

**38 CFR Part 17****RIN 2900-AR55****CHAMPVA Coverage of Audio-Only Telehealth, Mental Health Services, and Cost Sharing for Certain Contraceptive Services and Contraceptive Products****Approved, Cleared, or Granted by FDA**

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) proposes amending its medical regulations regarding Civilian Health and Medical Program of the Department of Veterans Affairs (CHAMPVA) coverage. This rulemaking would align with the Department of Defense for benefits administered through TRICARE and more closely align with requirements of other Federal programs. This rulemaking would remove the exclusion from CHAMPVA coverage for audio-only telehealth. In addition, we propose removing limitations on outpatient mental health visits as well as removing cost sharing requirements for certain contraceptive services and contraceptive products approved, cleared, or granted by the U.S. Food and Drug Administration (FDA).

DATES: Comments must be received by VA on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Comments must be submitted through www.regulations.gov. Except as provided below, comments received before the close of the comment period will be available at www.regulations.gov for public viewing, inspection, or copying, including any personally identifiable or confidential business information that is included in a

comment. We post the comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. VA will not post on Regulations.gov public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm the individual. VA encourages individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments. Any public comment received after the comment period's closing date is considered late and will not be considered in the final rulemaking.

FOR FURTHER INFORMATION CONTACT Joseph Duran, Director, Policy, Office of Integrated Veteran Care (OIVC), Veterans Health Administration (VHA), Department of Veterans Affairs, Ptarmigan at Cherry Creek, Denver, CO 80209; 303-370-1637 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

The Department of Veterans Affairs (VA) proposes amending Civilian Health and Medical Program of the Department of Veterans Affairs (CHAMPVA) exclusions to allow coverage of telephonic (audio-only) medical visits and to remove limits on mental health coverage to be consistent with the Department of Defense (DoD) TRICARE program and current standards of practice in mental health and substance use care as well as the Mental Health Parity and Addiction Equity Act of 2008. In addition, we propose removing cost-sharing requirements for contraceptive services and contraceptive products approved, cleared, or granted by the U.S. Food & Drug Administration (FDA). VA believes these proposed changes are consistent with the goals and objectives of Executive Order (E.O.) 14070 (April 5, 2022) titled, "Continuing to Strengthen

Americans' Access to Affordable, Quality Health Coverage.” The E.O. directs federal agencies “with responsibilities related to Americans' access to health coverage” to “review agency actions to identify ways to continue to expand the availability of affordable health coverage.”

Pursuant to 38 U.S.C. 1781, CHAMPVA is a health benefits program in which VA shares the cost of covered medical care services and supplies with certain spouses, children, survivors, and caregivers of veterans who meet specific eligibility criteria. Under section 1781(b), VA “shall provide for medical care in the same or similar manner and subject to the same or similar limitations as medical care is furnished to certain dependents and survivors of active duty and retired members of the Armed Forces under chapter 55 of title 10 [United States Code] (CHAMPUS).” VA has implemented this requirement through the promulgation of its regulations at 38 CFR 17.270 et seq. We note that VA has consistently interpreted the “same or similar” language in 38 U.S.C. 1781(b) to mean that CHAMPVA is not required to provide coverage identical to that provided by TRICARE. When warranted, CHAMPVA coverage and exclusions may differ from TRICARE due to factors such as dissimilarities in the respective patient populations, or policy considerations.

We note that CHAMPUS was the original program administered by DoD to provide civilian health benefits for active duty military personnel, military retirees, and their dependents. 32 CFR 199.1. Although the CHAMPUS program is still referenced in DoD regulations, DoD effectively replaced the CHAMPUS program with what was commonly known as the “TRICARE Standard” plan (“TRICARE”). See 32 CFR 199.1(r), 199.17(a)(6)(ii)(D) (identifying “TRICARE Standard” as the basic CHAMPUS program available prior to January 1, 2018). In December 2017, Section 701 of the National Defense Authorization Act for Fiscal Year 2017, Pub. L. 114-328, required inter alia the termination of TRICARE Standard as a distinct plan and the establishment of the

TRICARE Select healthcare option. The CHAMPUS basic program benefits under 32 CFR 199.4 continue as the baseline of benefits for TRICARE Select. VA, therefore, administers CHAMPVA in the same or similar manner as TRICARE Select and, except where we discuss laws or regulations generally applicable to all TRICARE program options, references in this rulemaking to “TRICARE” are to TRICARE Select.

