

VI. Environmental Analysis

101. The Commission is required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a significant adverse effect on the human environment.¹¹¹ We conclude that neither an Environmental Assessment nor an Environmental Impact Statement is required for this final rule under § 380.4(a)(15) of the Commission's regulations, which provides a categorical exemption for approvals of actions under sections 205 and 206 of the FPA relating to the filing of schedules containing all rates and charges for the transmission or sale of electric energy subject to the Commission's jurisdiction, plus the classification, practices, contracts, and regulations that affect rates, charges, classifications, and services.¹¹²

VII. Regulatory Flexibility Act

102. The Regulatory Flexibility Act of 1980 (RFA)¹¹³ generally requires a description and analysis of final rules that will have significant economic impact on a substantial number of small entities. The Small Business Administration (SBA) sets the threshold for what constitutes a small business. Under SBA's size standards,¹¹⁴ RTOs/ISOs fall under the category of Electric Bulk Power Transmission and Control (NAICS code 221121) with a size threshold of 950 employees (including the entity and its associates).¹¹⁵

103. The RTOs/ISOs (*i.e.*, SPP, MISO, PJM, ISO-NE, NYISO, and CAISO) each employ more than 950 employees and are not considered small.

104. According to SBA guidance, the determination of significance of impact "should be seen as relative to the size of the business, the size of the competitor's business, and the impact the regulation has on larger competitors."¹¹⁶ The Commission does

not consider the estimated cost to be a significant economic impact, nor does it effect a significant amount of small entities. As a result, we certify that the reforms in this final rule would not have a significant economic impact on a substantial number of small entities.

VIII. Document Availability

105. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (<http://www.ferc.gov>). At this time, the Commission has suspended access to the Commission's Public Reference Room due to the President's March 13, 2020 proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID-19).

106. From the Commission's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

107. User assistance is available for eLibrary and the Commission's website during normal business hours from FERC Online Support at 202-502-6652 (toll free at 1-866-208-3676) or email at ferconlinesupport@ferc.gov, or the Public Reference Room at (202) 502-8371, TTY (202) 502-8659. Email the Public Reference Room at public.referenceroom@ferc.gov.

IX. Effective Date and Congressional Notification

108. These regulations are effective August 21, 2023. The Commission has determined, with the concurrence of the Administrator of the Office of Information and Regulatory Affairs of OMB, that this rule is not a "major rule" as defined in section 351 of the Small Business Regulatory Enforcement Fairness Act of 1996.

List of Subjects in 18 CFR Part 35

Electric power rates, Electric utilities, Reporting and recordkeeping requirements By the Commission.

Issued: June 15, 2023.

Debbie-Anne A. Reese,
Deputy Secretary.

In consideration of the foregoing, the Commission amends part 35, subpart J, title 18, *Code of Federal Regulations*, as follows:

PART 35—FILING OF RATE SCHEDULES AND TARIFFS

■ 1. The authority citation for part 35 continues to read as follows:

Authority: 16 U.S.C. 791a–825r, 2601–2645; 31 U.S.C. 9701; 42 U.S.C. 7101–7352.

■ 2. Amend § 35.47 by adding paragraph (h) to read as follows:

§ 35.47 Tariff provisions regarding credit practices in organized wholesale electric markets.

* * * * *

(h)(1) Subject to paragraph (h)(2) of this section:

(i) Permit organized wholesale electric markets to share market participant credit-related information with, and receive market participant credit-related information from, other organized wholesale electric markets for the purpose of credit risk management and mitigation; and

(ii) Permit the receiving organized wholesale electric market to use credit-related information received from another organized wholesale electric market to the same extent and for the same purposes that the receiving organized wholesale electric market may use credit-related information collected from its own market participants.

(2) Require the receiving organized wholesale electric market to treat credit-related information an organized wholesale electric market receives from another organized wholesale electric market as confidential under the terms set forth in the tariff or other governing document of the receiving organized wholesale electric market.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1301

[Docket No. DEA-574]

RIN 1117-AB57

Reporting Theft or Significant Loss of Controlled Substances

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration (DEA) is publishing this final rule amending the regulations regarding DEA Form 106, used by DEA registrants to formally report thefts or significant losses of controlled

¹¹¹ *Reguls. Implementing the Nat'l Env't Pol'y Act*, Order No. 486, 52 FR 47897 (Dec. 17, 1987), FERC Stats. & Regs. Preambles 1986-1990 ¶ 30,783 (1987) (cross-referenced at 41 FERC ¶ 61,284).

¹¹² 18 CFR 380.4(a)(15).

