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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1301

[Docket No. DEA-574]

RIN 1117-AB57

Reporting of Theft or Significant Loss of Controlled Substances

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule would amend Drug Enforcement Administration (DEA) regulations regarding DEA Form 106, used by DEA registrants to report thefts or significant losses of controlled substances, to clarify that all such forms must be submitted electronically. In addition, the proposed rule would add new requirements for the form to be submitted accurately and within a 15-day time period. This proposed rule will not change the requirement that registrants 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 discovery of such loss or theft.

DATES: Comments must be submitted electronically or postmarked on or before [INSERT DATE 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. Commenters should be aware that the electronic Federal Docket Management System will not accept any comments after 11:59 p.m. Eastern Time on the last day of the comment period.

All comments concerning collection of information under the Paperwork Reduction Act must be submitted to the Office of Management and Budget (OMB) on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure proper handling of comments, please reference “Docket No. DEA-574” on all electronic and written correspondence, including any attachments.

- *Electronic comments:* The Drug Enforcement Administration encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Please go to <http://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on *Regulations.gov*. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

- *Paper comments:* Paper comments that duplicate electronic submissions are not necessary. Should you wish to mail a paper comment, *in lieu of* an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

- *Paperwork Reduction Act Comments:* All comments concerning collections of information under the Paperwork Reduction Act must be submitted to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for DOJ,

725 17th Street NW, Washington, DC 20503. Please state that your comment refers to RIN 1117- AB57/ Docket No. DEA-547.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section (DPW), Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362-3261.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration (DEA) for public inspection online at <http://www.regulations.gov>. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase “PERSONAL IDENTIFYING INFORMATION” in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase “CONFIDENTIAL BUSINESS INFORMATION” in the first paragraph of your comment. You must also

prominently identify the confidential business information to be redacted within the comment.

Comments containing personal identifying information or confidential business information identified as directed above will be made publicly available in redacted form. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to <http://www.regulations.gov> may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this proposed rule is available at <http://www.regulations.gov> for easy reference.

Background and Legal Authority

The Controlled Substances Act (CSA) authorizes the Administrator of 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; and for the efficient execution of his statutory functions. 21 U.S.C. 821, 827, 871(b). Currently, 21 CFR 1301.74(c) requires a non-practitioner registrant to notify DEA's Field Division Office in his or her area, in writing, of any theft or significant loss of any controlled substances within one business day upon discovery of such theft or loss. The provision stipulates this same notification requirement and one-day time period regarding in-transit losses of controlled substances for suppliers, importers, and exporters with certain exceptions. In addition to the requirement to notify DEA within one business day of the discovery of a theft or loss, this

provision requires a non-practitioner registrant to complete and submit to the same field division office a DEA Form 106 regarding the theft or loss. This provision is silent as to the actual submission method of the DEA Form 106 (*e.g.*, mail, hand delivery, electronic) and the time period in which these reports are due. This proposed rule will not change the requirement that registrants notify the Field Division Office of the Administration in their area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft.

Similarly, 21 CFR 1301.76(b) currently requires practitioner registrants to notify DEA's Field Division Office in his area, in writing, of the theft or significant loss of any controlled substances within one business day upon discovery of the theft or loss; and to complete and submit DEA Form 106 to the same Field Division Office. Again, this provision is silent as to the actual submission method of DEA Form 106 and the due date for this report.

This proposed rule will not change the requirement under 21 CFR 1301.74(c) and 1301.76(b), respectively, that non-practitioner and practitioner registrants notify DEA's Field Division Office in their area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft.

Currently, 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. See Regulatory Analyses section for additional information.

Amendments to Revise Submission Process for DEA Form 106

This proposed rule would set a 15-day calendar period for submitting a complete and accurate DEA Form 106 and clarify the form submission process, requiring all forms be

submitted electronically. This would match the submission process for DEA Form 107, a form used by regulated persons¹ to report loss or disappearance of listed chemicals. As set forth in 21 CFR 1310.05(b)(1), a regulated person must file a complete and accurate DEA Form 107 with DEA through the DEA Diversion Control Diversion secure network application (available on the DEA Diversion Control Division Web site) within 15 calendar days after discovery of the circumstances requiring the report.

These proposed changes would make clear to registrants that all DEA Form 106 submissions must go through the secure online database, and physical copies will no longer be accepted. Through the secure online database, forms will be more easily submitted and organized.²

Regulatory Analyses

Executive Orders 12866, 13563, and 13771, Regulatory Planning and Review, Improving Regulation and Regulatory Review, and Reducing Regulation and Controlling Regulatory Costs

This proposed rule was developed in accordance with the principles of Executive Orders (EOs) 12866, 13563, and 13771. EO 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). EO 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in EO 12866. EO 12866 classifies a “significant regulatory

¹ The term “regulated person” is defined at 21 U.S.C. 802(38).