Audio-only telehealth.

Historically, TRICARE regulations excluded audio-only telehealth. 32 CFR 199.4(g)(52) (2019). Similarly, the CHAMPVA regulations at 38 CFR 17.272(a)(44) specifically exclude coverage for audio-only telehealth. However, on January 31, 2020, the Secretary of Health and Human Services (HHS) determined that a public health emergency existed since January 27, 2020. On March 13, 2020, the President declared a national emergency due to COVID-19. In light of the spread of COVID-19, the Centers for Disease Control and Prevention (CDC) urged Americans to work and engage in schooling from home whenever possible as well as to avoid congregating in groups. Various States and localities imposed more rigid restrictions on gatherings, requiring many businesses to restrict or close their operations, to prevent further spread of the disease. To prevent the spread of COVID-19 in accordance with local restrictions and guidelines, and to prioritize in-person treatments for seriously ill patients, health care professionals around the country limited in-person medical appointments. While in-person appointments were converted to video telehealth visits when possible, some patients were limited to audio-only telehealth appointments because either they or their providers didn't have access to the communications equipment, internet service, or internet bandwidth required for video telehealth.

DoD published an interim final rule (IFR) on May 12, 2020, effective that same day, to temporarily remove the exclusion for audio-only telehealth. 85 FR 27927. DoD

temporarily removed the exclusion because doing so was necessary to ensure the health and safety of TRICARE beneficiaries. Allowing audio-only telehealth would permit beneficiaries to have their symptoms (which include COVID-19 symptoms, or symptoms of other covered illness or injury) evaluated by a provider over the telephone before, or in lieu of, obtaining an in-person appointment, which ultimately may not be necessary. In 2022, DoD provided that this temporary removal of the exclusion would cease to be in effect upon termination of the national emergency declared by the President in Proclamation 9994, in accordance with applicable law and regulation (e.g., 50 U.S.C. 1622(a)).

Following publication of the IFR, DoD reviewed claims data from TRICARE private sector care as well as published industry information from the Centers for Medicare & Medicaid Services (CMS), health insurance plans, and statements from physicians' professional organizations regarding telephonic office visits to determine if this should be a permanent telehealth benefit. 87 FR 33002 (June 1, 2022). This data reflected utilization rates for telehealth services including telephonic (audio-only) medical visits, while statements from physicians' professional organizations reflected opinions of many health care provider regarding telehealth. The TRICARE claims data between mid-March and mid-September 2020 indicated beneficiary utilization of telephonic office visits was a small portion of all telehealth claims. Medicare and health insurance plans reported data indicating substantial utilization of telephonic office visits. Physicians' professional organizations issued statements indicating that physicians had a favorable experience with telephonic office visits.

DoD published a final rule on June 1, 2022 (87 FR 33013) revising 32 CFR 199.4(g)(52)(i) to provide that services or advice rendered by telephone are excluded with the exception of medically necessary and appropriate telephonic office visits which are covered as authorized in 32 CFR 199.4(c)(1)(iii). That provision states in pertinent

part that “Health care services covered by TRICARE and provided through the use of telehealth modalities including telephone services for: telephonic office visits; telephonic consultations; electronic transmission of data or biotelemetry or remote physiologic monitoring services and supplies, are covered services to the same extent as if provided in person at the location of the patient if those services are medically necessary and appropriate for such modalities.” The final rule made these provisions permanent and not limited to the duration of the public health emergency. We note that, effective January 1, 2022, CMS rules have also permanently changed to allow for Medicare coverage of audio-only telehealth for mental health services or substance use disorders (MH/SUD) in certain circumstances. See 42 CFR 405.2463(b)(3) and 410.67(b)(4) as well as discussion at 86 FR 65059, (November 19, 2021). Additionally, states have broad flexibility to cover and pay for Medicaid services delivered via telehealth, including to determine which telehealth modalities may be used to deliver Medicaid-covered services. Nothing in federal Medicaid law or policy prevents states from covering and paying for Medicaid services that are delivered via audio-only technologies. This broad flexibility to cover and pay for Medicaid services delivered via telehealth, including via audio-only technologies, was in place prior to the COVID-19 public health emergency. CMS states that this flexibility will remain in place after the public health emergency ends. See <https://www.medicaid.gov/medicaid/benefits/downloads/medicaid-chip-telehealth-toolkit.pdf>.