¹¹³ 5 U.S.C. 601-612.

¹¹⁴ 13 CFR 121.201.

¹¹⁵ The RFA definition of "small entity" refers to the definition provided in the Small Business Act, which defines a "small business concern" as a business that is independently owned and operated and that is not dominant in its field of operation. The SBA's regulations at 13 CFR 121.201 define the threshold for a small Electric Bulk Power Transmission and Control entity (NAICS code 221121) to be 500 employees. See 5 U.S.C. 601(3) (citing section 3 of the Small Business Act, 15 U.S.C. 632).

¹¹⁶ U.S. Small Business Administration, "A Guide for Government Agencies How to Comply with the Regulatory Flexibility Act," at 18 (May 2012), https://www.sba.gov/sites/default/files/advocacy/rfguide_0512_0.pdf.

substances, to require that all such forms be submitted electronically, and to clarify the time frame registrants have to complete the necessary documentation. This final rule does not change the requirement that registrants preliminarily notify the DEA Field Division Office in their area, in writing, of the theft or significant loss of any controlled substances within one business day of discovering such loss or theft. Paper copies of DEA Form 106 simply will no longer be accepted once the final rule becomes effective.

DATES: The final rule is effective July 24, 2023.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 776-3882.

SUPPLEMENTARY INFORMATION:

Background and Legal Authority

The Controlled Substances Act (CSA) authorizes the Administrator of the Drug Enforcement Administration (DEA) (by delegation from the Attorney General) to promulgate rules and regulations relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances; maintenance and submission of records and reports related there to; and for the efficient execution of her statutory functions concerning controlled substances.¹ DEA regulations require DEA registrants—both practitioners and non-practitioners—to notify their local Field Division Office, in writing, of any theft or significant loss of any controlled substances within one business day of discovery of the theft or loss, and they complete and submit to the same Field Division a DEA Form 106 regarding the theft or loss.² However, the regulations are silent as to the actual submission method for DEA Form 106 (*e.g.*, mail, hand delivery, electronic) and the deadline for submitting DEA Form 106.

In contrast, DEA regulations set forth a mandatory electronic submission method and reporting deadline for DEA Form 107, a form used by regulated persons³ to report any unusual or excessive loss or disappearance of a listed chemical. Under 21 CFR 1310.05(b)(1), in addition to certain other specified reporting requirements,

a regulated person must file a complete and accurate DEA Form 107, in accordance with 21 CFR 1310.06(d), with DEA through DEA's Diversion Control Division secure network application within 15 calendar days after becoming aware of the circumstances requiring the report.

Based on submission data from 2018, 99.5 percent of all DEA Form 106 submissions are completed electronically via DEA's secure website. The remaining 0.5 percent of form submissions are completed by paper.

Proposed Rule

DEA published a notice of proposed rulemaking (NPRM) on July 29, 2020,⁴ proposing to require that DEA registrants electronically file a complete and accurate DEA Form 106 within 15 calendar days after discovery of the theft or significant loss of any controlled substances. The intent of this rule was to clarify the submission process, requiring that all forms be submitted electronically through DEA's secure online database similar to the submission process and reporting time period for DEA Form 107. Finally, per the NPRM, there's no change to specific requirements for 21 CFR 1301.74(c) and 1301.76(b) that non-practitioners and practitioners preliminarily notify their local DEA Field Division Office, in writing, of the theft or significant loss of any controlled substances within one business day of discovering such theft or loss.

Discussion of Comments

DEA received 22 comments in response to the NPRM. These comments were from associations, manufacturer registrants, healthcare systems, individuals, anonymous commenters, and others. Of these comments, two commenters were in support for the rule while having concerns for certain aspects of the proposed amendments and one commenter did not express a position on the rule. One comment was political in nature and does not relate to the proposed rule. The other commenters expressed concerns about the 15-day reporting time frame and other issues, and provided suggestions. This rule will not respond to the comment outside of the scope of the proposed rule. The other comments are described and considered below.

Support of the 15-Day Timeframe

Issue: There are two comments (SpecGX LLC, individual) in favor of the 15-day timeframe, provided DEA clarify certain aspects. SpecGX LLC supports

the 15-day timeframe as long as they are able to update the information on the already submitted DEA Form 106 if they have recovered more of the lost or stolen items that were previously reported "lost." This commenter believed that it is better to have a complete, accurate record in order to accurately assess and report. The individual commenter felt that the timeline for the submission is reasonable, but suggested that the timeline be expanded during the initial period for those who have not reported electronically.

