(2) *Recommendation Not to Board.* If CBP is unable to validate a passenger's travel documents, CBP will recommend that the carrier not board the passenger.

* * * * *

Alejandro N. Mayorkas,

Secretary, U.S. Department of Homeland Security.

[FR Doc. 2023–02139 Filed 2–1–23; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1311

[Docket No. DEA–732]

RIN 1117–AB79

Controlled Substances Ordering System (CSOS) Modernization

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: This rule proposes to amend the Drug Enforcement Administration's (DEA) regulations to conform to the Controlled Substances Ordering System (CSOS) modernization effort by requiring all CSOS enrollment applications and supporting materials to be submitted through the Diversion Control Division secure online portal. These amendments would improve the enrollment process by aligning it with DEA's current requirements for other online form submissions. The online submission of enrollment applications and supporting material through the secure network application portal would increase the efficiency of the enrollment, modification, and revocation processes, and ensure DEA's receipt of accurate documentation in a more timely and organized manner.

DATES: Electronic comments must be submitted, and written comments must be postmarked, on or before April 3, 2023. 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 April 3, 2023.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–732'' 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 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 776–2265.

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.[1] The Attorney General has delegated this authority to the Administrator of DEA.[2]

The CSA defines ''distribute'' as ''to deliver (other than by administering or dispensing) a controlled substance or a listed chemical'' and ''distributor'' as ''a person who so delivers a controlled substance or a listed chemical.'' [3] The CSA further provides that it ''shall be unlawful for any person to distribute a controlled substance in schedule I or II to another except in pursuance of a written order of the person to whom such substance is distributed, made on a form to be issued by the Attorney General in blank in accordance with subsection (d) of this section and regulations prescribed by him pursuant

[1] 21 U.S.C. 958(f).

[2] 28 CFR 0.100(b).

[3] 21 U.S.C. 802(11).

to this section.'' [4] ''Every person who gives an order required under subsection (a) of this section shall, at or before the time of giving such order, make or cause to be made a duplicate thereof on a form to be issued by the Attorney General in blank in accordance with subsection (d) of this section and regulations prescribed by him pursuant to this section, and shall, if such order is accepted, preserve such duplicate for a period of two years and make it available for inspection and copying . . . . '' [5] ''The Attorney General shall issue forms . . . only to persons validly registered under section 823 of this title (or exempted from registration under section 822(d) of this title). Whenever any such form is issued to a person, the Attorney General shall, before delivery thereof, insert therein the name of such person, and it shall be unlawful for any other person (A) to use such form for the purpose of obtaining controlled substances or (B) to furnish such form to any person with intent thereby to procure the distribution of such substances.'' [6]

Implementation of the CSA Written Order Form Requirement

Paper DEA Form 222

In 1971 DEA implemented the CSA's written order form requirement by publishing a final rule requiring triplicate paper DEA Form 222s.[7] In 2019, DEA amended its regulations to create a new single-sheet format for the paper DEA Form 222s.[8] The rule contained transition provisions allowing registrants to continue to use their existing stocks of the triplicate paper DEA Form 222s until their supply was exhausted, or until October 30, 2021, whichever came sooner.[9]

Electronic DEA Form 222

In 2005, DEA published a final rule amending its regulations to provide an electronic equivalent to the DEA Form 222 (also known as CSOS).[10] The amendments allowed registrants to order schedule I and II controlled substances electronically and maintain records of these orders electronically. The intent of these amendments was to reduce paperwork and transaction times for DEA registrants who sell or buy controlled substances.

Summary of Current CSOS Regulations

The current CSOS regulations are found in 21 CFR parts 1305 and 1311. DEA Registrants use CSOS as a secure system to track schedule I and II controlled substance orders. The system allows for secure electronic controlled substances orders without the need for a paper order form (DEA Form 222). Using Public Key Infrastructure (PKI), CSOS requires that each individual supplier and purchaser enroll with DEA to acquire a CSOS digital certificate. System enhancements will allow electronic documentation submission, self-service support options, and electronic processing of single and bulk applications, renewals, and revocations. Users will be able to electronically search for, revoke, report, retrieve, and renew secure digital certificates.

Purpose of Rule

Current regulations require registrants who wish to participate in the CSOS system to enroll using a labor intensive manual process which relies on paper applications. The paper application must be notarized and the package mailed to DEA, creating delays in the enrollment process and putting applications at risk of being lost.[11] The purpose of this rule is to simplify the application process by requiring all CSOS enrollment applications to be submitted online. All applicants for enrollment will follow the CSOS link on the *deadiversion.gov* website to the CSOS log-in page. From the CSOS log-in page the applicant will be redirected to *Login.gov* for Identification Verification. Upon arrival at the site, the applicant will be asked to create a *Login.gov* account by entering a valid email address, selecting a default language, and agreeing to *Login.gov's* Rules of Behavior. A confirmation email will then be sent to the applicant's selected email. Once the email has been confirmed, the applicant must create a *Login.gov* password by providing a telephone number to which a verification code can be sent. Once the code is sent and the applicant enters the given code on the *Login.gov* website, the applicant must agree to the site's security statement. *Login.gov* next requires applicants to upload photographs of one or more forms of identification as specified by *Login.gov* and to enter a Social Security Number, after which the applicant is asked to verify the given information. The applicant is next asked to re-enter their *Login.gov* password to receive a Personal Key by separate message. The applicant is then asked to enter that Personal Key and review their information. Upon review of the information, the applicant is then directed back to the CSOS website for further processing. Upon return to the CSOS website, the applicant is asked to agree to the CSOS User Agreement and can apply for one of three system user roles (Registrant, Coordinator, or Power of Attorney in order of superiority) with enrollment requests approved or rejected by the superior role. After the Registrant role is established, all subordinate applications for enrollment for the Coordinator role must be approved by the Registrant. Upon establishment of a Coordinator, all subordinate applications for enrollment for the Power of Attorney role must be approved in the system by the responsible Coordinator. This proposed rule would amend DEA regulations to require electronic enrollment through a secure web-based system. Submission through the secure online system will be a streamlined process which will benefit both DEA and CSOS participants.