HHS Office of Civil Rights has issued guidance on how covered health care providers and health plans can use remote communication technologies to provide audio-only telehealth services when such communications are conducted in a manner that is consistent with the applicable requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy, Security, and Breach Notification Rule

(collectively, the “HIPAA Rules”). This guidance explains how the HIPAA Rules permit health care providers and plans to offer audio telehealth while protecting the privacy and security of individuals’ health information. See <https://www.hhs.gov/about/news/2022/06/13/hhs-issues-guidance-hipaa-audio-telehealth.html>.

VA proposes amending its regulations at 38 CFR 17.272(a)(44) to remove the exclusion of audio-only telehealth for CHAMPVA beneficiaries for services provided on or after May 12, 2020. This proposed amendment would align the administration of CHAMPVA to be the same or similar as TRICARE. VA believes this proposed change appropriate in order to ensure the safety of CHAMPVA beneficiaries as well as others in the community. The TRICARE rulemaking on audio-only telehealth was initially based on the need to respond to a new reality for clinical care delivery due to the declared COVID-19 public health emergency. DoD later determined that this exception should remain in place. As explained by DoD in its rulemaking, while existing telehealth platforms that incorporate both audio and video/visual two-way communication are preferred and already allowable for beneficiaries, there may be instances when this is not possible. For example, a provider, especially in a rural or medically underserved area, may not have access to broadband capability, or a beneficiary may not have in-home technology to support two-way audio/video communication. VA shares these concerns relative to CHAMPVA beneficiaries, many of whom live in rural areas or may have insufficient disposable income to purchase and maintain two-way audio/video communication in the home. As discussed below, demand by CHAMPVA beneficiaries for audio-only telehealth remains steady (per 2021 data).

We note that this proposed amendment does not expand the services available to CHAMPVA beneficiaries; instead, it would make otherwise-covered services, when

rendered via telephone (audio-only), eligible for reimbursement and cost sharing when care is medically necessary and appropriate and meets all other requirements.

This proposed amendment would apply retroactively to episodes of health care rendered during the President's declared national emergency in the US. Retroactivity would allow reimbursement of medically necessary audio-only telehealth services dating back to the date TRICARE published its rulemaking, if such claims are timely filed within 180 days of publication of the final rulemaking, in accordance with the provisions of 38 CFR 17.276(a)(3). VA intends to provide notice to affected beneficiaries and providers when the final rule publishes, stating that claims for payment or reimbursement must be filed within 180 days of the effective date of the final rule. Retroactivity provides the greatest benefit to CHAMPVA beneficiaries and is consistent with the requirement under 38 USC 1781(b) to provide medical care in a manner that is the same or similar to TRICARE, whose dates of coverage began on May 12, 2020. Additionally, audio-only telehealth claims submitted to the program were denied, requiring the beneficiary to pay for their audio-only telehealth visit, further exacerbating the financial burden of the beneficiary. Allowing retrospective reimbursement up to the CHAMPVA allowable amount will provide the beneficiary compensation for their payment for medically necessary care during the declared national emergency.

CHAMPVA claims data indicate that audio-only telehealth visits appear to be utilized to a greater extent by CHAMPVA beneficiaries than usage reflected in TRICARE claims data as reported at 87 FR 33002. Claims data indicate that the greatest financial burden to CHAMPVA beneficiaries due to denials of audio-only telehealth claims occurred early in the pandemic before they and their health care providers were able to adapt to the pandemic-caused shift towards conducting business online. The highest demand for CHAMPVA coverage of audio-only telehealth occurred in April 2020 when approximately 18,400 audio-only visits were billed to CHAMPVA.

Claims data indicates that demand for audio-only telehealth has continued throughout the pandemic period but tapered off in 2021 to a monthly average of approximately 3,000 audio-only telehealth visits.