DEA Response: DEA appreciates the support of the proposed 15-day timeframe and the electronic submission of DEA Form 106. It is unclear to DEA what the individual commenter means by the "initial" period. However, when proposing the 15-day timeframe, DEA wanted to mirror the submission process and reporting time frame for DEA Form 107.⁵ As explained in the NPRM preamble, and in the above background section, DEA regulations require that DEA Form 107 be submitted through the DEA Diversion Control Division secure network application within 15 calendar days after becoming aware of the circumstances requiring the report.⁶ As noted above, DEA regulations, 21 CFR 1301.74(c) and 1301.76(b), also require that registrants preliminarily notify their local DEA Field Division Office, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of theft or loss. For those that have never submitted the report online, this will give them more time to complete their investigations and get acquainted with the online submission system.

Objection to the 15-Day Timeframe

Issue: A majority of the commenters did not favor the 15-day timeframe, and instead suggested that DEA implement a 30-day, 45-day, or 60-day timeframe. The National Community Pharmacists Association (NCPA) stated that DEA should adopt the 15-day timeframe instead of the 60-day timeframe, but asked that DEA delay the implementation of the time limit until the current public health emergency of coronavirus disease (COVID-19) ends. The American Pharmacists Association (APhA) stated that the 15-day timeframe was insufficient because it was not enough time to complete all required documentation and investigations, and would be unduly burdensome to the registrants.

¹ 21 U.S.C. 821, 827, and 871(b).

² 21 CFR 1301.74(c) and 1301.76(b) for non-practitioner and practitioner registrants, respectively. The provision at 21 CFR 1301.74(c) sets forth certain exceptions regarding in-transit losses and import/export transactions.

³ The term "regulated person" is defined at 21 U.S.C. 802(38).

⁴ 85 FR 45547.

⁵ 85 FR 45547, 45549.

⁶ 21 CFR 1310.05(b)(1).

DEA Response: DEA appreciates the concerns noted in the comments. DEA understands that adequate time is needed in order to complete an accurate and thorough investigation. DEA will allow registrants 45 days to submit DEA Form 106, which DEA believes is more than enough time to conduct investigations. DEA disagrees with postponing the effective date of this rule.

One-Day Reporting Requirement

Issue: A few commenters (NACDS; two individuals) expressed concerns about DEA's current requirements to preliminarily report, in writing, to the local DEA Field Division office any theft or significant loss of any controlled substances within one business day of discovering such theft or loss, and also to separately file DEA Form 106 with the local DEA Field Division office within a non-specified time frame (noting that the proposal would change the submission of DEA Form 106 to an electronic submission only and stipulate a 15-day reporting time frame). These commenters contended that the one-day reporting requirement is arbitrary, confusing, and redundant to that of the DEA Form 106 reporting requirement. In order to streamline reporting and reduce administrative burden, two of the commenters requested that DEA abolish the one-day reporting requirement altogether. Alternatively, these two commenters suggested that DEA make the reporting time frame for the one-day report match that of DEA Form 106, and the registrant could utilize one online reporting tool to satisfy both requirements. The third commenter requested that DEA only have one reporting requirement, in which a registrant would "immediately file" a report electronically at a "central location" with DEA; the central location could then electronically notify the registrant's regional office; and the regional office could follow up with the registrant for more details as appropriate.

DEA Response: DEA believes it is appropriate to retain the two-step reporting requirement, consisting of the preliminary one-day reporting and the DEA Form 106 reporting. The one-day reporting notification allows DEA to know right away about the theft and significant loss, to have an immediate record of the initial incident, and allows DEA to promptly institute any actions deemed appropriate to the situation, including working with the registrant to address the theft or loss. With the one-day reporting documentation, DEA is able to have a record of any registrant that reports the theft and loss. As well,

the registrant will have a record of the date of the documentation and to whom it was sent. Also, the commenter's suggestion for follow-up by the regional office would shift the burden to DEA, and may well lead to non-uniform reporting of these incidents. Therefore, DEA will not make any changes to that requirement in this final rule. The second report—the submission of DEA Form 106—is important because it allows the registrant time to adequately investigate the theft or loss and make a final determination. As discussed above, this final rule implements a 45-day time frame (instead of the proposed 15-day time frame) for registrants to electronically submit DEA Form 106. As the time frames for the preliminary reporting and DEA Form 106 are different, it is not possible for the registrant to utilize an online reporting tool to satisfy both reporting requirements at one time.

Responsibility for Filing

Issue: One commenter stated that a clinic owned by multiple doctors who each have individual DEA registrations, may not necessarily know whose controlled substances were lost. The commenter said that it is not clear from the regulation how that issue would be resolved and asked whether one or all of the practitioners should file DEA Form 106.

