after July 1, 2017. Until that applicability date, States, MCOs, PIHPs, and PAHPs are required to continue to comply with subpart F contained in the 42 CFR parts 430 to 481, edition revised as of October 1, 2015.

(2) Provisions in this part affecting applicable integrated plans, as defined in § 422.561 of this chapter, are applicable no later than January 1, 2021.

■ 40. Effective January 1, 2021, § 438.402 is amended by revising paragraph (a) to read as follows:

§ 438.402 General requirements.

(a) *The grievance and appeal system.* Each MCO, PIHP, and PAHP must have a grievance and appeal system in place for enrollees. Non-emergency medical transportation PAHPs, as defined in § 438.9, are not subject to this subpart F. For grievances and appeals at the plan level, an applicable integrated plan as defined in § 422.561 of this chapter is not subject to this subpart F, and is instead subject to the requirements of §§ 422.629 through 422.634 of this chapter. For appeals of integrated reconsiderations, applicable integrated plans are subject to § 438.408(f).

* * * * *

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF ICFs/IID AND CERTAIN NFs IN THE MEDICAID PROGRAM

■ 41. The authority for part 498 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1320a–7j, and 1395hh.

■ 42. Effective June 17, 2019, § 498.5 is amended by revising paragraph (n)(1) to read as follows:

§ 498.5 Appeal rights.

* * * * *

(n) * * *

(1)(i) Any individual or entity that is dissatisfied with an initial determination or revised initial determination that they are to be included on the preclusion list (as defined in § 422.2 or § 423.100 of this chapter) may request a reconsideration in accordance with § 498.22(a).

(ii)(A) If the individual's or entity's inclusion on the preclusion list is based on a Medicare revocation under § 424.535 of this chapter and the individual or entity receives contemporaneous notice of both actions, the individual or entity may request a joint reconsideration of both the preclusion list inclusion and the revocation in accordance with § 498.22(a).

(B) The individual or entity may not submit separate reconsideration requests under paragraph (n)(1)(ii)(A) of this section for inclusion on the preclusion list or a revocation if the individual or entity received contemporaneous notice of both actions.

* * * * *

Dated: March 27, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: March 28, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2019–06822 Filed 4–5–19; 4:15 pm]

BILLING CODE 4120–01–P