

DEPARTMENT OF JUSTICE**Drug Enforcement Administration****21 CFR Parts 1305 and 1311****[Docket No. DEA-217P]****RIN 1117-AA60****Electronic Orders for Controlled Substances****AGENCY:** Drug Enforcement Administration (DEA), Justice.**ACTION:** Notice of proposed rulemaking.

SUMMARY: DEA is proposing to revise its regulations to provide an electronic equivalent to the DEA official order form, which is legally required for all distributions involving Schedule I and II controlled substances. These proposed regulations will allow registrants to order Schedule I and II substances electronically and maintain the records of these orders electronically. The proposed regulations would reduce paperwork and transaction times for DEA registrants who handle, sell, or buy these controlled substances. This proposed rule has no effect on patients' ability to receive prescriptions for controlled substances from practitioners, nor on their ability to have those prescriptions filled at pharmacies. In fact, this rule will help to ensure the appropriate supply of controlled substances throughout the distribution system.

DATES: Written comments must be postmarked on or before September 25, 2003.

ADDRESSES: Comments should be submitted to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative/CCR.

FOR FURTHER INFORMATION CONTACT: Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307-7297.

SUPPLEMENTARY INFORMATION:**I. Background**

- What is DEA's Legal Authority for these Regulations?
- What are the current requirements for distributing Schedule I and II controlled substances?
- Why is this level of control necessary?
- If the current system works to limit diversion, why is a change needed?
- What is the Electronic Signatures in Global and National Commerce Act?

II. Proposed Approach

- What is DEA's objective with this proposed rule?

- How did DEA develop its approach?
- What approach has DEA selected?
- Why are authentication, nonrepudiation, and message integrity requirements necessary?
- What existing technologies meet these proposed criteria?
- Why do other electronic signature systems not meet the performance standards?
- Why is a digital signature approach necessary?
- How is a digital certificate an electronic equivalent of a Form 222?
- In simple terms, how does a digital signature work?
- In simple terms, how would this system work for the user?
- What is a Certification Authority and why is it needed?
- What would the Certification Authority do?
- Who would serve as the Certification Authority?

III. Discussion of the proposed rule on electronic orders**A. Digital Certificates**

- How are digital certificates obtained?
- Who are CSOS Coordinators and what is their role in the digital certificate enrollment process?
- How would a person obtain a digital certificate?
- Why does the application need to be notarized?
- How many certificates will be required?
- What is the renewal period for digital certificates?
- What are the requirements for companies that grant power of attorney to authorize use of their DEA registrations?
- What systems are required to use a digital signature?
- What systems are required to be able to process a digital signature?
- What are the FIPS Standards and why are they needed?
- How is it possible to determine whether a specific system meets these criteria?
- What are the requirements for safeguarding private keys?
- What are the conditions that would lead DEA to revoke a certificate?

B. Orders

- What is DEA proposing for electronic orders?
- What are the differences between DEA Form 222 and electronic orders?
- What data must be included in an electronic order?
- How can electronic orders be annotated?
- Can an order be endorsed to another supplier?
- Can a centralized processing facility be used?
- What information is a supplier required to report to DEA?
- Why does the reporting period change for electronic orders?
- Can a digital certificate be used to sign orders for Schedule III through V controlled substances?

IV. Section by Section Discussion of the Proposed Rule

- How is the proposed rule structured?
- Incorporation by Reference

V. Required Analyses

- Executive Order 12866
- Regulatory Flexibility Act
- Small Business Regulatory Enforcement Fairness Act of 1996
- Paperwork Reduction Act
- Executive Order 12988
- Executive Order 13132
- Unfunded Mandates Reform Act of 1995

I. Background*What Is DEA's Legal Authority for These Regulations?*

DEA enforces the Controlled Substances Act (CSA) (21 U.S.C. 801 *et seq.*), as amended. DEA regulations implementing this statute are published in title 21 of the Code of Federal Regulations (CFR), part 1300 to 1399. These regulations are designed to establish a framework for the legal distribution of controlled substances to deter their diversion to illegal purposes and to ensure that there is a sufficient supply of these drugs for legitimate medical purposes.

What Are the Current Requirements for Distributing Schedule I and II Controlled Substances?

The CSA prohibits distribution of Schedule I and II controlled substances except in response to a written order from the purchaser on a form DEA issues (21 U.S.C. 828(a)). DEA issues Form 222 to registrants for this purpose, preprinting on each form the registrant's name, registered location, DEA registration number, schedules, and business activity. DEA serially numbers the forms and requires registrants to maintain and account for all forms issued. Executed and unexecuted Forms 222 must be available for DEA inspection. The CSA requires that executed Forms 222 be maintained for two years (21 U.S.C. 828(c)).

When ordering a Schedule I or II substance, the purchaser must provide two copies of the Form 222 to the supplier and retain one copy. Upon filling the order, the supplier must annotate both copies of the form with details of the controlled substances distributed, retain one copy as the official record of the distribution, and send the second copy of the annotated Form 222 to DEA. Upon receipt of the order, the purchasers must also annotate their copy, noting the quantity of controlled substances received and date of receipt.

Why Is This Level of Control Necessary?

The purpose of DEA's regulations is to establish a framework for the legal distribution of controlled substances and to prevent their diversion to the illegal markets. Controlled substances are those substances listed in the