DEA Response: DEA regulations require each registrant to provide effective controls and procedures to guard against theft and diversion of controlled substances⁷ and to maintain complete and accurate records of controlled substances.⁸ Individual registrants in a multiple registrant clinic setting should be responsible for their own records and controlled substance storage. Records and controlled substances for each individual DEA registrant should be kept separate from all other registrants to aide in distinguishing which controlled substances belong to which DEA registrant. Therefore, each registered practitioner whose stock was affected by the theft or loss, is responsible for providing the one-day notification to DEA's Field Division Office and for filing DEA Form 106. Each practitioner is responsible for designating who files a report of theft or loss within their clinic or pharmacy, therefore, DEA leaves this decision solely for the practitioner.

⁷ 21 CFR 1301.71(a).

⁸ 21 CFR 1304.21(a).

Definition of Terms

Issue: One commenter requested that DEA distinguish "significant" loss from "normal" loss.

DEA Response: DEA regulations require registrants to provide effective controls and procedures to guard against theft and diversion of controlled substances,⁹ but the regulations do not provide a specific definition of "significant loss". What constitutes a significant loss for one registrant may be construed as comparatively insignificant for another. A manufacturer may experience continuous losses in the manufacturing process due to, for example, atmospheric changes or mixing procedures. Such losses may not be deemed by the registrant to be significant and may be recorded in batch records. Conversely, for registrants other than manufacturers, the repeated loss of even small quantities of controlled substances over a period of time may indicate a significant aggregate significant loss that must be reported to DEA, even though the individual quantity of each occurrence is not significant. The distinction between a significant loss and a normal loss is case and circumstance specific, and registrants are best positioned to determine whether a loss rises to the level of a significant loss. Therefore, DEA declines to add a definition for "significant loss" in this final rule.

Issue: One commenter requested that DEA define the term "discover."

DEA Response: DEA previously acknowledged that there is some confusion on the meaning of "discovery" and recognized that the discovery occurs in incremental stages.¹⁰ At that time, DEA did not define "discovery" in the regulatory text. DEA is planning on addressing the definition of Discovery in a future rulemaking. For the purposes of this final rule, DEA is only addressing the parameters surrounding the DEA Form 106 submission timeframe and the 1-day reporting requirement.

Other Comments

Issue: One commenter, CVS Health, asked whether the electronic DEA Form 106 should include more categories, specifically "Unknown" and "Other," as they believe this would enable them to more accurately report if the existing categories did not apply to the particular situation. This commenter noted that the "Unknown" category previously existed, and asked that it be reinstated. The Healthcare Distribution Alliance (HDA) mentioned that they

⁹ 21 CFR 1301.71(a).

¹⁰ 70 FR 47094, 47095, August 12, 2005.

would like the “Other” category to be reinstated as that will allow for accurate reporting of the potential theft or loss incidents that do not fit the current response options. HDA also encouraged DEA to create a guidance document that not only would guide registrants on how to complete DEA Form 106, but also establish a compliance procedure in the event that the electronic submission is not operable (e.g., several-day power outage, a natural disaster that’s out of the registrant’s control, etc.).

DEA Response: DEA will continue to use the categories that are currently listed on DEA Form 106. DEA wants accurate information, and the categories “unknown” and “other” would provide vague information and confusion to DEA officials. In addition, DEA has provided guidelines for completing DEA Form 106, which can be found at [https://www.deadiversion.usdoj.gov/pubs/manuals/\(DEA-DC-046\)\(EO-DEA154\)_Pharmacist_Manual.pdf](https://www.deadiversion.usdoj.gov/pubs/manuals/(DEA-DC-046)(EO-DEA154)_Pharmacist_Manual.pdf) in Appendix I of the Pharmacist’s Manual. Finally, regarding the request to establish a compliance procedure in the event that the electronic submission is not operable (e.g., several-day power outage, a natural disaster that’s out of the registrant’s control, etc.), it is the responsibility of the registrant to maintain effective controls against diversion and design and operate compliance procedures to that end. However, in the event of any technical issues involving the DEA system being down, the registrant can report the issues by calling the DEA Help Center at 1–800–882–9539. If there is a need to submit DEA Form 106 while the DEA system is down, the registrant can document the day and time of their attempted submission(s) and their successful submission, and retain these records.

Issue: One commenter asked if DEA has an alternative for rural residents who are unable to make their submissions electronically, as well as if there are any alternate submission plans should the network be down.