Discussion of Regulatory Changes

Need for Regulatory Changes

Regulatory changes are needed to conform existing DEA regulations regarding the submission of the paper CSOS system enrollment forms to DEA's current requirements that other DEA forms be submitted online.[12] The paper enrollment process is prone to errors, creates wasteful and unnecessary paper records, requires manual processing,

[4] 21 U.S.C. 828(a).

[5] 21 U.S.C. 828(c)(2).

[6] 21 U.S.C. 828(d)(1).

[7] 36 FR 7776, April 24, 1971.

[8] DEA Notice of Proposed Rulemaking titled ''New Single-Sheet Format for U.S. Official Order form for Schedule I and II Controlled Substances (DEA Form 222),'' published in the **Federal Register** on February 21, 2019, *and* DEA Final Rule titled ''New Single-Sheet Format for U.S. Official Order Form for schedule I and II Controlled Substances (DEA Form 222),'' published in the **Federal Register** on September 30, 2019, at 84 FR 51368.

[9] 21 CFR 1305.20.

[10] DEA Notice of Proposed Rulemaking titled ''Electronic Orders for Controlled Substances,'' published in the **Federal Register** on June 27, 2003, at 68 FR 38557 *and* DEA Final Rule titled ''Electronic Orders for Controlled Substances,'' published in the **Federal Register** on April 1, 2005, at 70 FR 16901.

[11] 21 CFR part 1311 *et seq.*

[12] See Reporting of Theft or Significant Loss of Controlled Substances, 85 FR 146 (July 29, 2020) (published NPRM proposing to require all DEA Form 106's to be submitted electronically); Suspicious Orders of Controlled Substances, 85 FR 212 (Nov. 02, 2020) (published NPRM proposing centralized electronic reporting for SORS based on Congressional mandate); Agency Rule List—Spring 2021 (2021), *https://www.reginfo.gov/public/do/eAgendaMain?operation=OPERATION_GET_AGENCY_RULE_LIST&currentPub=true&agencyCode=&showStage=active&agencyCd=1100&csrf_token=F19C7C599C70B80C228EC16B60AEB150F6339AF3C80E56FE003EEB7D3A758895BC8E16A215E8A0466326EBFBA8639F799E09* (Spring 2021 Unified Agenda of Regulatory and Deregulatory Actions, Active Regulatory Actions Listed By Agency, Agency Rule list noting proposed rule stage for Electronic Submission of DEA Form 41 (Registrant Record of Controlled Substances Destroyed) –1117–AB59).

and is expensive to process and store. This rule proposes to amend existing DEA regulations in one part—Title 21 Chapter II Part 1311. DEA is proposing to amend 21 CFR 1311 to require all CSOS enrollment applications and supporting materials to be submitted to DEA through the CSOS secure network portal. This amendment would improve the submission process by aligning it with DEA's current policy of reducing and/or eliminating the reliance on wasteful paper applications and expediting enrollment by utilizing modern technology. The online submission of applications and supporting materials through the secure database will ensure DEA's receipt of documentation in a more timely and organized manner.

Section by Section Analysis

DEA is proposing to amend 21 CFR 1311.20, 1311.25, 1311.40, and 1311.60 by eliminating the ability of registrants to submit paper CSOS enrollment application forms. Registrants would thus be required to submit all their application materials through the secure online portal. Moreover, DEA is proposing to amend these regulations by eliminating certain recordkeeping requirements, as those records would now be accessible as a digital version in the system. DEA believes these amendments would expedite the enrollment process for registrants and facilitate the Agency-wide goal of reducing DEA's reliance on paper forms.

DEA is proposing to amend § 1311.20, which describes the role and responsibilities of the CSOS Coordinator. Current regulations require the CSOS Coordinator to complete the paper application process by submitting the notarized enrollment package to DEA Certification Authority for processing. This proposed amendment would streamline the process by eliminating the paper process and requiring Coordinator applicants to enroll using the secure online portal.

Additionally, DEA is proposing to amend § 1311.25, which establishes the requirements for a registrant, or authorized representative with a Power of Attorney, to complete the manual application process by submitting the notarized enrollment package to the DEA Certification Authority for processing. This proposed amendment would streamline the process by eliminating the manual paper process and require all Registrants, or authorized representative with a Power of Attorney to enroll using the secure online portal.

DEA is also proposing to amend § 1311.40, which establishes the criteria for renewal of a CSOS digital certificate by the manual paper process. This proposed amendment would streamline the renewal process by eliminating the manual paper process and require that all renewal applications be submitted using the secure online portal.

Last, DEA is proposing to amend § 1311.60, which establishes recordkeeping requirements on the part of the CSOS Certificate holder by requiring that a copy of the subscriber agreement be maintained for the life of the certificate. This proposed amendment would remove the requirement of the CSOS Certificate holder to maintain a copy of the subscriber agreement by enabling registrants to sign and access a digital version of the agreement in the online portal.

Regulatory Analyses

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)

This proposed 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 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 proposed rule is not a ''significant regulatory action'' under E.O. 12866, section 3(f).

Analysis of Benefits and Costs

Current regulations require registrants who wish to participate in the CSOS system to enroll using a labor-intensive manual process which relies on paper applications. This proposed rule would amend DEA regulations to require electronic enrollment through a secure web-based system.

The current regulations related to CSOS enrollment are summarized below.

(1) 21 CFR 1311.20(b)–(c) requires coordinators to enroll in writing.

(2) 21 CFR 1311.25(a)–(b) requires a registrant, or authorized representative with a Power of Attorney, to enroll in writing.

(3) 21 CFR 1311.40(c)–(d) requires submitting a new application in writing for every third renewal and for expired certificates.

(4) 21 CFR 1311.60(c) requires maintaining a copy of the subscription agreement for the life of the certificate.

The proposed rule would change this to:

(1) 21 CFR 1311.20(b)–(c) would require coordinators to enroll online.

(2) 21 CFR 1311.25(a) (with (b) removed) would require all registrants, or authorized representative with a Power of Attorney, to enroll online.

(3) 21 CFR 1311.40(c)–(d) would require, for every third renewal and expiration, a new application online.

