



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1301, 1309, and 1321

[Docket No. DEA-587]

RIN 1117-AB58

Amending Regulations to Require Online Submission of Applications for and Renewals of DEA Registration

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: This rule proposes to amend the Drug Enforcement Administration (DEA) regulations to require all initial and renewal applications for DEA registration to be submitted online.

DATES: Electronic comments must be submitted, and written comments must be postmarked, on or before [INSERT DATE 60 DAYS AFTER DATE OF 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 collections of information under the Paperwork Reduction Act must be submitted to the Office of Management and Budget 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-587” on all correspondence, including any attachments.

- *Electronic comments:* The Drug Enforcement Administration (DEA) 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.

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

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received 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 confidential as directed above.

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

Legal Authority

The Controlled Substances Act (CSA) grants the Attorney General authority to promulgate rules and regulations relating to: the registration and control of the manufacture, distribution, and dispensing of controlled substances and listed chemicals; reporting changes to professional or business addresses; and the efficient execution of his statutory functions. 21 U.S.C. 821, 822(a), 827(h), 871(b), 957(a). The Attorney General is further authorized by the CSA to promulgate rules and regulations relating to the registration and control of importers and exporters of controlled substances and listed chemicals. 21 U.S.C. 958(f). The Attorney General has delegated this authority to the Administrator of DEA. 28 CFR 0.100(b).

DEA Form 224 applies to new registration applications for retail pharmacy, hospital/clinic, practitioner, teaching institution, or mid-level practitioner registrations.¹ DEA Form 225 applies to new registration applications for manufacturer, distributor, researcher, canine handler, analytical laboratory, importer, or exporter registrations.² DEA Form 363 applies to new registration applications for narcotic treatment program registrations.³ DEA Form 510 applies to new registration applications for domestic chemical registrations.⁴ DEA Forms 224a, 225a, 363a, and 510a apply to registration renewal applications.⁵

Purpose of the Proposed Rule

The purpose of this notice of proposed rulemaking is to simplify the form submission process by requiring that all registration and renewal applications be submitted online. Currently, DEA regulations permit DEA Registration Forms (224/224a, 225/225a, 363/363a, and 510/510a) to be submitted either through the secure online database, or by paper forms delivered to DEA Headquarters.⁶ This proposed rule will amend DEA regulations to require that all registration and renewal applications be submitted through the secure online database, and that paper forms will no longer be accepted. Submission through the secure online database will be a streamlined process which will benefit both DEA and registrants.

Discussion of Regulatory Changes

Need for Regulatory Changes

Regulatory changes are needed to conform existing DEA regulations regarding the submission of registration and renewal applications to the Administration's current requirements that other DEA forms be submitted online. This rule proposes to amend

¹ 21 CFR 1301.13(e)(1)(iv).

² 21 CFR 1301.13(e)(1)(i)-(iii), (v)-(vi), and (viii)-(x).

³ 21 CFR 1301.13(e)(1)(vii).

⁴ 21 CFR 1309.21.

⁵ 21 CFR 1301.13(e)(1) and 1309.21

⁶ <https://www.deadiversion.usdoj.gov/drugreg/index.html#regapps>.

existing DEA regulations in seven sections.⁷ Title 21 CFR 1301.13 and 1301.14 are proposed to be amended to remove the option to submit paper forms and provide instructions for online application and payment instructions. The rule also proposes removing 21 CFR 1301.14 (b), which will become obsolete with the adoption of the secure application portal. 21 CFR 1309.12 is proposed to be amended to clarify payment options. Title 21 CFR 1309.32 is proposed to be amended to remove the option to submit paper forms and provide instruction for online applications and payments for listed chemical handlers. Title 21 CFR 1309.33 is proposed to be amended to clarify the online application and payment process while removing § 1309.33 (b), which will become obsolete with the adoption of the secure application portal. Title 21 CFR 1309.34 is proposed to be amended to clarify the handling of defective applications. Title 21 CFR 1321.01 is proposed to be amended to remove reference to submitting paper forms by mail to any DEA Registration Unit address.