DEA Response: Should a DEA registrant that lives in a rural residency feel the need to request an exception from the electronic submission requirement, they can write DEA to request an exception to regulations pursuant to 21 CFR 1307.03. In the event of any technical issues involving the network being down or otherwise unable to submit DEA Form 106 online, the registrant can report the issues by calling the DEA Help Center at 1–800–882–9539.

Issue: The National Association of Chain Drug Stores (NACDS) and the HDA stated that when a registrant fills

out DEA Form 106, enters a National Drug Code (NDC), and submits the form via the secure online system, if the NDC isn’t up to date, then the submission is rejected by the secure network application. When new or changed drug codes are not present, this creates challenges when reporting and results in inaccurate reports. In these cases, when a form is rejected electronically, the only other option is to report it via paper. NACDS also mentioned that there are some field office conflicts. Some offices prefer faxes while others want written letters sent to particular email addresses. NACDS is suggesting that there be consistency with the DEA field offices.

DEA Response: The NDC is updated on a monthly basis and as needed when a registrant reports an NDC as not listed. Should the registrant have any questions, they can send an email at ODT@usdoj.gov, or the registrant can indicate which NDC is missing or not included in the NDC library on the one day reporting notification. Currently, registrants are required to notify their local DEA Field Office, preliminarily in writing, of any theft or significant loss.¹¹ While faxing is one method of notifying, it isn’t the only option. DEA leaves the decision of which method of writing is preferred to the discretion of the local DEA Field Offices.

Section-by-Section Description of Rule Changes

This final rule sets forth in 21 CFR 1301.74(c) and 1301.76(b) that DEA registrants will have a 45-day calendar period (instead of the proposed 15-day calendar period), upon discovery of the theft or significant loss of any controlled substances, to submit DEA Form 106. This rule finalizes the other proposed provisions that DEA Form 106 be complete and accurate, and the submission be done electronically through DEA’s Diversion Control Division secure network application (available on DEA’s Diversion Control Division website).

Regulatory Analyses

Executive Orders 12866 and 13563, Regulatory Planning and Review and Improving Regulation and Regulatory Review

This final rule was developed in accordance with the principles of Executive Orders (E.O.) 12866 and 13563. E.O. 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits

(including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in E.O. 12866. E.O. 12866 classifies a “significant regulatory action,” requiring review by the Office of Management and Budget (OMB), as any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the E.O. OMB has determined that this final rule is not a “significant regulatory action” under E.O. 12866, section 3(f).

Analysis of Benefits and Costs

DEA has examined the benefits and costs of this final rule. Currently, based on submissions received in 2018, 99.5 percent of all DEA Form 106 reports are reported electronically via DEA’s secure website. This final rule impacts the remaining 0.5 percent of responses that are reported by paper, representing 181 of a total of 37,047 responses. Benefits include costs savings, as discussed in the following paragraphs, increased simplicity in reporting theft and loss on controlled substances, and clarity in the regulations. This final rule adds clarity to the submission method by matching the electronic submission process to that of “Reports of Loss or Disappearance of Listed Chemicals”—DEA Form 107. Additionally, electronic submissions will allow all report submissions to be received more quickly and stored in a central database, as well as allow for analysis.

There is no new cost associated with this final rule. The labor burden to submit DEA Form 106 is estimated to be the same for electronic and paper submissions. However, DEA anticipates there will be cost savings associated with electronic submissions. Some cost savings are described qualitatively and some are quantified. Based on submissions received in 2018, DEA estimates approximately 181 paper submissions per year. Many of these

¹¹ 21 CFR 1301.74(c).

paper forms contain illegible or erroneous information, requiring DEA to call respondents to correct or clarify the information in the paper form, consuming both DEA's and the respondent's time and resources. Electronic submissions are expected to virtually eliminate the requirement for DEA to call back respondents for clarifications of form data. As DEA has not tracked the number of call backs or the average duration of calls, DEA does not have a strong basis to quantify the cost savings.

This final rule eliminates the need to print paper forms and transmit by mail or courier service. DEA estimates there will be a cost savings of \$0.63, \$0.55 for postage plus \$0.08 for an envelope, or a total of \$114 per year for an estimated 181 responses per year. DEA assumes the cost savings associated with not having to print is negligible. In summary, DEA estimates the economic impact of this final rule is *de minimis*.

In the event particular registrants feel the need to request an exception from the electronic submission requirement, they can write DEA to request an exception to regulations pursuant to 21 CFR 1307.03. In the event of any technical issues involving the network being down or otherwise unable to submit DEA Form 106 online, the registrant can report the issues by calling the DEA Help Center at 1-800-882-9539.