(4) 21 CFR 1311.60(c) would be removed, allowing electronic subscription agreements to be held online and no longer requiring a paper copy be maintained.

Table 1 summarizes the changes from current regulations to the proposed rule.

TABLE 1—SUMMARY OF CURRENT REGULATIONS AND THE PROPOSED RULE

21 CFR Location	Current	Proposed
1311.20(b)–(c)	requires coordinators to enroll in writing	would require coordinators to enroll online.
1311.25(a)–(b)	requires a registrant, or authorized representative with a Power of Attorney, to enroll in writing.	would require all registrants, or authorized representative with a Power of Attorney, to enroll online.

TABLE 1—SUMMARY OF CURRENT REGULATIONS AND THE PROPOSED RULE—Continued

21 CFR Location	Current	Proposed
1311.40(c)–(d)	requires submitting a new application in writing, for every third renewal and for expired certificates.	would require, for every third renewal and expiration, a new application online.
1311.60(c)	requires maintaining a copy of the subscription agreement.	(removal) would allow subscription agreements to be held online and no longer require a copy be maintained.

DEA has examined the benefits and costs of this proposed rule and believes it is of net economic benefit. DEA believes the cost savings to registrants, as well as the DEA, heavily outweigh any cost to the DEA associated with implementing and maintaining the necessary computer systems to allow for online enrollment and renewal to CSOS.

Affected Parties and Number of CSOS Applications

This proposed rule would affect registrants who wish to participate in the CSOS system and DEA. A registrant, designated person, or an authorized representative, who wishes to enroll in the CSOS system can apply for one of three system user roles: Registrant, Coordinator, or Power of Attorney. New and renewal enrollment applications are submitted online. DEA processes the applications in addition to operating and maintaining the systems used in the enrollment and certificate management process. The economic impact of this proposed rule is a function of changes in requirement for each CSOS enrollment application and the estimated number of applications.

Each year DEA receives a mix of new and renewal applications for enrollment. In 2021, DEA received 31,172 new applications. These applications include 11,411; 6,974; and 12,787 new applications for Registrant, Coordinator, and Power of Attorney roles, respectively. For every third renewal, the CSOS certificate holder must submit a new application.[13] Therefore, for the purposes of this analysis, a third renewal is considered as a new application. Based on this renewal requirement, DEA estimates that new applications are approximately one-third of total applications and the number of renewals is approximately twice the number of new applications. Therefore, DEA estimates there were 62,344 renewal applications for a total of 93,516 (31,172 + 62,344) total applications in 2021.

As pharmacies are the largest registration business activity that participate in CSOS, representing approximately 73% of CSOS registered locations,[14] DEA believes the growth in the number of pharmacies registered with the DEA represents a good proxy for the growth of CSOS-participating registrants, and the number of CSOS applications for enrollment.

The number of DEA registered pharmacies has declined from 72,353 in 2015 to 70,628 in 2019 and has roughly stayed constant, with no growth, from 2019 to 2021, with 70,789 and 70,670 pharmacy registration if 2020 and 2021, respectively. So, DEA believes that zero net growth in CSOS applications is a reasonable estimate. Therefore, DEA estimates the numbers of applications stay constant at 31,172 new and 62,344 renewal, for a total of 93,516 applications over the 10-year analysis period.

Registrant Impact

New Applications

Below is a description of the estimated impact of the proposed rule on new enrollment applications for Registrant, Coordinator, and Power of Attorney roles.

1. *Time To Complete New Application:* DEA estimates there will be labor cost savings from reduced time to complete a new application. DEA estimates that the current time to complete a new application is three hours, which includes an estimated 1.5 hours to prepare and provided the necessary information and 1.5 hours calling the DEA for assistance or status of application. Under the proposed rule, while an applicant is expected to require the same 1.5 hours to prepare and provide the necessary information, the online system will allow self-viewing of status, reducing the need or duration of calls to DEA. DEA estimates the required time to complete a new application would be 1.75 hours, including an estimated 0.25 hours for logging to CSOS system or calls to DEA for assistance. Using a loaded hourly rate of $87.65 for Pharmacists,[15] [16] [17] the labor cost would decrease from $262.95 ($87.65 × 3) to $153.39 ($87.65 × 1.75), resulting in an estimated cost savings of $109.56 ($262.95 − $153.39) per application.

2. *Postage Cost:* Under current regulations paper application forms and supporting information need to be shipped to DEA. The proposed rule would eliminate the need to ship paper applications. Not having to ship the enrollment package is estimated to reduce postage costs by $11.13 per application.[18]

3. *Notary Cost:* Under current regulations, a new application for a Registrant or a Coordinator role requires a notary. The proposed rule would eliminate the notary requirement. Not having to get a notary (due to online verification methods that are free) is expected to eliminate an estimated notary cost of $5.00 per enrollment package.[19] [20] The notary requirement only applies to Registrant and Coordinator roles, and as discussed earlier, of the estimated 31,172 total new applications, 11,411 and 6,974 are for Registrant and Coordinator, respectively, making up 59 percent ((11,411 + 6,974)/31,174) of total registrations. Therefore, 59 percent of $5.00, $2.95 is the average notary cost savings for all new applications.

4. *Agreement Storage Costs:* Under current regulations, a CSOS certificate holder is required to maintain a copy of

[13] 21 CFR 1311.40(c).

[14] Source: DEA.

[15] U.S. Bureau of Labor Statistics (BLS), Occupational Employment and Wages, May 2021, 29–1051 Pharmacists. *https://www.bls.gov/oes/current/oes291051.htm.* (Accessed 4/25/2022.)

[16] BLS, ''Employer Costs for Employee Compensation—December 2021'' (ECEC).

[17] As pharmacies represent a large majority of CSOS participants and pharmacists are expected to be the most prevalent CSOS users, DEA believes pharmacists wages therefore represent a good estimate of the wage for all applicants. BLS reports that the median wage of pharmacists is $61.81. BLS also reports that average benefits for private industry is 29.5 percent of total compensation. The 29.5 percent of total compensation equates to 41.8 percent (29.5 percent/70.5 percent) load on wages and salaries. The load of 41.8 percent is added to each of the hourly rates to estimate the loaded hourly rates. $61.81 × 1.418 = $87.65.