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 (E.O.) 12866, 13563, and 13771. 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 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

⁷ 21 CFR 1301.13, 1301.14, 1309.12, 1309.32, 1309.33, 1309.34, and 1321.01.

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. DEA has determined that this proposed 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 proposed rule. There has been a continued decrease in the use of paper forms from 2016 to 2020. Paper forms as a percentage of total applications decreased annually from 7.5 percent in 2016 to 2.8 percent, 1.5 percent, and 1.1 percent, in years 2017, 2018, and 2019, respectively. In the first three months of 2020, 99.3 percent of all DEA registration forms were submitted electronically via DEA’s secure website and 0.7 percent were submitted by paper. While it is possible the percentage of paper submissions will continue to drop, DEA believes 0.7 percent is a reasonable estimate. Therefore, this proposed rule will impact the remaining 0.7 percent of registration forms that are submitted by paper, approximately 4,453 registrations per year.⁸ Benefits include cost savings, as discussed in the following paragraphs, and increased simplicity in the registration process. This proposed rule will simplify the form submission process and require that all new applications and renewals be submitted online. Additionally, electronic submissions will increase efficiency and accuracy.

There are no new costs associated with this proposed rule. The labor burden to submit an application is estimated to be the same for electronic and paper submissions. No

⁸ The average annual number of applications from 2017 to 2019 is 636,097. $636,097 \times 0.7 \text{ percent} = 4,453$.

special software is needed to complete an online application via DEA's public website. Furthermore, all applicants, including the estimated 0.7 percent of applicants using paper forms, are assumed to be able to access the internet without incurring additional costs. DEA believes providing a contact email address on the application is indicative of internet access. Although the applicant's contact email address is an optional field, virtually all paper submissions include contact email addresses.⁹ Although online applications are available at no additional cost, DEA acknowledges some applicants have a preference for paper forms. DEA does not have a basis to quantify this preference; however, DEA believes any cost of eliminating this preference is offset by the qualitative cost savings discussion below.

DEA anticipates there will be cost savings associated with electronic submissions. Some cost savings are described qualitatively and some are quantified. Many paper submissions contain illegible or erroneous information or omit required information. Many such errors or omissions, such as not including a signature or paying the wrong amount require DEA to contact applicants for corrections or clarifications, a time-consuming process for both DEA and the applicant. Electronic submissions are expected to virtually eliminate the requirement for DEA to contact applicants for clarification of form data or for correction of submission errors, as validation features in the system will flag common errors before transmission. DEA has not tracked the number or the duration of such delays and does not have a strong basis to quantify these cost savings.

This proposed rule would eliminate the need to print paper forms and transmit them 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 \$2,805 per year for an estimated 4,453

⁹ Based on review of applications from January 2020 to March 2020, there were 307 applications for initial registration using the paper form. Six of 307 applications did not contain a contact email address. DEA believes it is likely the six applicants have email addresses (and have access to the internet), but opted to not provide the email address. Including the online applications, six of 30,509 applications for new registrations over the three-month period, January-March 2020, did not contain email addresses.

responses per year. DEA assumes the cost savings associated with eliminating printing costs is negligible.

Furthermore, DEA anticipates cost savings from the elimination of production costs (i.e., paper forms, envelopes, postage, equipment, and labor). Based on the information collection requests for the registration forms, recently approved by OMB, DEA's production costs of \$49,910 will be eliminated.¹⁰ In summary, DEA estimates this proposed rule will result in an annual cost savings of \$52,715 (\$2,805 to applicants and \$49,910 to DEA).

Section 2(a) of E.O. 13771¹¹ 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 E.O. 13771 requires that the new incremental costs associated with new regulations, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations. Because this proposed rule is estimated to have a total cost of less than zero (cost savings of \$52,715 per year), DEA expects the rule will be considered an E.O. 13771 deregulatory action.