Executive Order 12988, Civil Justice Reform

This final regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988, Civil Justice Reform, to eliminate drafting errors and ambiguity, minimize

litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This final rule does not have federalism implications warranting the application of E.O. 13132. The final rule does not have substantial direct effects on the States, on the relationship between the National Government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This final rule does not have tribal implications warranting the application of E.O. 13175. This final rule does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act (RFA), 5 U.S.C. 601-612, DEA has reviewed the economic impact of this final rule on small entities. DEA's economic impact evaluation indicates that the rule will not have a significant economic impact on a substantial number of small entities.

The RFA requires agencies to analyze options for regulatory relief of small entities unless it can certify that the rule will not have a significant impact on a substantial number of small entities. For the purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental

jurisdictions. DEA has analyzed the economic impact of each provision of this final rule and estimates that the final rule will have minimal economic impact on affected entities, including small entities.

The final rule amends regulations regarding DEA Form 106 to clarify that all submissions of the form must be submitted online. Based on actual submissions in 2018, DEA estimates there are 181 paper submissions per year, submitted by six entities: One distributor, two pharmacies, one researcher, one veterinarian service entity, and one hospital.

DEA estimates the affected entities are in the following North American Industry Classification System (NAICS) industries:

- 424210—Drugs and Druggist's Sundries Merchant Wholesalers
- 446110—Pharmacies and Drug Stores
- 541712—Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology)
- 541940—Veterinary Services
- 622110—General Medical and Surgical Hospitals

The U.S. Census Bureau's Statistics of U.S. Businesses (SUSB) is an annual series that provides economic data by enterprise size and industry. SUSB data contains the number of firms for various employment or revenue size ranges for each industry. Comparing the size ranges to the U.S. Small Business Administration (SBA) size standards, DEA estimated the number of entities in each affected industry, number of small entities in each affected industry, and number of affected small entities. The table below summarizes the results.

NAICS	Description	Number of firms	SBA size standards	Number of small entities	Number of affected small entities
424210	Drugs and Druggists' Sundries Merchant Wholesalers	6,833	250 employees	6,569	0
446110	Pharmacies and Drug Stores	18,852	\$30.0 million*	18,503	0
541715	Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology).	9,864	1,000 employees	9,325	0
541940	Veterinary Services	27,708	\$8.0 million*	27,564	1
622110	General Medical and Surgical Hospitals	2,904	\$41.5 million*	1,199	0

* Annual revenue. Sources: 2016 SUSB Annual Datasets by Establishment Industry, "U.S. & states, NAICS, detailed employment sizes (U.S., 6-digit and states, NAICS sectors)," <https://www.census.gov/data/datasets/2016/econ/susb/2016-susb.html>. (Accessed 1/14/2020.) 2012 SUSB Annual Data Tables by Establishment Industry, "U.S., 6-digit NAICS." <https://www.census.gov/data/tables/2012/econ/susb/2012-susb-annual.html>. (Accessed 1/14/2020.) U.S. Small Business Administration, Table of size standards, effective Aug 19, 2019. <https://www.sba.gov/document/support--table-size-standards>. (Accessed 1/14/2020.)

There is no new cost associated with this final rule. The labor burden to submit DEA Form 106 is estimated to be the same for electronic and paper submissions. However, DEA anticipates there will be cost savings associated with electronic submissions. Some cost savings are described qualitatively and some are quantified. From submissions

received in 2018, DEA estimates the one affected small entity submits one paper submission per year. Many of these paper forms contain illegible or erroneous information, requiring DEA to call respondents to correct or clarify the information in the paper form, consuming DEA's and the respondent's time and resources. Electronic

submissions are expected to virtually eliminate the requirement for DEA to call back the respondent for clarifications of form data. As DEA has not tracked the number of call backs or the average duration of calls, DEA does not have a strong basis to quantify the cost savings.

DEA estimates there will be a cost saving associated with eliminating the need to print paper forms and transmit by mail or courier service. The estimated cost savings is \$0.63, \$0.55 for postage plus \$0.08 for an envelope, per paper submission.

In summary, DEA estimates this rule will affect six entities who submit 181 paper DEA Form 106's. Of the affected six entities, one entity (veterinary services entity) is a small entity, submitting one paper form per year. The estimated cost savings for the affected small entity is minimal (\$0.63 per year). Therefore, this final rule will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

On the basis of information contained in the RFA section above, DEA has determined and certifies pursuant to the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1501 *et seq.*, that this action would not result in any Federal mandate that may result "in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any 1 year. . .". Therefore, neither a Small Government Agency Plan nor any other action is required under provisions of UMRA.