[18] FedEx Ground rates for a one-pound package using zone five, effective January 4, 2021 and downloaded on 4/6/2022.

[19] National Notary Association, ''2022 Notary Fees by State''. *https://www.nationalnotary.org/knowledge-center/about-notaries/notary-fees-by-state* (accessed 4/6/2022).

[20] Notary fees can range from $1 to $25. DEA has decided to use $5 as its estimate of notary fees. DEA believes many applicants can get documents notarized at low costs, *i.e.,* at banks, employees with public notary, etc.

the subscriber agreement. The proposed rule would eliminate this requirement. DEA does not believe there is a material impact from not having to store written subscription agreements and having them be stored online in CSOS.

Table 2 summarizes the impact of the proposed rule for new applications.

TABLE 2—REGISTRANT IMPACT: NEW APPLICATION

	Current ($)	New ($)	Cost savings ($)
Labor cost per New app	262.95	153.39	109.56
Postage cost per New app	11.13		11.13
Cost of notary per New app	2.95		2.95
Total new application			123.64

Renewal Applications

Below is a description of the estimated impact of the proposed rule on renewal enrollment applications for Registrant, Coordinator, and Power of Attorney roles.

1. *Time Spent Requested Renewal:* DEA estimates there will be labor cost savings from reduced time to complete a renewal application. DEA estimates that the time spent requesting a renewal will fall from 1.5 hours using the phone method to 0.25 hours using the online method. Using a loaded hourly rate of $87.65 for Pharmacists,[21] the labor cost would decrease from $131.48 ($87.65 × 1.5) to $21.91 ($87.65 × 0.25), resulting in an estimated cost savings of $109.56 ($131.48 − $21.91) per application.

Table 3 summarizes the impact of the proposed rule for renewal applications.

TABLE 3—REGISTRANTS IMPACT—RENEWAL APPLICATIONS

	Current ($)	New ($)	Cost savings ($)
Labor cost per Renewal app	131.48	21.91	109.56

Total Registrant Impact

The total registrant cost savings is $10,684,716 per year, calculated by multiplying the cost of a new and renewal application by the number of new and renewal applications. Table 4 details the calculation.

TABLE 4—TOTAL REGISTRANT IMPACT

Number of new applications	31,172
Number of renewal applications	62,344
Number of total applications	93,516
Cost savings per new application ($)	123.64
Subtotal, all new applications ($)	3,854,152
Cost savings per renewal application ($)	109.56
Subtotal, all renewal applications ($)	6,830,565
Total cost savings to registrants ($)	10,684,716

Additional Benefits

There are additional benefits of the proposed rule. These include:

(1) *Shorter end-to-end process time (submission to certificate):* Allowing earlier use of CSOS for ordering Schedule II controlled substances and realizing the benefits of electronic ordering rather than using paper order forms.

(2) *Insight into status and workflows to track the progress of the submission:* Allowing Coordinators to get status updates online, see how the application progresses, and plan for additional CSOS users.

(3) *No longer needing to wait for the call center to request Certificate management action revocations:* Allowing Coordinators to self-manage and remove user certificates.

(4) *Safer submission process:* Allowing secure delivery of potentially sensitive information.

(5) *Error checking:* Allowing programmatic review for erroneous or incomplete information, reducing delays in application processing.

DEA Impact

DEA's costs are driven by the personnel and technology resources required to process the applications. Below is a list of the cost activities and anticipated impact.

1. *Certification Authority (CA) Cost:* The CA serves as the central element responsible for establishing a trust relationship between controlled substance manufacturers, distributors, pharmacies, and other DEA authorized ordering entities. CA issues user digital certificates used to digitally sign electronic transactions. DEA believes that the personnel resources and costs to certify enrollment and issue digital certificates will not change as a result of this proposed rule. Based on current CA resources, DEA estimates the annual CA cost will remain at $732,922.[22]

[21] Note 17.

[22] Source: DEA.

2. *Registration Authority (RA) Cost:* The RA is the entity that collects and verifies each applicant's identity and information that are to be entered into his or her public key certificates. Receiving electronic applications would eliminate the need to scan paper applications. DEA estimates that the personnel resources and costs to process enrollment applications will fall by 30 percent starting with the second year of implementation of the rule. However, in the first year of implementation, DEA anticipates the decrease in resource requirements from elimination of scanning requirement will be offset by increase in applicant questions referred to RA. DEA estimates the total annual RA cost of $597,688 [23] will remain the same in year 1 and will be $418,382 ($597,688 × 0.7) in year 2 and thereafter.

3. *Mail Reception Cost:* Currently, DEA requires personnel to receive, sort, and deliver paper applications to the RA at an estimated annual cost of $34,562.[24] Under the proposed rule, applications would be received online, eliminating this cost.

4. *Data Entry Cost:* Currently, personnel resources are needed to verify the accuracy of the scanned paper applications and make any needed corrections. Under the proposed rule, online applications would eliminate the need for this task. The estimated total current annual cost of $109,138 [25] would be eliminated if this proposed rule were implemented.

5. *Call Center Support Cost:* DEA operates a CSOS call center to service questions, or provide assistance, regarding CSOS enrollment and certificate management. The estimated total current annual cost as $1,749,946.[26] While DEA anticipates a reduction in the number of calls and duration of each call, DEA anticipates this reduction will result in lower wait-times for callers rather than reduced call center resources. Therefore, DEA estimates this cost will remain the same at $1,749,946.

6. *Information Technology (IT) Cost:* DEA currently spends approximately $255,000 per year on its IT enrollment-related systems and software. DEA anticipates IT costs will increase to $2,935,200 per year.[27] IT cost includes, but are not limited to, cloud services, workflow management, identity verification, identity management functionality, professional services for continuous development, integration and deployment, and maintenance and troubleshooting.

All costs are expected to scale with the volume of new applications, except IT cost, which does not vary with the volume of applications. Table 5 summarizes the DEA's impact.