Executive Order 12988, Civil Justice Reform

This proposed rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988, Civil Justice Reform to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burdens. DEA expects the instant validation of online registration applications to reduce ambiguity and reduce the number of errors in submissions and reduce burdens on both DEA and registrants.

Executive Order 13132, Federalism

¹⁰ The estimated production cost is the sum of the estimated production cost for each of the forms. Office of Information and Regulatory Affairs, Inventory of Currently Approved Information Collections, April 13, 2020, <https://www.reginfo.gov/public/do/PRAMain> (accessed April 13, 2020). See Paperwork Reduction Act section below for specific OMB control numbers.

¹¹ 82 FR 9339.

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

Executive Order 13175, Consultation and Coordination with Indian Tribal Governments

The 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), the 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 an agency to analyze options for regulatory relief of small entities unless it can certify that the rule will not have a significant impact on substantial number of small entities. DEA has analyzed the economic impact of each provision of this proposed rule and estimates that it will have minimal economic impact on affected entities, including small businesses, nonprofit organizations, and small governmental jurisdictions.

This proposed rule will simplify the form submission process by requiring all initial registration and renewal applications be submitted online. The rule would affect all applicants for DEA registration or re-registration who would use paper forms. There has been a continued decrease in the use of paper applications from 2016 to 2020. Paper applications, as a percentage of total applications, decreased annually from 7.5 percent in 2016 to 2.8 percent, 1.5 percent, and 1.1 percent, in years 2017, 2018, and 2019, respectively. In the first three months of 2020, 99.3 percent of all DEA Registration Forms were submitted electronically via DEA's secure website and 0.7 percent were submitted by paper. While it is

possible the percentage of paper submissions will continue to drop, DEA believes 0.7 percent is a reasonable estimate. Therefore, this proposed rule will impact the remaining 0.7 percent of registration forms that are submitted by paper, approximately 4,453 registrations per year.¹²

All registration business activities (registrant-type) have used paper registration forms in the past three years. DEA estimated the number of applications by business activity based on the three-year average, 2017-2019, of actual paper application submissions. DEA applied the percentages for each business activity to the estimated 4,453 paper registration per year. For example, on average, 5.73 percent of total paper registration forms were for pharmacy registrations. Applying 5.73 percent to the 4,453 estimated total paper registrations, the estimated number of paper registrations for pharmacy registrations was 255 ($4,453 \times 5.73$ percent). This calculation was conducted for each business activity and the results are in Table 1 below.

Table 1: Percentage and Number of Paper Registrations by Business Activity

| Business Activity | 2017 (percent) | 2018 (percent) | 2019 (percent) | Average (percent) | Number of Registrations |
|------------------------------|---------------------------|---------------------------|---------------------------|------------------------------|------------------------------------|
| Pharmacy | 3.12 | 6.25 | 7.81 | 5.73 | 255 |
| Hospital/Clinic | 2.11 | 2.67 | 3.57 | 2.78 | 124 |
| Practitioner | 79.73 | 77.99 | 74.13 | 77.29 | 3,442 |
| Teaching Institution | 0.03 | 0.04 | 0.01 | 0.03 | 1 |
| Manufacturer | 0.23 | 0.33 | 0.39 | 0.32 | 14 |
| Distributor | 0.15 | 0.18 | 0.28 | 0.20 | 9 |
| Researcher/Canine Handler | 3.00 | 3.61 | 2.96 | 3.19 | 142 |
| Analytical Lab | 0.41 | 0.53 | 0.51 | 0.48 | 22 |
| Importer | 0.07 | 0.10 | 0.10 | 0.09 | 4 |
| Exporter | 0.03 | 0.04 | 0.07 | 0.05 | 2 |
| Reverse Distributor | 0.01 | 0.02 | 0.04 | 0.03 | 1 |
| Mid-level Practitioner (MLP) | 10.38 | 7.62 | 9.40 | 9.14 | 407 |
| Narcotic Treatment Program | 0.38 | 0.33 | 0.38 | 0.36 | 16 |
| Chemical Manufacturer | 0.11 | 0.11 | 0.10 | 0.11 | 5 |
| Chemical Importer | 0.06 | 0.02 | 0.03 | 0.04 | 2 |
| Chemical Distributor | 0.13 | 0.10 | 0.13 | 0.12 | 5 |
| Chemical Exporter | 0.03 | 0.04 | 0.09 | 0.05 | 2 |
| Total | 100.00 | 100.00 | 100.00 | 100.00 | 4,453 |