Paperwork Reduction Act

Pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521), DEA has identified that this final rule modifies an existing collection of information: 1117–0001. A person is not required to respond to a collection of information unless it displays a valid OMB control number. Copies of existing information collections approved by OMB may be obtained at <https://www.reginfo.gov/>.

A. Collections of Information Associated With the Final Rule

Title: Amending Regulations Regarding DEA Form 106.
OMB Control Number: 1117–0001.
Form Number: DEA–106.

DEA is amending its regulations for reporting thefts or significant losses of controlled substances to implement the requirement of electronic submissions for reporting the thefts or significant losses of controlled substances to clarify that all such reports must be submitted electronically within 45 days of discovery of the circumstances requiring the report. This amendment clarifies the submission process by aligning it with the current electronic submission requirements of reporting losses of

disappearance of listed chemicals on DEA Form 107 and no longer accepting physical copies. Form 107 (OMB Control Number 1117–0024) is also only submitted electronically; however, the reporting time frame for Form 107 is within 15 days of discovery of the circumstances requiring the report instead of the 45-day time frame, finalized in this rule, for DEA Form 106.

Currently, based on 2018 submission data, 99.5 percent of all DEA Form 106 reports are reported electronically via DEA's secure website. This final rule impacts the remaining 0.5 percent of responses that are reported by paper. Electronic submissions are expected to virtually eliminate the requirement for DEA to call back the respondent for clarifications of form data. Furthermore, this final rule eliminates the need for respondents to print paper forms and transmit by mail or courier service, resulting in cost savings for the 0.5 percent of responses per year transitioning from paper to electronic forms.

The electronic submission must be filed with DEA through DEA's Diversion Control Division secure network application (available on DEA's Diversion Control Division website). The submissions of forms will be more easily submitted and organized through the secure database.

DEA estimates the following number of respondents and burden associated with this collection of information:

- *Number of respondents:* 10,693.
- *Frequency of response:* 3.4646 (calculated).
- *Number of responses:* 37,047.
- *Burden per response:* 0.3333 hours.
- *Total annual hour of burden:* 12,349 hours.

If you need a copy of the information collection instrument(s) with instructions or additional information, please contact the Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (571) 776–2265.

Any additional comments on this collection of information, may be sent in writing to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for DOJ, Washington, DC 20503. Please state that your comment refers to OMB Control Number 1117–0001.

Congressional Review Act

This final rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of this rule to both Houses of

Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1301

Administrative practice and procedure, Drug traffic control, Security measures.

For the reasons set out above, DEA amends 21 CFR part 1301 as follows:

PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1301 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 831, 871(b), 875, 877, 886a, 951, 952, 956, 957, 958, 965 unless otherwise noted.

■ 2. In § 1301.74, revise the fifth sentence of paragraph (c) introductory text to read as follows:

§ 1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounding for narcotic treatment programs.

* * * * *

(c) * * * The registrant must also file a complete and accurate DEA Form 106 with the Administration through the DEA Diversion Control Division secure network application within 45 calendar days after discovery of the theft or loss.

* * *

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■ 3. In § 1301.76, revise the second sentence of paragraph (b) introductory text to read as follows:

§ 1301.76 Other security controls for practitioners.

* * * * *

(b) * * * The registrant must also file a complete and accurate DEA Form 106 with the Administration through DEA's Diversion Control Division secure network application within 45 days after discovery of the theft or loss. * * *

* * * * *

Signing Authority

This document of the Drug Enforcement Administration was signed on June 14, 2023, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this

document upon publication in the **Federal Register**.

Scott Brinks,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2023-13085 Filed 6-21-23; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 591

Publication of Venezuela Sanctions Regulations Web General License 8L

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Publication of a web general license.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing one general license (GL) issued pursuant to the Venezuela Sanctions Regulations: GL 8L, which was previously made available on OFAC's website.

DATES: GL 8L was issued on May 23, 2023. See **SUPPLEMENTARY INFORMATION** for additional relevant dates.

FOR FURTHER INFORMATION CONTACT: OFAC: Assistant Director for Licensing, 202-622-2480; Assistant Director for Regulatory Affairs, 202-622-4855; or Assistant Director for Compliance, 202-622-2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document and additional information concerning OFAC are available on OFAC's website: <https://ofac.treasury.gov/>.

Background

On May 23, 2023, OFAC issued GL 8L to authorize certain transactions otherwise prohibited by the Venezuela Sanctions Regulations, 31 CFR part 591. GL 8L was made available on OFAC's website (<https://ofac.treasury.gov/>) when it was issued. GL 8L was issued on May 23, 2023 and has an expiration date of November 19, 2023. The text of this GL is provided below.