TABLE 5—TOTAL DEA IMPACT

[Initial and remaining years]

	Current ($)	Year 1 ($)	Year 1, change from current ($)	Year 2 * ($)	Year 2, change from current ($)
Number of applications	31,172	31,172	.....	31,172	.....
Certificate Authority	732,992	732,992	.....	418,382	−314,610
Registration Authority **	597,688	418,382	−179,306	418,382	−179,306
Mail preparation (received mail)	34,562	.....	−34,562	.....	−34,562
Data Entry	109,138	.....	−109,138	.....	−109,138
Call Center Support	1,749,946	1,749,946	.....	1,749,946	.....
Information Technology	255,000	2,935,200	2,680,200	2,935,200	2,680,200
Total cost	3,479,325	5,836,519	2,357,194	5,521,909	2,042,584

* Years 2 through 10 are all assumed to be the same.
** New cost starts on second year.

Additional Benefits

There are additional benefits to the DEA from the proposed rule. These include:

(1) That the CSOS System will be supported, secure, reliable, and scalable: Reducing the risk of lost or stolen data and long-term reduction in costs associated with to maintenance, operations, and growth.

(2) The Certificate management process no longer involves a help desk call: Call center resources will be freed up to reduce hold-times for registrants allowing meeting call management service level agreements and improving user satisfaction.

(3) Possible increase in CSOS adoption due to ease of enrollment process: Reducing DEA costs associated with printing and mailing paper order forms.

(4) The ease at which enhancements can be made as needed, for example Enterprise Certificates with multiple DEA numbers: Allowing efficient future improvements to CSOS.

Registrant and DEA Total Impact

Using the registrant and DEA impacts from table 5 the estimated net cost savings of this proposed rule for the 10-year analysis period is listed in Table 8.

TABLE 6—DEA AND REGISTRANT TOTAL IMPACT

Year	Total cost savings to registrants ($)	Net cost savings to DEA (net cost) ($)	Total net cost savings, registrant + DEA ($)
1	10,684,716	(2,536,501)	8,148,216
2	10,684,716	(2,357,194)	8,327,522

[23] Source: DEA.
[24] Source: DEA.
[25] Source: DEA.
[26] Source: DEA.
[27] Source: DEA.

TABLE 6—DEA AND REGISTRANT TOTAL IMPACT—Continued

Year	Total cost savings to registrants ($)	Net cost savings to DEA (net cost) ($)	Total net cost savings, registrant + DEA ($)
3	10,684,716	(2,357,194)	8,327,522
4	10,684,716	(2,357,194)	8,327,522
5	10,684,716	(2,357,194)	8,327,522
6	10,684,716	(2,357,194)	8,327,522
7	10,684,716	(2,357,194)	8,327,522
8	10,684,716	(2,357,194)	8,327,522
9	10,684,716	(2,357,194)	8,327,522
10	10,684,716	(2,357,194)	8,327,522

The present value of the net cost savings over the 10-year analysis period is $70,861,367 and $58,321,453 at three and seven percent discount rates, respectively. The annualized net benefit is $8,307,114 and $8,303,663 at three and seven percent, respectively.

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

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 enrollment process by requiring all initial registration and renewal applications be submitted online. The rule would affect all enrollment and renewals for CSOS, whose users currently use paper applications. However, once a registrant is enrolled the DEA already requires them to order using CSOS. So, there is no additional cost to obtaining access to CSOS, since registrants will already be required to use it eventually.

There is a total of 94,011 CSOS participating entities, as can be seen in Table 7, with approximately 325,000 active certificates. Certificates have to be renewed every one or three years, based on the registrants' DEA registration renewal cycle. In 2021, the number of new applications were 31,172. For every third renewal, the CSOS certificate holder must submit a new application.[28] Therefore, for the purposes of this analysis, a third renewal is considered as a new application. DEA estimate that the total applications, including renewals, is 93,516.

TABLE 7—PERCENTAGE AND NUMBER OF REGISTERED LOCATIONS BY BUSINESS ACTIVITY

Business activity	Number of entities	Percent	Renewal cycle (years)
Pharmacy	62,291	66.26	3
Hospital/Clinic	11,898	12.66	3
Practitioner/Mid-Level Practitioner (MLP)	18,095	19.25	3
Teaching Institution	14	0.01	3
Manufacturer	103	0.11	1
Distributor/Importer/Exporter	444	0.47	1
Researcher	247	0.26	1
Analytical Lab	26	0.03	1
Reverse Distributor	5	0.01	1
Narcotic Treatment Program (NTP)	888	0.94	1
Total	94,011	100.00	*2.97

*Weighted average.
(Source: DEA).

[28] 21 CFR 1311.40(c).

This proposed rule affects all new and renewal enrollment applications for CSOS, as applications will have to take place online, and all entities who would submit new and renewal applications. This proposed rule would affect small entities in industries associated with the above business activities, primarily industries associated with pharmacy, hospital/clinic, and practitioner/MLP registrations, as these business activities make up 98.17% of the CSOS-participating registrations. Table 8 indicates the sectors, as defined by the North American Industry Classification System (NAICS), that best correlate with business activities affected by the proposed rule.

TABLE 8—INDUSTRIAL SECTORS AFFECTED BY THE PROPOSED RULE

Business activity	NAICS code	NAICS code description
Pharmacy	445110	Supermarkets and Other Grocery (except Convenience) Stores.
	446110	Pharmacies and Drug Stores.
	452210	Department Stores.
	452311	Warehouse Clubs and Supercenters.
NTP, Hospital/Clinic, Practitioner, MLP*	621111	Offices of Physicians (except Mental Health Specialists).
	621112	Offices of Physicians, Mental Health Specialists.
	621330	Offices of Mental Health Practitioners (except Physicians).
	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.
	622310	Specialty (except Psychiatric and Substance Abuse) Hospitals.
Teaching Institute	611310	Colleges, Universities and Professional Schools.
Manufacturer	325411	Medicinal and Botanical Manufacturing.
	325412	Pharmaceutical Preparation Manufacturing.
Distributor, Importer, Exporter	424210	Drugs and Druggists' Sundries Merchant Wholesalers.
Researcher	541715	Research and Development in the Physical, Engineering, and Life Sciences (except Nanotechnology and Biotechnology).
Analytical Labs	541380	Testing Laboratories.
Reverse Distributor	562213	Solid Waste Combustors and Incinerators.
	562219	Other Nonhazardous Waste Treatment and Disposal.