¹² The average annual number of applications from 2017 to 2019 is 636,097. $636,097 \times 0.7$ percent = 4,453.

(Source: DEA)

As this proposed rule affects all business activities that are required to obtain a registration with DEA pursuant to the CSA, this proposed rule would affect small entities in a wide variety of industries. Table 2 indicates the sectors, as defined by the North American Industry Classification System (NAICS), affected by the proposed rule. Most DEA registrants are, or are employed by, small entities under Small Business Administration (SBA) standards.

Table 2: Industrial Sectors of DEA Registrants

| Business Activity | NAICS Code | NAICS Code Description |
|--|---|--|
| Manufacturer | 325411 | Medicinal and Botanical Manufacturing |
| | 325412 | Pharmaceutical Preparation Manufacturing |
| Distributor, Importer, Exporter | 424210 | Drugs and Druggists' Sundries Merchant Wholesalers |
| Reverse Distributor | 5621 | Waste Collection |
| | 5622 | Waste Treatment and Disposal |
| Pharmacy | 445110 | Supermarkets and Other Grocery (except Convenience) Stores |
| | 446110 | Pharmacies and Drug Stores |
| | 452210 | Department Stores |
| | 452311 | Warehouse Clubs and Supercenters |
| Analytical Labs | 541380 | Testing Laboratories |
| Teaching institute | 611310 | Colleges, Universities and Professional Schools |
| Researcher | 541715 | Research and Development in the Physical, Engineering, and Life Sciences (except Nanotechnology and Biotechnology) |
| Canine Handler | 561612 | Security Guards and Patrol Services |
| Practitioner, Mid-level Practitioner,* Narcotic Treatment Program, Hospital/Clinic | 541940 | Veterinary Services |
| | 621111 | Offices of Physicians (except Mental Health Specialists) |
| | 621112 | Offices of Physicians, Mental Health Specialists |
| | 621210 | Offices of Dentists |
| | 621330 | Offices of Mental Health Practitioners (except Physicians) |
| | 621391 | Offices of Podiatrists |
| | 621420 | Outpatient Mental Health and Substance Abuse Centers |
| | 621491 | HMO Medical Centers |
| | 621493 | Freestanding Ambulatory Surgical and Emergency Centers |
| | 622110 | General Medical and Surgical Hospitals |
| 622210 | Psychiatric and Substance Abuse Hospitals | |

| Business Activity | NAICS Code | NAICS Code Description |
|--|------------|--|
| | 622310 | Specialty (except Psychiatric and Substance Abuse) Hospitals |
| Chemical Manufacturer | 325 | Chemical Manufacturing |
| Chemical Distributor, Chemical Importer, Chemical Exporter | 424690 | Other Chemical and Allied Products Merchant Wholesalers |

*Practitioners and mid-level practitioners are generally employed in one of these industries.

As shown in Table 2, the proposed rule would affect a wide variety of entities across many industry sectors. As some industry sectors are expected to consist primarily of DEA registrants (i.e., 446110-Pharmacies and Drug Stores, 622110-General Medical and Surgical Hospitals, etc.), this proposed rule is expected to affect some small entities. For reference, Table 3 lists the average annual revenue for the smallest of small businesses in each industry sector. The table below lists the results.