OFFICE OF FOREIGN ASSETS CONTROL

Venezuela Sanctions Regulations

31 CFR Part 591

GENERAL LICENSE NO. 8L

Authorizing Transactions Involving Petróleos de Venezuela, S.A. (PdVSA) Necessary for the Limited Maintenance of Essential Operations in Venezuela or the Wind Down of Operations in Venezuela for Certain Entities

(a) Except as provided in paragraphs (c) and (d) of this general license, all transactions and activities prohibited by Executive Order (E.O.) 13850 of November 1, 2018, as amended by E.O. 13857 of January 25, 2019, or E.O. 13884 of August 5, 2019, each as incorporated into the Venezuela Sanctions Regulations, 31 CFR part 591 (the VSR), that are ordinarily incident and necessary to the limited maintenance of essential operations, contracts, or other agreements, that: (i) are for safety or the preservation of assets in Venezuela; (ii) involve PdVSA or any entity in which PdVSA owns, directly or indirectly, a 50 percent or greater interest; and (iii) were in effect prior to July 26, 2019, are authorized through 12:01 a.m. eastern standard time, November 19, 2023, for the following entities and their subsidiaries (collectively, the "Covered Entities"):

- Halliburton
- Schlumberger Limited
- Baker Hughes Holdings LLC
- Weatherford International, Public Limited Company

Note to paragraph (a): Transactions and activities necessary for safety or the preservation of assets in Venezuela that are authorized by paragraph (a) of this general license include: transactions and activities necessary to ensure the safety of personnel, or the integrity of operations and assets in Venezuela; participation in shareholder and board of directors meetings; making payments on third-party invoices for transactions and activities authorized by paragraph (a) of this general license, or incurred prior to April 21, 2020, provided such activity was authorized at the time it occurred; payment of local taxes and purchase of utility services in Venezuela; and payment of salaries for employees and contractors in Venezuela.

(b) Except as provided in paragraph (d) of this general license, all transactions and activities prohibited by E.O. 13850, as amended, or E.O. 13884, each as incorporated into the VSR, that are ordinarily incident and necessary to the wind down of operations, contracts, or other agreements in Venezuela involving PdVSA or any entity in which PdVSA owns, directly or indirectly, a 50 percent or greater interest, and that were in effect prior to July 26, 2019, are authorized through 12:01 a.m. eastern standard time, November 19, 2023, for the Covered Entities.

(c) Paragraph (a) of this general license does not authorize:

- (1) The drilling, lifting, or processing of, purchase or sale of, or transport or shipping of any Venezuelan-origin petroleum or petroleum products;

(2) The provision or receipt of insurance or reinsurance with respect to the transactions and activities described in paragraph (c)(1) of this general license;

(3) The design, construction, installation, repair, or improvement of any wells or other facilities or infrastructure in Venezuela or the purchasing or provision of any goods or services, except as required for safety;

(4) Contracting for additional personnel or services, except as required for safety; or

(5) The payment of any dividend, including in kind, to PdVSA, or any entity in which PdVSA owns, directly or indirectly, a 50 percent or greater interest.

(d) This general license does not authorize:

(1) Any transactions or dealings related to the exportation or reexportation of diluents, directly or indirectly, to Venezuela;

(2) Any loans to, accrual of additional debt by, or subsidization of PdVSA, or any entity in which PdVSA owns, directly or indirectly, a 50 percent or greater interest, including in kind, prohibited by E.O. 13808 of August 24, 2017, as amended by E.O. 13857, and incorporated into the VSR; or

(3) Any transactions or activities otherwise prohibited by the VSR, or any other part of 31 CFR chapter V, or any transactions or activities with any blocked person other than the blocked persons identified in paragraphs (a) and (b) of this general license.

(e) Effective May 23, 2023, General License No. 8K, dated November 26, 2022, is replaced and superseded in its entirety by this General License No. 8L.

Dated: May 23, 2023.

Andrea M. Gacki,

Director, Office of Foreign Assets Control.

[FR Doc. 2023-13359 Filed 6-21-23; 8:45 am]

BILLING CODE 4810-AL-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[USCG-2023-0524]

RIN 1625-AA00

Safety Zone; Atlantic Ocean, Virginia Beach, VA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for all navigable waters within 200-yards of the Virginia Beach oceanfront. The safety zone is needed to protect mariners from the potential hazards which would result if a large congregation of spectator vessels anchors in close proximity to a shoreline concert on the Virginia Beach oceanfront. Entry of vessels or persons into this zone when it is subject to enforcement is prohibited unless