

DEA-222a: Order Form Requisition. Applicable component of the Department sponsoring the collection: Office of Diversion Control, Drug Enforcement Administration, U.S. Department of Justice.

(4) Affected public who will be asked or required to respond, as well as a brief abstract:

Primary: Business or other for-profit. Other: Non-profit, state and local governments.

Abstract: DEA-222 is used to transfer or purchase Schedule I and II controlled substances and data is needed to provide an audit of transfer and purchase. DEA-222a Requisition Form is used to obtain the DEA-222 Order Form. Persons may also digitally sign and transmit orders for controlled substances electronically, using a digital certificate. Orders for Schedule I and II controlled substances are archived and transmitted to DEA. Respondents are DEA registrants eligible to handle these controlled substances.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply: DEA estimates that the proposed rule would affect 100,000 registrants. The average time for requisitioning Form 222 is 0.05 hours. The average time for completing, annotating and filing paper orders for both purchasers and suppliers is 0.333 hours. Suppliers spend, on average, 9 hours a month logging and tracking order forms and preparing the mailing to DEA. The average time for signing and annotating electronic orders is estimated to be 0.031 hours per order for purchasers; the average time for validating and annotating electronic orders is estimated to be 0.046 hours per order for suppliers, who also spend 0.05 hours every other business day sending orders to DEA.

(6) An estimate of the total public burden (in hours) associated with the collection: As registrants adopt the proposed electronic ordering, the annual burden hours would average 1.9 million hours a year. During this period, DEA assumes that 20 percent of orders would be electronic in year 1, 60 percent in year 2, and 80 percent in year 3, based on a 6% growth rate for orders per year.

Overview of Reporting and Recordkeeping for Digital Certificates Information Collection

(1) Type of information collection: New collection.

(2) The title of the form/collection: Reporting and Recordkeeping for Digital Certificates.

(3) The agency form number, if any, and the applicable component of the Department sponsoring the collection: Form No.: (numbers not yet assigned). New CSOS DEA Registrant Certificate Application.

New CSOS Principal Coordinator/Alternate Coordinator Certificate Application.

New CSOS Power of Attorney Certificate Application.

Applicable component of the Department sponsoring the collection: Office of Diversion Control, Drug Enforcement Administration, U.S. Department of Justice.

(4) Affected public who will be asked or required to respond, as well as a brief abstract:

Primary: Business or other for-profit. Other: Non-profit, state and local governments.

Abstract: Persons use these forms to apply for DEA-issued digital certificates to order Schedule I and II controlled substances. Certificates must be renewed upon renewal of the DEA registration to which the certificate is linked. Certificates may be revoked at the discretion of the registrant.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply: DEA estimates that the proposed rule would affect 100,000 registrants and 160,000 certificate holders. The average time for completing the application for a digital certificate to order controlled substances is estimated to be from 0.72 hours to 1.24 hours. Certificate renewal is estimated to take 0.083 hours.

(6) An estimate of the total public burden (in hours) associated with the collection: As registrants adopt the proposed electronic ordering, the annual burden hours would average 167,000 hours a year. During this period, DEA assumes that 80 percent of the potential certificate holders will apply for a digital certificate.

If additional information is required regarding these collections of information, contact: Robert B. Briggs, Department Clearance Officer, Information Management and Security Staff, Justice Management Division, United States Department of Justice, Patrick Henry building, Suite 1600, 601 D Street, NW., Washington, DC 20530.

Executive Order 12988

This regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

Executive Order 13132

This rulemaking does not preempt or modify any provision of state law; nor

does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

List of Subjects

21 CFR 1305

Drug traffic control, Reporting and recordkeeping requirements.

21 CFR 1311

Administrative practice and procedure, Certification authorities, Controlled substances, Digital certificates, Drug traffic control, Electronic signatures, Prescription drugs, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR part 1305 is proposed to be revised, and part 1311 is proposed to be added as follows:

1. Part 1305 is revised to read as follows:

PART 1305—ORDERS FOR SCHEDULE I AND II CONTROLLED SUBSTANCES

Subpart A—General Requirements

- 1305.01 Scope of part 1305.
- 1305.02 Definitions.
- 1305.03 Distributions requiring a Form 222 or digitally signed electronic order.
- 1305.04 Persons entitled to order Schedule I and II controlled substances.
- 1305.05 Persons entitled to fill orders for Schedule I and II controlled substances.
- 1305.06 Special procedure for filling certain orders.

Subpart B—DEA Form 222

- 1305.11 Procedure for obtaining DEA Forms 222.
- 1305.12 Procedure for executing DEA Forms 222.
- 1305.13 Procedure for filling DEA Forms 222.
- 1305.14 Procedure for endorsing DEA Forms 222.
- 1305.15 Unaccepted and defective DEA Forms 222.
- 1305.16 Lost and stolen DEA Forms 222.