Table 3: Average Annual Revenue of Smallest of Small Entities

| NAICS Code | NAICS Code Description | Enterprise Size (number of employees) | Number of Establishments | Average Revenue per Establishment (\$) |
|------------|---|---------------------------------------|--------------------------|--|
| 325 | Chemical Manufacturing | 0-4 | 3,148 | 1,938,546 |
| 325411 | Medicinal and Botanical Manufacturing | 0-4 | 108 | 727,444 |
| 325412 | Pharmaceutical Preparation Manufacturing | 5-9* | 129 | 2,639,287 |
| 424210 | Drugs and Druggists' Sundries Merchant Wholesalers | 0-4 | 3,630 | 1,367,131 |
| 424690 | Other Chemical and Allied Products Merchant Wholesalers | 0-4 | 3,352 | 2,007,996 |
| 445110 | Supermarkets and Other Grocery (except Convenience) Stores | 0-4 | 23,710 | 453,787 |
| 446110 | Pharmacies and Drug Stores | 0-4 | 6,360 | 1,069,655 |
| 452112 | Discount Department Stores | 0-4 | 6 | 266,167 |
| 452910 | Warehouse Clubs and Supercenters | 0-4 | 12 | 326,333 |
| 541380 | Testing Laboratories | 0-4 | 2,415 | 297,737 |
| 541712 | Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology) | 0-4 | 5,013 | 427,790 |
| 541940 | Veterinary Services | 0-4 | 8,881 | 292,166 |
| 561612 | Security Guards and Patrol Services | 0-4 | 2,162 | 114,198 |
| 5621 | Waste Collection | 0-4 | 3,853 | 365,902 |
| 5622 | Waste Treatment and Disposal | 0-4 | 616 | 461,159 |
| 611310 | Colleges, Universities, and Professional Schools | 0-4 | 372 | 913,078 |
| 621111 | Offices of Physicians (except Mental Health Specialists) | 0-4 | 95,648 | 447,715 |

| NAICS Code | NAICS Code Description | Enterprise Size (number of employees) | Number of Establishments | Average Revenue per Establishment (\$) |
|------------|--|---------------------------------------|--------------------------|--|
| 621112 | Offices of Physicians, Mental Health Specialists | 0-4 | 8,980 | 253,837 |
| 621210 | Offices of Dentists | 0-4 | 50,781 | 330,868 |
| 621320 | Offices of Optometrists | 0-4 | 10,939 | 269,348 |
| 621330 | Offices of Mental Health Practitioners (except Physicians) | 0-4 | 16,149 | 145,005 |
| 621391 | Offices of Podiatrists | 0-4 | 5,300 | 288,546 |
| 621420 | Outpatient Mental Health and Substance Abuse Centers | 0-4 | 1,810 | 211,249 |
| 621491 | HMO Medical Centers | 5-9* | 16 | 620,188 |
| 621493 | Freestanding Ambulatory Surgical and Emergency Centers | 0-4 | 1,011 | 549,974 |
| 622110 | General Medical and Surgical Hospitals | 0-4 | 39 | 10,621,308 |
| 622210 | Psychiatric and Substance Abuse Hospitals | 20-99* | 27 | 5,142,444 |
| 622310 | Specialty (except Psychiatric and Substance Abuse) Hospitals | 0-4 | 21 | 8,561,238 |

*The revenue figure for the smallest size category is unavailable. The revenue figure for the smallest size category with available revenue figure is used.

There are no new costs associated with this proposed rule. The labor burden to submit an application is estimated to be the same for electronic and paper submissions. No special software is needed to complete an online application via DEA's public website. Furthermore, all applicants, including the estimated 0.7 percent of applicants using paper forms, are assumed to be able to access the internet without incurring additional costs. DEA believes using email for contact is indicative of having internet access. Although the applicant's contact email address is an optional field on a paper registration application, virtually all applications submitted include contact email addresses.¹³ Although online applications are available at no additional cost, DEA acknowledges some applicants have a preference for paper forms. DEA does not have a basis to quantify this preference; however, DEA believes any costs associated with eliminating this preference is offset by the qualitative cost savings discussion below.