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

As shown in Table 8, the proposed rule would affect a wide variety of entities across many industry sectors. Some industry sectors are expected to consist primarily of DEA CSOS registrants (*i.e.,* 446110—Pharmacies and Drug Stores, 622110—General Medical and Surgical Hospitals, etc.). Therefore, this proposed rule is expected to affect a substantial number of small entities in some industries.

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. All CSOS registered location will already need to have access to the internet in order to use CSOS. DEA acknowledges some applicants prefer 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 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 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, generating an estimated cost savings of $11.13 per each paper application not submitted.[29] DEA assumes the cost savings associated with eliminating printing costs and envelopes is negligible. This proposed rule would also eliminate the need to get a notary for new applications, which will save $5.00 each for applications for registrant and coordinator roles.[30] An application for POA role does not require a notary; and while there would be no notary cost savings for these applications, $5 cost savings is included in the analysis to be conservative and because applications for registrant and coordinator roles are slightly more than half of all applications.

As discussed in the E.O. 12866 section above, DEA estimates that the time savings from this proposed rule will save $109.56 per new and renewal application.

Total cost savings for a new application is $125.69 (109.56 + 11.13 + 5.00 = 125.69), as can be seen in Table 9.

[29] Note 18.

[30] Note 20.

TABLE 9—COST SAVINGS PER NEW APPLICATION

	Current ($)	New ($)	Cost savings ($)
Labor cost per New app	262.95	153.39	109.56
Postage cost per app	11.13	.....	11.13
Cost of notary	5.00	.....	5.00
Total	.....	.....	125.69

As also calculated in the E.O. 12866 section above, total cost savings for renewals is $109.56, as can be seen in Table 10.

TABLE 10—COST SAVINGS PER RENEWAL APPLICATION

	Current ($)	New ($)	Cost savings ($)
Labor cost per Renewal app	131.48	21.91	109.56
Total	.....	.....	109.56

There were 31,172 new applications in 2021. DEA estimates there were also 62,344 renewal applications for a total of 93,516 applications. Given there are 94,011 CSOS participating entities, there is less than one application per year per entity on average (93,516/94,011 = 0.99). Given that there are at approximately 325,000 active digital certificates, the vast majority of which are on three-year renewal cycles, DEA expects approximately 108,333 certificates to be renewed annually (325,000/3 = 108,333). There are then approximately 1.15 certificates per entity (108,333/94,011 = 1.15). Given that smaller firms should have less certificates than larger firms, DEA believes using one certificate or one application per entity per year is a reasonable assumption for the smallest of small entities.

To determine whether the proposed rule would have a significant economic impact on small entities, DEA conducted a revenue test by comparing the estimated annual cost savings to the average annual revenue for the smallest of small entities in industries affected by the proposed rule. Based on the Statistics of U.S. Businesses data from the Census Bureau, table 11 lists the enterprise size, number of establishments, and the average annual revenue for the smallest of small businesses in each industry sector.[31] [32]

TABLE 11—AVERAGE ANNUAL REVENUE OF SMALLEST OF SMALL ENTITIES

NAICS	NAICS description	Enterprise size (number of employees)	Number of establish-ments	Average revenue per establishment ($ thousands)
325411 ..	Medicinal and Botanical Manufacturing	0–4	239	690
325412 ..	Pharmaceutical Preparation Manufacturing	0–4	390	1,173
424210 ..	Drugs and Druggists' Sundries Merchant Wholesalers	0–4	4,076	1,512
445110 ..	Supermarkets and Other Grocery (except Convenience) Stores	0–4	20,741	519
446110 ..	Pharmacies and Drug Stores	0–4	7,052	1,328
452210 ..	Department Stores	0–4	3	467
452311 ..	Warehouse Clubs and Supercenters	0–4	20	475
541380 ..	Testing Laboratories	0–4	2,427	316
541715 ..	Research and Development in the Physical, Engineering, and Life Sciences (except Nanotechnology and Biotechnology).	0–4	4,895	449
562213 ..	Solid Waste Combustors and Incinerators	0–4	15	949
562219 ..	Other Nonhazardous Waste Treatment and Disposal	0–4	183	580
611310 ..	Colleges, Universities, and Professional Schools	0–4	458	802
621111 ..	Offices of Physicians (except Mental Health Specialists)	0–4	91,892	465
621112 ..	Offices of Physicians, Mental Health Specialists	0–4	9,031	291
621330 ..	Offices of Mental Health Practitioners (except Physicians)	0–4	22,653	165
621420 ..	Outpatient Mental Health and Substance Abuse Centers	0–4	3,019	248
621491 ..	HMO Medical Centers	0–4	27	98
621493 ..	Freestanding Ambulatory Surgical and Emergency Centers	0–4	1,188	666
622110 ..	General Medical and Surgical Hospitals	0–4	79	15,559
622210 ..	Psychiatric and Substance Abuse Hospitals	0–4	10	1,024
622310 ..	Specialty (except Psychiatric and Substance Abuse) Hospitals	0–4	8	1,965

[31] Census Bureau, Statistics of U.S. Businesses Revenue Data by Size, 2017. *https://www.census.gov/programs-surveys/susb.html.* (Released 5/28/2021).

[32] Census Bureau, Statistics of U.S. Businesses Number of Establishment Data by Size, 2019. *https://www.census.gov/programs-surveys/susb.html.* (Released 2/11/2022).

The estimated cost savings of $125.69 for new applications and $109.56 for renewal applications were compared to the average annual revenue for each of the NAICS codes in Table 11. For example, taking the smallest possible entities, HMO Medical Centers with 0–4 people, with an average revenue of $98,000, the benefit, in the form of cost savings, from new applications is $125.69 (109.56 + 11.13 + 5 = 125.69), or 0.13 percent of revenues (125.69/98,000 = 0.0013). The benefit from renewals is 0.11 percent of revenues (109.56/98,000 = 0.0011). Table 12 details the revenue test results for all affected NAICS codes.