Therefore, in this rulemaking, we would revise 38 CFR 17.272(a)(44) to state that services or advice rendered by telephone (audio only) are not excluded when otherwise covered CHAMPVA services are provided to a beneficiary through this modality if the services are medically necessary and appropriate. Specifically, section 17.272(a)(44) would be amended to read: "Telephone Services, with the following exceptions:" Section 17.272(a)(44)(i) would be redesignated as 38 CFR 17.272(a)(44)(ii)(A) and 17.272(a)(44)(i) would read: "Services or advice rendered by telephone (audio only) on or after May 12, 2020, are not excluded when the services are otherwise covered CHAMPVA services provided through this modality and are medically necessary and appropriate." Section 17.272(a)(44)(ii) would be redesignated as 38 CFR 17.272(a)(44)(ii)(B) and 17.272(a)(44)(ii) would read: "A diagnostic or monitoring procedure which incorporates electronic transmission of data or remote detection and measurement of a condition, activity, or function (biotelemetry) is covered when:". Current section 17.272(a)(44)(iii) would be redesignated as 38 CFR 17.272(a)(44)(ii)(C) without change to the text.

Parity for mental health services.

The first federal law specifically related to the coverage of mental health services by private health insurers and group health plans was the Mental Health Parity Act (MHPA) of 1996 (Title VII, § 702 of Pub. L. 104-204, September 26, 1996) which required annual or lifetime dollar limits on mental health benefits to be no lower than any such dollar limits for medical and surgical benefits offered by a group health plan or health insurance issuer offering coverage in connection with a group health plan.

The MHPA was largely superseded by the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) (Title V, Subtitle B, §§ 511 and 512 of Pub. L. 110-343, October 3, 2008). MHPAEA generally prevents group health plans and health insurance issuers that provide mental health and/or substance use disorder (MH/SUD) benefits from imposing less favorable (e.g., separate costs or more restrictive) benefit limitations on those benefits than those imposed on medical/surgical benefits. The Patient Protection and Affordable Care Act (Pub. L. 111-148, March 23, 2010), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152, March 30, 2010), collectively referred to as the “Affordable Care Act” or the ACA, extended this requirement by operation of law to individual health insurance coverage. See also E.O. 13625 August 31, 2012; E.O. 14009 (January 28, 2021); E.O. 14070 (April 5, 2022).

In general, under these laws, financial requirements (such as coinsurance and copayments) and treatment limits (such as visit limits) imposed on MH/SUD benefits must be no more restrictive than the predominant financial requirements or treatment limitations that apply to substantially all medical/surgical benefits in a classification of benefits (this is referred to as the “substantially all/predominant test”). MH/SUD benefits also may not be subject to any separate cost sharing requirements or treatment limitations that only apply to such benefits.

The above-referenced legal provisions related to MH/SUD benefits parity with medical/surgical benefits are not applicable to CHAMPVA or TRICARE benefits. On August 26, 2014, VA and DoD issued a joint fact sheet in conjunction with issuance of a series of Executive Orders regarding mental health services for veterans, service members, and their families. DoD stated that it had initiated action to do what it can under its authority to eliminate unnecessary quantitative limits under TRICARE for MH/SUD coverage, thus achieving parity between MH/SUD and medical/surgical

benefits. With publication of a final rule on September 2, 2016 (81 FR 61085), TRICARE established parity for MH/SUD coverage, similar to that required of plans covered by the ACA. CHAMPVA's current practice is to routinely waive day limitations/exclusions on mental health services to ensure that beneficiaries receive needed mental health care. VA recognizes that the existing regulatory language regarding quantitative limits on mental health care should be amended to remove any ambiguity. In the past this was not a high priority for VA, as the practical end result of CHAMPVA waiving such limitations and exclusions is that a beneficiary experienced no discontinuity in care. In addition, we note that CHAMPVA has responded to several Congressional inquiries related to removal of the day limitations for mental health care, stating we plan to amend the existing regulation following publication of the final rulemaking that published July 13, 2022 (87 FR 41599). We are now addressing this oversight, in conjunction with making proposed changes to cost sharing for contraceptive care and services that would more closely align with ACA requirements for private health insurers.