¹³ Based on a review of applications submitted from January 2020 to March 2020, there were 307 applications for initial registrations submitted using the paper form. Six of those 307 applications did not contain a contact email address. Including the online applications, six of 30,509 applications for new registrations over the three month period, January-March 2020, did not contain email addresses.

DEA anticipates there will be cost savings associated with electronic submissions. Some cost savings are described qualitatively and some are quantified. Many paper applications submitted contain illegible or erroneous information or omit required information. Many such errors or omissions, such as not including a signature or paying the wrong amount, require DEA to contact applicants to correct or clarify the information in the paper form, consuming DEA's and the applicant's time and resources. Electronic submissions are expected to virtually eliminate the requirement for DEA to contact applicants for clarifications of form data or correction of submission errors, as validation features in the system will flag common errors prior to transmission. As DEA has not tracked the number of delays or the duration of such delays, DEA does not have a basis to quantify the cost savings.

Furthermore, 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) per each paper form not submitted. DEA assumes the cost savings associated with eliminating printing costs is negligible.

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

In accordance with the Unfunded Mandates Reform Act of 1995 (UMRA),¹⁴ DEA has determined 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 the UMRA.

Paperwork Reduction Act

¹⁴ 2 U.S.C. 1501, *et seq.*

This proposed rule would modify existing collection(s) of information requirement under the Paperwork Reduction Act (PRA).¹⁵ Pursuant to the PRA,¹⁶ DEA has identified the collections of information below related to this proposed rule. A person is not required to respond to a collection of information unless it displays a valid OMB control number.¹⁷

A. Collections of Information Associated with the Proposed Rule

1. Title: Application for Registration-DEA 224, Application of Registration Renewal-DEA 224A

OMB Control Number: 1117-0014

Form Number: DEA-224/224a

DEA is proposing to amend its regulations for all new and renewal registration applications to implement the requirement of online submission through the DEA Diversion Control Division website. This amendment would improve the submission process by aligning it with the Administration's current requirements for other online form submissions. The online submission of DEA Forms 224/224a by a Retail Pharmacy, Hospital/Clinic, Practitioner, Teaching Institution, or Mid-Level Practitioner would be filed with DEA through the DEA Diversion Control Division secure network (available on the DEA Diversion Control Division website). The online submission of new and renewal applications through the secure database will ensure the Administration's receipt of applications in a more timely and organized manner.

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

- Number of respondents: **617,086**
- Frequency of response: **1**

¹⁵ 44 U.S.C. 3501–3521.

¹⁶ 44 U.S.C. 3507(d).

¹⁷ Copies of existing information collections approved by OMB may be obtained at <http://www.reginfo.gov/public/do/PRAMain>.

- Number of responses: **617,086**
- Burden per response: **0.202186¹⁸**
- Total annual hour burden: **124,766**

2. *Title:* Application for Registration (DEA Form 225); Application for Registration Renewal (DEA Form 225a); Affidavit for Chain Renewal (DEA Form 225B)

OMB Control Number: 1117-0012

Form Number: DEA-225/225(A)

DEA is proposing to amend its regulations for all new and renewal registration applications to implement the requirement of electronic only submission. This amendment would clarify the submission process by aligning it with the Administration's current requirements for other online form submissions. The online submission of DEA Forms 225/225a by Manufacturer, Distributor, Researcher, Canine Handler, Analytical Laboratory, Importer, or Exporter would be filed with DEA through the DEA Diversion Control Diversion secure network (available on the DEA Diversion Control Division website). The online submission of new and renewal applications through the secure database will ensure the Administration's receipt of applications in a more timely and organized manner.

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

- Number of respondents: **16,338**
- Frequency of response: **1**
- Number of responses: **16,338**
- Burden per response (hour): **0.199106¹⁹**
- Total annual hour burden: **3,253**

¹⁸ Calculated based on total annual hour burden and the number of respondents (124,766 / 617,086 = 0.202186).