TABLE 12—REVENUE TEST OF SMALLEST OF SMALL ENTITIES

NAICS	NAICS description	Average revenue per establishment ($ thousands)	Benefit from new applications ($)	Percent of revenue (%)	Benefit from renewal applications ($)	Percent of revenue (%)
325411 ..	Medicinal and Botanical Manufacturing	690	125.69	0.02	109.56	0.02
325412 ..	Pharmaceutical Preparation Manufacturing	1,173	125.69	0.01	109.56	0.01
424210 ..	Drugs and Druggists' Sundries Merchant Wholesalers.	1,512	125.69	0.01	109.56	0.01
445110 ..	Supermarkets and Other Grocery (except Convenience) Stores.	519	125.69	0.02	109.56	0.02
446110 ..	Pharmacies and Drug Stores	1,328	125.69	0.01	109.56	0.01
452210 ..	Department Stores	467	125.69	0.03	109.56	0.02
452311 ..	Warehouse Clubs and Supercenters	475	125.69	0.03	109.56	0.02
541380 ..	Testing Laboratories	316	125.69	0.04	109.56	0.03
541715 ..	Research and Development in the Physical, Engineering, and Life Sciences (except Nanotechnology and Biotechnology).	449	125.69	0.03	109.56	0.02
562213 ..	Solid Waste Combustors and Incinerators	949	125.69	0.01	109.56	0.01
562219 ..	Other Nonhazardous Waste Treatment and Disposal.	580	125.69	0.02	109.56	0.02
611310 ..	Colleges, Universities, and Professional Schools.	802	125.69	0.02	109.56	0.01
621111 ..	Offices of Physicians (except Mental Health Specialists).	465	125.69	0.03	109.56	0.02
621112 ..	Offices of Physicians, Mental Health Specialists.	291	125.69	0.04	109.56	0.04
621330 ..	Offices of Mental Health Practitioners (except Physicians).	165	125.69	0.08	109.56	0.07
621420 ..	Outpatient Mental Health and Substance Abuse Centers.	248	125.69	0.05	109.56	0.04
621491 ..	HMO Medical Centers	98	125.69	0.13	109.56	0.11
621493 ..	Freestanding Ambulatory Surgical and Emergency Centers.	666	125.69	0.02	109.56	0.02
622110 ..	General Medical and Surgical Hospitals	15,559	125.69	0.00	109.56	0.00
622210 ..	Psychiatric and Substance Abuse Hospitals.	1,024	125.69	0.01	109.56	0.01
622310 ..	Specialty (except Psychiatric and Substance Abuse) Hospitals.	1,965	125.69	0.01	109.56	0.01

As shown in Table 12, the revenue test for the smallest of small entities (0–4 employees) ranges from 0.00 percent with rounding for NAICS code 622110 to 0.13 percent for NAICS code 621491. Therefore, the economic impact of this proposed rule is not significant for the smallest of small entities, and the economic impact is estimated to be not significant on any small entity.

In conclusion, while the proposed rule will impact a substantial number of small entities in at least some industries, the economic impact will not be significant. 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),[33] 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

This proposed rule would modify existing collection(s) of information requirement under the Paperwork Reduction Act (PRA).[34] The proposed rule will combine all information collection into one on-line enrollment process eliminating the need for individual forms. Pursuant to the PRA,[35] 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.[36]

A. Collections of Information Associated With the Proposed Rule

1. Title: CSOS Certificate Application. *OMB Control Number:* 1117–0038.

[33] 2 U.S.C. 1501 *et seq.*

[34] 44 U.S.C. 3501–3521.

[35] 44 U.S.C. 3507(d).

[36] Copies of existing information collections approved by OMB may be obtained at *http://www.reginfo.gov/public/do/PRAMain.*

Form Number: DEA–251.

DEA is proposing to amend its regulations to require that all CSOS applications and supporting materials must be submitted to DEA through the DEA Diversion Control Division secure network application. This amendment would improve the submission process by aligning it with DEA's current requirements for other online form submissions. The online submission of applications and supporting material through the secure database will ensure DEA's receipt of documentation in a more timely and organized manner. This combined online form will be used for all CSOS user roles: DEA Registrant, Principal Coordinator/Alternate Coordinator, and Power of Attorney.

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

- *Number of respondents:* 94,011.
- *Frequency of response:* 0.994735 (as needed, calculated).[37]
- *Number of responses:* 93,516.
- *Burden per response:* 0.75.[38]
- *Total annual hour burden:* 70,137.

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,[39] 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.
- 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–AB79/Docket No. DEA–732. All comments must be submitted to OMB on or before April 3, 2023. 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.

[37] Calculated by dividing the number of responses (93,516) by the number of respondents (94,011).

[38] Weighted average of new and renewal applications. There are 31,172 new applications and they take 1.75 hours. There are 62,344 renewals and they take 0.25 hours. New applications represent 33 percent of applications (31,172/93,516 = 0.33) and renewals represent 67 percent of applications (62,344/93,516 = 0.67). The weighted average is then 0.75 ([0.33 × 1.75] + [0.67 * 0.25] = 0.75).

[39] 44 U.S.C. 3506(c)(2).

List of Subjects in 21 CFR Part 1311

Administrative practice and procedure, Control substances, Drug traffic control, Prescription drugs, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, DEA proposes to amend 21 CFR part 1311 as follows:

PART 1311—REQUIREMENTS FOR ELECTRONIC ORDERS AND PRESCRIPTIONS

■ 1 The authority citation for part 1311 continues to read as follows:

Authority: 21 U.S.C. 821, 828, 829, 871(b), 958(e), 965, unless otherwise noted.

■ 2. Amend § 1311.20 by revising paragraphs (b) and (c) to read as follows:

§ 1311.20 Coordinators for CSOS digital certificate holders.

* * * * *

(b) If the designated coordinator changes at any time, the Certification Authority must immediately be notified of the change and the new responsibilities assumed by each of the registrant's coordinators, if applicable. New Coordinators must complete the online application as provided in § 1311.25.

(c) The registrant's coordinator must inform the Certification Authority of all digital certificate applications, renewals and revocations for the registrant's users and approve applicants applying for a power of attorney digital certificate for a DEA registrant by means instructed by the Certification Authority within the system.