Current 38 CFR 17.272(a)(57)-(62) addresses exclusions from CHAMPVA coverage related to mental health services. These provisions cover exclusions for inpatient and outpatient mental health service, residential treatment care, institutional services for partial hospitalization, detoxification in a hospital setting or rehabilitation facility, outpatient substance abuse services, and family therapy for substance abuse. The exclusions vary by mental health service provided, some exclusions are per fiscal year while others are per benefit period, and all have exclusions for specific services in excess of certain time periods. Some exclusions apply unless a waiver for extended coverage is granted in advance. CHAMPVA does not apply similar quantitative limits on the receipt of outpatient, residential, or inpatient services for other classes of medical care provided to eligible beneficiaries.

VA is required in 38 U.S.C. 1781(b) to provide medical care in a manner that is the same or similar to TRICARE medical benefits and subject to the same or similar limitations. VA supports parity in CHAMPVA coverage between MH/SUD benefits and other medical benefits. There are no CHAMPVA quantitative limits on non-MH/SUD medical benefits, and limitations on the number of mental health visits without the need for further approval is inconsistent with establishing parity. VA believes there are no dissimilarities in the respective TRICARE and CHAMPVA patient populations that would support continuation of quantitative limits on MH/SUD visits, and no similar limitation is imposed on mental health care for eligible veterans receiving health care from VA. Although the current regulatory allowance for waivers on the quantitative limits is imposed on outpatient, inpatient, and institutional MH coverage based on medical need, we acknowledge regulatory waivers based on medical need do not apply to SUD services described in current § 17.272(a)(57)-(62). We therefore seek to remove unnecessary quantitative limits on MH/SUD coverage so that CHAMPVA is fully aligned with TRICARE MH/SUD coverage. More important, this change is in the best health care interests of our beneficiaries. VA proposes removing current paragraphs (a)(57) through (62) and redesignating subsequent paragraphs accordingly. In addition, we would remove current § 17.273(c) which requires preauthorization for outpatient mental health visits in excess of 23 per calendar year and/or more than two (2) sessions per week. Current § 17.273(d) through (f) would be redesignated paragraphs (c) through (e).

Cost sharing for contraceptive services, and contraceptive products approved, cleared, or granted by FDA.

Under the ACA, contraceptive care is considered to be a preventive health service for women and as such most private health plans in the United States must

cover the full range of contraceptive methods, services, and counseling without patient out-of-pocket costs like coinsurance, copayments, or deductibles. See 42 U.S.C. 300gg–13(a)(4), 45 CFR 147.130(a)(1)(iv), 29 CFR 2590.715-2713(a)(1)(iv), 26 CFR 54.9815–2713(a)(1)(iv), and Health Resources and Services Administration (HRSA) Women’s Preventive Services Guidelines <https://www.hrsa.gov/womens-guidelines>. As noted in a letter dated June 27, 2022, issued jointly by HHS, the Department of the Treasury, and the Department of Labor, “The ACA requires that all FDA-approved, cleared, or granted contraceptive products that are determined by an individual’s medical provider to be medically appropriate for the individual must be covered under the individual’s non-grandfathered group health plan or health insurance coverage without cost sharing.” The ACA provisions cited above do not apply to TRICARE or CHAMPVA.

The scope of TRICARE’s family planning benefit is found at 32 CFR 199.4(e)(3), and is consistent with that provided through CHAMPVA, including plan exclusions. TRICARE Policy Manual 6010.60-M (April 1, 2015) Chapter 7, section 2.3 provides that certain family planning procedures and methods are subject to cost sharing. CHAMPVA is established as a cost sharing program. See 38 CFR 17.270(a). VA shares the cost of medically necessary services and supplies for eligible beneficiaries as set forth in 38 CFR 17.271 through 17.278. With the exception of services obtained through VA facilities, CHAMPVA pays the CHAMPVA-determined allowable amount less the deductible, if applicable, and less the beneficiary cost share. 38 CFR 17.274.