¹⁹ Calculated based on total annual hour burden and the number of respondents (3,253 / 16,338 = 0.199106).

3. *Title:* Application for Registration (DEA Form 363) and Application for Registration Renewal (DEA Form 363a)

OMB Control Number: 1117-0015

Form Number: DEA-363/363a

DEA is proposing to amend its regulations for all new and renewal registration applications to implement the requirement of online submission. This amendment would clarify the submission process by aligning it with the Administration's current requirements for other online form submissions. The electronic submission of DEA Forms 363/363a by a Narcotic Treatment Program would be filed with DEA through the DEA Diversion Control Diversion secure network (available on the DEA Diversion Control Division website). The online submission of new and renewal applications through the secure database will ensure the Administration's receipt of applications in a more timely and organized manner.

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

- Number of respondents: **1,900**
- Frequency of response: **1**
- Number of responses: **1,900**
- Burden per response: **0.187895²⁰**
- Total annual hour burden: **357**

4. *Title:* Application for Registration Under Domestic Chemical Diversion Control Act of 1993 and Renewal Application for Registration under Domestic Chemical Diversion Control Act of 1993

OMB Control Number: 1117-0031

Form Number: DEA 510/510a

²⁰ Calculated based on total annual hour burden and the number of respondents (357 / 1,900 = 0.187895).

DEA is proposing to amend its regulations for all new and renewal registration applications to implement the requirement of online submission. This amendment would clarify the submission process by aligning it with the Administration's current requirements for other form submissions. The electronic submission of DEA Forms 510/510a by a Domestic Chemical Handler would be filed with DEA through the DEA Diversion Control Diversion secure network (available on the DEA Diversion Control Division website). The online submission of new and renewal applications through the secure database will ensure the Administration's receipt of applications in a more timely and organized manner.

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

- Number of respondents: **1,001**
- Frequency of response: **1**
- Number of responses: **1,001**
- Burden per response (hour): **0.182817²¹**
- Total annual hour burden: **183**

B. Request for Comments Regarding the Proposed Collections of Information

Written comments and suggestions from the public and affected entities concerning the proposed collections of information are encouraged. Under the PRA, DEA is required to provide a notice regarding the proposed collections of information in the FR with the notice of proposed rulemaking and solicit public comment. Pursuant to the PRA,²² DEA solicits comments on the following issues:

- 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.

²¹ Calculated based on total annual hour burden and the number of respondents (183 / 1,001 = 0.182817).

²² 44 U.S.C. 3506(c)(2).

- 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.

All comments concerning collections of information under the PRA must be submitted to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for the Department of Justice, Washington, DC 20503. Please state that your comments refer to RIN 1117-0014, 1117-0012, 1117-0015, or 1117-0031/Docket No. DEA-587. 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; Telephone: (571) 362-3261.

List of Subjects

21 CFR Part 1301

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

21 CFR Part 1309

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

Administrative practice and procedure.

For the reasons stated in the preamble, DEA proposes to amend 21 CFR parts 1301 and 1309 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 § 1301.13, revise paragraphs (e)(2) and (3) to read as follows:

§ 1301.13 Application for registration; time for application; expiration date; registration for independent activities; application forms, fees, contents and signature; coincident activities.

* * * * *

(e) * * *

(2) DEA Forms 224, 225, and 363 may be obtained online at www.DEAdiversion.usdoj.gov. Only applications submitted online through the secure application portal on DEA’s website will be accepted for processing.

(3) DEA will send renewal notifications via email to registrants approximately 60 days prior to their registration expiration date. Registrants are responsible for keeping their email address current in the secure application portal on DEA’s website throughout the duration of their registration. DEA Forms 224a, 225a, and 363a may be obtained online at www.DEAdiversion.usdoj.gov. Only applications submitted online through the secure application portal on DEA’s website will be accepted for processing.