■ 3. Revise § 1311.25 to read as follows:

§ 1311.25 Requirements for obtaining a CSOS digital certificate.

(a) To obtain a certificate to use for signing electronic orders for controlled substances, a registrant, coordinator, or person with power of attorney authorized to obtain a certificate for signing electronic orders for controlled substances for a registrant must complete the online enrollment process at *www.deaecom.gov* by:

(1) Completing the online identification proofing process;

(2) Providing a current listing of DEA registrations for which the individual has authority to sign controlled substances orders.

(3) Uploading all copies of the power of attorney forms authorized by the registrant, when applicable.

(4) Acknowledging that the applicant has read and understands the Subscriber Agreement and agrees to all terms contained in the Statement of Subscriber Obligations contained online.

(b) When the Certification Authority verifies the applicant's identity and employment and approves the application, it will send the applicant a one-time use reference number and access code, via separate channels, and information on how to use them. Using this information, the applicant must then electronically submit a request for certification of the public digital signature key. After the request is approved, the Certification Authority will provide the applicant with the signed public key certificate.

(c) Once the applicant has generated the key pair, the Certification Authority must prove that the user has possession of the key. For public keys, the corresponding private key must be used to sign the certificate request. Verification of the signature using the public key in the request will serve as proof of possession of the private key.

■ 4. Amend § 1311.40 by revising paragraphs (c) and (d) to read as follows:

§ 1311.40 Renewal of CSOS digital certificates.

* * * * *

(c) If a CSOS certificate holder applies for a renewal before the certificate expires, the certificate holder may renew online at *www.deaecom.gov* twice. For every third renewal, the CSOS certificate holder must submit a new application and documentation, as provided in § 1311.25.

(d) If a CSOS certificate expires before the holder applies for a renewal, the certificate holder must submit a new application and all required documentation, as provided in § 1311.25.

§ 1311.60 [Amended]

■ 5. Amend § 1311.60 by removing paragraph (c).

Signing Authority

This document of the Drug Enforcement Administration was signed on January 24, 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. 2023–01804 Filed 2–1–23; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 402, 880, 881, 883, 884, 886, 891

[Docket No. FR–6320–A–01]

RIN 2502–AJ62

Federal Housing Administration (FHA): Section 8 Project-Based Rental Assistance: Standard Program Regulation and Renewal Contract; Advance Notice of Proposed Rulemaking and Request for Public Comment

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, Office of Multifamily Housing Programs, HUD.

ACTION: Advance notice of proposed rulemaking and request for public comment.

SUMMARY: The Office of Multifamily Housing Programs (MFH) seeks comments from the public regarding an initiative under which MFH, in partnership with owners, tenants, and other program stakeholders, would move toward a single Section 8 program regulation and single contract form pursuant to which the Secretary would renew project-based Section 8 Housing Assistance Payments (HAP) contracts under section 524 of the Multifamily Assisted Housing Reform and Affordability Act of 1997 (MAHRA). Section 524 authorizes the Secretary to establish the terms and conditions under which expiring contracts are renewed, subject to the requirements of section 524. Currently, the Secretary issues one of several section 524 renewal contracts, which is subject to one of seven Section 8 regulatory parts under which the original contract was issued, as well as other HUD regulations implementing section 524. To reduce regulatory complexities, MFH envisions promulgating a single Section 8 project-based rental assistance program regulation consisting of a standardized set of Section 8 program requirements and a single form of section 524 renewal contract.

DATES: *Comment Due Date:* Written comments must be received on or before April 3, 2023.

ADDRESSES: Interested persons are invited to submit comments regarding this advance notice of proposed rulemaking. There are two methods for submitting public comments. All submissions must refer to the above docket number and title.

1. *Submission of Comments by Mail.* Members of the public may submit comments by mail to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW, Room 10276, Washington, DC 20410–0500. Due to security measures at all federal agencies, however, submission of comments by standard mail often results in delayed delivery. To ensure timely receipt of comments, HUD recommends that comments submitted by standard mail be submitted at least two weeks in advance of the deadline. HUD will make all comments received by mail available to the public at *https://www.regulations.gov.*

2. *Electronic Submission of Comments.* Interested persons may submit comments electronically through the Federal eRulemaking Portal at *www.regulations.gov.* HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make comments immediately available to the public. Comments submitted electronically through the *www.regulations.gov* website can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that site to submit comments electronically.

Note: To receive consideration as public comments, comments must be submitted through one of the two methods specified above. All submissions must refer to the docket number and title of the rule.

No Facsimile Comments. Facsimile (FAX) comments are not acceptable.

3. *Public Inspection of Public Comments.* All properly submitted comments and communications submitted to HUD are available for public inspection and copying between 8 a.m. and 5 p.m. weekdays at the above address. Due to security measures at the HUD Headquarters building, an advance appointment to review the public comments must be scheduled by calling the Regulations Division at 202–708–3055 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number via teletypewriter (TTY) by calling the Federal Relay Service at 800–877–8339 (this is a toll-free number). Copies of all comments submitted are available for inspection and downloading at *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jennifer Lavorel, Director, Program Administration Division, Office of Asset Management Portfolio Oversight, U.S. Department of Housing and Urban Development, 451 7th Street, SW, Washington, DC 20410, telephone number 202–402–2515 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number via TTY by calling the Federal Relay Service at 800–877–8339 (this is a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

The Housing and Community Development Act of 1974, Public Law 93–383 (Aug. 22, 1974) amended the United States Housing Act of 1937 to add Section 8. Congress established a new project-based rental assistance (PBRA) program under which public housing agencies under contract with HUD were authorized to enter into Housing Assistance Payments (HAP) contracts on behalf of eligible low-income families occupying new, substantially rehabilitated, or existing rental units. In 1983, Congress repealed PBRA authority for new construction and substantial rehabilitation HAP contracts. As original HAP contracts began to expire, Congress enacted the Multifamily Assisted Housing Reform and Affordability Act of 1997, Public Law 105–65 (Oct. 27, 1997), which authorized the renewal of expiring HAP contracts. Section 524 of MAHRA authorizes the renewal of HAP contracts at market rents (524(a)(4)(c)) and above-market rents (524(a)(4)(B)), for contracts