As noted, VA is required to furnish medical care in CHAMPVA in the same or similar manner as TRICARE and subject to the same or similar limitations as TRICARE. However, as previously stated, VA has not interpreted the “same or similar” language in 38 U.S.C. 1781(b) to mean that CHAMPVA coverage must be identical per service item or limitation to that provided under TRICARE, particularly in light of the differing size and

composition of our two beneficiary populations. The words “or similar” would be surplusage if CHAMPVA coverage had to be identical to that under TRICARE. Rather, VA interprets the statutory phrase “or similar” to allow it to deviate from TRICARE when VA determines that a deviation would best serve the needs of CHAMPVA beneficiaries. The CHAMPVA beneficiary population is a fraction of that covered by TRICARE, and the average age of those receiving CHAMPVA benefits is higher than that for TRICARE. A primary focus of CHAMPVA is providing such health care that would better promote the long-term health of CHAMPVA beneficiaries. As such, not every aspect of CHAMPVA will be identical to TRICARE. VA has regulated services covered by CHAMPVA to mean those medical services that are medically necessary and appropriate for the treatment of a condition and that are not specifically excluded. 38 CFR 17.270 et seq.

An example of CHAMPVA exclusions differing from TRICARE is coverage for annual physical exams. TRICARE does not include an annual physical exam benefit for all TRICARE beneficiaries while CHAMPVA determined that this benefit should be available to all CHAMPVA beneficiaries. 38 CFR 17.272(a)(30)(xiii). VA did not believe that limiting the provision of annual exams was appropriate from a clinical perspective because these types of comprehensive physical examinations may identify incipient medical problems. 83 FR 2401 (January 17, 2018).

Additionally, VA has previously deviated from TRICARE in amending its CHAMPVA regulations to provide care that is broader than that offered by TRICARE when it determined that these deviations were necessary to best provide services to the CHAMPVA population while remaining “similar” to TRICARE. For instance, Pub. L. 110-417 § 711(b) prohibits waiver of copayments for preventive care provided to Medicare-eligible TRICARE beneficiaries. Conversely, CHAMPVA waives cost-sharing requirements for preventive services for Medicare-eligible beneficiaries. 38 CFR 17.274.

VA determined that enforcing cost-sharing requirements for Medicare-eligible beneficiaries for preventive services would unfairly disadvantage them as compared to CHAMPVA beneficiaries with other health insurance. 83 FR 2396, 2404 (January 17, 2018).

In these examples, VA provided CHAMPVA benefits beyond those benefits offered by TRICARE when it determined that providing such health care would better promote the long-term health of CHAMPVA beneficiaries. In so doing, VA is providing for health care in a manner similar to TRICARE, but the care is being provided in a manner that best serves the CHAMPVA population. Similarly, here, VA is aligning CHAMPVA benefits with TRICARE benefits in certain ways, but VA is also providing benefits beyond those offered by TRICARE to better promote the long-term health of CHAMPVA beneficiaries.

While TRICARE currently requires cost sharing for certain family planning care and services not provided by a military treatment facility, CHAMPVA beneficiaries are a smaller population comprised of dependents of service members who died in service, veterans who are permanently and totally disabled, or veterans who are severely injured and qualify for a VA-recognized caregiver and who are not otherwise eligible for TRICARE. In contrast to TRICARE dependents, these beneficiaries' family planning goals or objectives may be affected by these eligibility-based life circumstances. Some CHAMPVA beneficiaries may not have other health insurance through which they could receive this type of care or service at no cost to them. If so, current CHAMPVA cost sharing obligations may constitute a barrier to access. For these reasons, VA believes that contraceptive care should be exempt from CHAMPVA cost share requirements, and, in this regard, more closely aligned with the ACA.

VA proposes amending § 17.274 to exempt contraceptive services, and contraceptive products approved, cleared, or granted by FDA from cost sharing requirements. We would amend § 17.274 by adding a new paragraph (f) to state that cost sharing and annual deductible requirements under 38 CFR 17.274(a) and (b) do not apply to: (1) surgical insertion, removal, and replacement of intrauterine systems and contraceptive implants; (2) measurement for, and purchase of, contraceptive diaphragms or similar FDA approved, cleared, or granted medical devices, including remeasurement and replacement; (3) prescription contraceptives, and prescription or nonprescription contraceptives used as emergency contraceptives; (4) surgical sterilization; and (5) outpatient care or evaluation associated with provision of services listed in proposed paragraph (f)(1)-(4).

We would also amend § 17.272(a)(28) to conform to proposed § 17.274(f)(3). Currently, § 17.272(a)(28) excludes non-prescription contraceptives from CHAMPVA coverage. We would amend that paragraph to state that nonprescription contraceptives are excluded, except those non-prescription contraceptives used as emergency contraceptives.

30-day comment period.