* * * * *

3. Amend § 1301.14 by:

- a. Revising paragraph (a);
- b. Removing paragraph (b);
- c. Redesignating paragraphs (c) and (d) as paragraphs (b) and (c); and
- d. Revising newly redesignated paragraph (b).

The revisions read as follows:

§ 1301.14 Filing of application; acceptance for filing; defective applications.

- (a) All applications for registration shall be submitted for filing online using the secure application portal at www.DEAdiversion.usdoj.gov.
- (b) Application submitted for filing are dated by the system upon receipt. If found to be complete, the application will be accepted for filing. Applications failing to comply with the requirements of this part will be rejected by the system, with the applicant receiving error messages at the time of application.

* * * * *

**PART 1309—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS,
IMPORTERS AND EXPORTERS OF LIST I CHEMICALS**

4. The authority citation for part 1309 continues to read as follows:

Authority: 21 U.S.C. 802, 821, 822, 823, 824, 830, 871(b), 875, 877, 886a, 952, 953, 957, 958.

5. Revise § 1309.12 to read as follows:

§1309.12 Time and method of payment; refund.

(a) For each application for registration or reregistration to manufacture, distribute, import, or export the applicant shall pay the fee when the application for registration or reregistration is submitted for filing online using the secure application portal at www.DEAdiversion.usdoj.gov.

(b) Payment shall be made online by credit card at the time of submission using the secure application portal at www.DEAdiversion.usdoj.gov.

6. In § 1309.32, revise paragraphs (a) through (c) to read as follows:

§ 1309.32 Application forms; contents; signature.

(a) Any person who is required to be registered pursuant to §1309.21 and is not so registered, shall apply on DEA Form 510 using the secure application portal at www.DEAdiversion.usdoj.gov.

(b) Any person who is registered pursuant to Section 1309.21, shall apply for reregistration on DEA Form 510a using the secure application portal at www.DEAdiversion.usdoj.gov.

(c) DEA Forms 510 and 510a may be obtained online at www.DEAdiversion.usdoj.gov. DEA will send renewal notifications via email to registrants approximately 60 days prior to their registration expiration date. Registrants are responsible for keeping their email address current in the secure application portal on DEA's website throughout the duration of their registration. Only applications submitted online through the secure application portal on DEA's website will be accepted for processing.

* * * * *

7. Revise § 1309.33 to read as follows:

§ 1309.33 Filing of application; joint filings.

All applications for registration shall be submitted online at www.DEAdiversion.usdoj.gov for filing. The appropriate registration fee and any required attachments must accompany the application.

8. Amend § 1309.34 by revising paragraph (a) to read as follows:

§ 1309.34 Acceptance for filing; defective applications.

(a) Applications submitted for filing are dated upon receipt. If the application is found to be complete, the application will be accepted for filing. Applications failing to comply with the requirements of this part will not be accepted for filing.

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PART 1321—DEA MAILING ADDRESSES

9. The authority citation for part 1321 continues to read as follows:

Authority: 21 U.S.C. 871(b).

10. Amend § 1321.01 by revising the table heading and the entry under “DEA Registration Section” to read as follows:

§1321.01 DEA mailing addresses.

* * * * *

Table 1 to §1321.01 -- DEA Mailing Addresses

| Code of Federal Regulations Section— Topic | DEA mailing address |
|--|--|
| * * * * * | |
| DEA Registration Section | |
| 1301.03—Procedures information request (controlled substances registration). 1301.18(c)—Research project controlled substance increase request. 1301.51—Controlled substances registration modification request. 1301.52(b)—Controlled substances registration transfer request. 1301.52(c)—Controlled substances registration discontinuance of business activities notification. 1309.03—List I chemicals registration procedures information request. 1309.61—List I chemicals registration modification request. | Drug Enforcement Administration, Attn: Registration Section/DRR P.O. Box 2639, Springfield, VA 22152 |
| * * * * * | |

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Timothy J. Shea,
Acting Administrator.