² https://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html.

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 EO. DEA has determined that this proposed rule is not a “significant regulatory action” under EO 12866, section 3(f).

Analysis of Benefits and Costs

DEA has examined the benefits and costs of this proposed rule. Currently, 99.5 percent of all DEA Form 106 reports are reported electronically via DEA’s secure website. This proposed rule will impact 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, and increased simplicity in reporting theft and loss on controlled substances and clarity in the regulations. This proposed rule will add clarity to the submission method by matching the submission process and requirements for “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 proposed 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 approximately 181 paper submissions 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 both 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.

This proposed rule would eliminate 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 proposed rule is *de minimis*.

EO 13771 was issued on January 30, 2017, and published in the *Federal Register* on February 3, 2017.³ Section 2(a) of EO 13771 requires an agency, unless prohibited by law, to identify at least two existing regulations to be repealed when the agency publicly proposes for notice and comment or otherwise promulgates a new regulation. In furtherance of this requirement, Section 2(c) of EO 13771 requires that the new incremental costs associated with new regulations, to the extent permitted by law, be offset by the elimination of existing

³ 82 FR 9339.

costs associated with at least two prior regulations. DEA expects this proposed rule will not be considered an EO 13771 regulatory action. The estimated economic impact of proposed rule is *de minimis*.

Executive Order 12988, Civil Justice Reform

This proposed regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of EO 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 proposed rulemaking does not have federalism implications warranting the application of EO 13132. The proposed 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 proposed rule does not have tribal implications warranting the application of EO 13175. This proposed 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), DEA has reviewed the economic impact of this proposed rule on small entities. DEA's economic impact evaluation indicates that the rule will not, if promulgated, 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 proposed rule and estimates that the proposed rule will have minimal economic impact on affected entities, including small entities.

This proposed rule would amend 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 Druggists' 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 proposed 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 Forms 106. 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 proposed rule, if promulgated, 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 “Regulatory Flexibility Act” 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 (PRA) (44 U.S.C. 3501-3521), DEA has identified the following collection of information related to this proposed rule. This action would modify existing collection 1117-0001 and DEA will be submitting the revision to OMB for approval. 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/>. DEA has submitted this collection request to OMB for review and approval.

A. Collections of Information Associated with the Proposed Rule

Title: Amending Regulations Regarding DEA Form 106

OMB Control Number: 1117-0001

Form Number: DEA-106

DEA is proposing to amend 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 15 days of discovery of the circumstances requiring the report. This amendment would clarify the submission process by aligning it with the current 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, within 15 days of discovery of the circumstances requiring the report.

Currently, 99.5 percent of all DEA Form 106 reports are reported electronically via DEA's secure website. This proposed rule will impact 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 proposed rule would eliminate 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 would be filed with DEA through the DEA Diversion Control Diversion secure network application (available on the DEA Diversion Control Division Web site). The submissions of forms will be more easily submitted and organized through the secure database.

The 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 burden: 12,349 hours

B. Request for Comments Regarding the Proposed Collections of Information

Written comments and suggestions from the public and affected entities concerning the proposed revision of this collection of information are encouraged. Under the PRA, DEA is required to provide a notice regarding the proposed collections of information in the *Federal Register* with the notice of proposed rulemaking and solicit public comment.

Pursuant to section 3506(c)(2) of the PRA (44 U.S.C. 3506(c)(2)), DEA is soliciting comment on the following issues related to this information of collection:

- Whether the proposed collection of information is necessary for the proper performance of the functions of DEA, including whether the information will have practical utility.
- The accuracy of DEA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

- Recommendations to enhance the quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology.

Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for DOJ, 725 17th Street NW, Washington, DC 20503.

Please state that your comments refer to RIN 1117-AB57/Docket No. DEA-574. All comments must be submitted to OMB on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposed rule.

If you need a copy of the proposed information collection instrument(s) with instructions or additional information, please contact the Regulatory Drafting and Policy Support Section (DPW), Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152-2639; Telephone: (571) 362-3261.

List of Subjects in 21 CFR Part 1301

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

For the reasons set out above, the DEA proposes to amend 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 compounders 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 15 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.

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(b) * * * 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 15 calendar days after the discovery of theft or loss. * * *

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Timothy J. Shea,
Acting Administrator.

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