The Administrative Procedure Act requires federal agencies to publish a notice of proposed rulemaking in the Federal Register and give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. 5 U.S.C. 553(b) and (c). There is no minimum period specified in the statute for the comment period to remain open, and it often varies with the complexity of the rule. Most comment periods last between 30 and 60 days, and some are re-opened if the agency believes that there was insufficient time for the public to respond or that the agency did not receive as much feedback as it

would like. The agency must then consider all comments that are submitted in determining the content of the final rulemaking. Executive Order 12866 Regulatory Planning and Review (September 30, 1993) provides at section 6(a)(1) that “each agency should afford the public a meaningful opportunity to comment on any proposed regulation, which in most cases should include a comment period of not less than 60 days.”

VA has determined that a 30-day public comment period should be provided for this proposed rulemaking. VA believes the proposed changes to CHAMPVA program exclusions and cost sharing are not complex and would align the program with longstanding legislative initiatives. If, after the close of the public comment period, VA determines that additional public input is necessary, we will provide additional opportunity for public comment.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. The Office of Information and Regulatory Affairs has determined that this rule is a significant regulatory action under Executive Order 12866. The Regulatory Impact Analysis associated with this rulemaking can be found as a supporting document at www.regulations.gov.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by state, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year. This rule will have no such effect on State, local, or tribal governments, or on the private sector.

Paperwork Reduction Act

This proposed rule includes provisions constituting a revised collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521) that require approval by OMB. Accordingly, under 44 U.S.C. 3507(d), VA has submitted a copy of this rulemaking action to OMB for review and approval.

OMB assigns control numbers to collections of information it approves. In this case, OMB assigned OMB Control Number 2900-0219 for this approved information collection. VA may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. If OMB does not approve the revised collection of information as requested, VA will immediately remove the provisions containing the collection of information or take such other action as is directed by OMB.

Comments on the revised collection of information contained in this rulemaking should be submitted through www.regulations.gov. Comments should indicate that they are submitted in response to “RIN 2900-AR55 CHAMPVA coverage of audio-only telehealth, mental health services, and cost sharing for certain contraceptive services and contraceptive products approved, cleared, or granted by FDA” should be sent within 30 days of publication of this rulemaking. The collection of information

associated with this rulemaking can be viewed at:

www.reginfo.gov/public/do/PRAMain.

OMB is required to make a decision concerning the revised collection of information contained in this rulemaking between 30 and 60 days after publication of this rulemaking in the Federal Register (FR). Therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication. This does not affect the deadline for the public to comment on the provisions of this rulemaking.

The Department considers comments by the public on new collections of information in-

- Evaluating whether the new collections of information are necessary for the proper performance of the functions of the Department, including whether the information will have practical utility;
- Evaluating the accuracy of the Department's estimate of the burden of the new collection of information, including the validity of the methodology and assumptions used;
- Enhancing the quality, usefulness, and clarity of the information to be collected; and
- Minimizing the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

The collection of information associated with this rulemaking contained in 38 CFR § 17.272 is described immediately following this paragraph, under its respective title. The paragraph below addresses only the revised number of respondents

attributable to this rulemaking. OMB has previously approved information collection related to filing of CHAMPVA health benefits claims based on an estimate of 55,000 respondents annually.

Title: Civilian Health and Medical Program of the Department of Veterans Affairs (CHAMPVA) Benefits Forms.

OMB Control No: 2900-0219

CFR Provision: 38 CFR 17.272(a)(44)

- Summary of collection of information: Proposed 38 CFR 17.272(a)(44) would remove the exclusion of CHAMPVA benefits coverage for audio-only telehealth. Previously denied claims for audio-only telehealth would have to be resubmitted by the provider, or by the CHAMPVA beneficiary if the beneficiary has already paid for that medical service. To receive payment or reimbursement, submission of a VA Form 10-5979a CHAMPVA claim form is required with supporting evidence.

- Description of need for information and proposed use of information: VA cannot pay for medical benefits, or reimburse a CHAMPVA beneficiary for previously paid medical expenses, in the absence of a filed claim. In this case, that claim would be related to a previously denied claim for an audio-only telehealth visit.

- Description of likely respondents: Health care providers and CHAMPVA beneficiaries.

- Estimated number of respondents: 74,914 in FY2022. This represents health care providers and CHAMPVA beneficiaries with denied claims for audio-only telehealth.

- Estimated frequency of responses: One time.

- Estimated average burden per response: 10 minutes for respondents.

- Estimated total annual reporting and recordkeeping burden: Using the annual number of 74,914 respondents, VA estimates a total annual reporting and recordkeeping burden of 12,486 hours for respondents.
- Estimated cost to respondents per year: VA estimates the annual cost to respondents to be \$349,732.86. This is based on Bureau of Labor Statistics mean hourly wage data for BLS wage code “00-0000 All Occupations” of \$28.01 per hour X 12,486 hours.

Regulatory Flexibility Act

The Secretary hereby certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601-612. This proposed rule would allow for payment or reimbursement of audio-only telehealth services on behalf of CHAMPVA beneficiaries, provide for parity between mental health and substance use disorder care and other medical care, and eliminate cost sharing for certain contraceptive services and contraceptive products approved, cleared, or granted by FDA. Therefore, it would only affect individuals who are CHAMPVA beneficiaries. Without this rulemaking, health care providers who may be small entities would still receive payment for services, the payment would be from the CHAMPVA beneficiary and not from VA. Therefore, pursuant to 5 U.S.C. 605(b), the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604 do not apply.

Assistance Listing

The Assistance listing number and titles for the program affected by this document is 64.039 - CHAMPVA.

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Foreign relations, Government contracts, Grant programs-health, Grant programs-veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical and dental schools, Medical devices, Medical research, Mental health programs, Nursing homes, Philippines, Reporting and recordkeeping requirements, Scholarships and fellowships, Travel and transportation expenses, Veterans.

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved this document on October 4, 2022, and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Jeffrey M. Martin,

Assistant Director,

Office of Regulation Policy & Management,

Office of General Counsel,

Department of Veterans Affairs.

For the reasons stated in the preamble, the Department of Veterans Affairs (VA) proposes to amend 38 CFR part 17 as follows:

PART 17 – MEDICAL

1. The general authority citation for part 17 continues to read as follows:

Authority: 38 U.S.C. 501, and as noted in specific sections.

2. Amend § 17.272 by:

- a. Revising paragraphs (a)(28) and (a)(44);
- b. Removing paragraphs (a)(57) through (62);
- c. Redesignating paragraphs (a)(63) through (83) as paragraphs (a)(57) through (77).

The revisions read as follows:

§ 17.272 Benefits limitations/exclusions.

(a) * * *

(28) Nonprescription contraceptives, except those nonprescription contraceptives used as emergency contraceptives.

* * *

(44) Telephone Services, with the following exceptions:

(i) Services or advice rendered by telephone (audio only) on or after May 12, 2020, are not excluded when the services are otherwise covered CHAMPVA services provided through this modality and are medically necessary and appropriate.

(ii) A diagnostic or monitoring procedure which incorporates electronic transmission of data or remote detection and measurement of a condition, activity, or function (biotelemetry) is covered when:

(A) The procedure, without electronic data transmission, is a covered benefit;
and

(B) The addition of electronic data transmission or biotelemetry improves the management of a clinical condition in defined circumstances; and

(C) The electronic data or biotelemetry device has been classified by the U.S. Food and Drug Administration, either separately or as part of a system, for use consistent with the medical condition and clinical management of such condition.

* * * * *

§ 17.273 [Amended]

3. Amend § 17.273 by removing paragraph (c), and redesignating paragraphs (d) through (f) as paragraphs (c) through (e).

4. Amend § 17.274 by adding a new paragraph (f) to read as follows:

§ 17.274 Cost sharing.

* * * * *

(f) Cost sharing and annual deductible requirements under paragraphs (a) and (b) of this section do not apply to:

(1) Surgical insertion, removal, and replacement of intrauterine systems and contraceptive implants;

(2) Measurement for, and purchase of, contraceptive diaphragms or similar FDA approved, cleared, or granted medical devices, including remeasurement and replacement;

(3) Prescription contraceptives, and prescription or nonprescription contraceptives used as emergency contraceptives;

(4) Surgical sterilization; and

(5) Outpatient care or evaluation associated with provision of family planning services listed in paragraph (f)(1) through (4) of this section.

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