

schedules of the CSA and 21 CFR 1308.11–1308.15, and generally include narcotics, stimulants, depressants, hallucinogens, and anabolic steroids that have a high potential for abuse and dependency. DEA's regulations require that people involved in the manufacture, distribution, research, dispensing, import, and export of controlled substances register with DEA, keep track of all stocks of controlled substances, and maintain records to account for all stocks received, distributed, or otherwise disposed of. For Schedule I and II controlled substances, which have the highest potential for abuse and dependency, the CSA mandates that distribution can only occur in response to an order signed by the purchaser on a form issued to the purchaser by DEA. For other schedules, the law requires recordkeeping by both DEA-registered parties.

If the Current System Works to Limit Diversion, Why Is A Change Needed?

Although the current regulatory structure limits diversion, it does not address or provide for the use of modern computer technologies. DEA issued more than five million individual order forms in fiscal year 2001. Using 2001 as an average year, because both the purchaser and supplier must maintain copies of the form for two years, the order system requires the maintenance of almost twenty million forms.

Many, if not most, of the registrants using Form 222 place all of their other orders electronically. Many suppliers receive electronic notice from their purchasers of their intention to place Schedule I and II orders, but the orders cannot be filled until the supplier receives the DEA-issued Form 222 from the purchaser. The processing of the Form 222 takes one to three days from the time the form is completed to the time the order is delivered; electronic orders can be processed and filled immediately. Industry has asked DEA to provide an electronic means to satisfy the legal requirements for order forms. This proposed rule is in response to that request and will not only satisfy the requirements for Schedule I and II transactions, but may also be used for Schedule III through V transactions. Use of this system for all controlled substances transactions will facilitate the verification and authentication of the registration status of customers.

In addition, two recent laws, the Government Paperwork Elimination Act of 1998 (GPEA) and the Electronic Signatures in Global and National Commerce Act of 2000 (E-Sign) require Federal agencies to allow electronic

recordkeeping and reporting and recognize electronic signatures.

What Is the Electronic Signatures in Global and National Commerce Act?

The Electronic Signatures in Global and National Commerce Act of 2000, commonly known as E-Sign, was signed into law on June 30, 2000. It establishes the basic rules for using electronic signatures and records in commerce. E-Sign was enacted to encourage electronic commerce by giving legal effect to electronic signatures and records and to protect consumers. E-Sign prohibits government agencies from denying the legal effect of electronic signatures and records of electronic commerce based solely on their electronic nature, but allows Federal, state, and local agencies to set performance standards where necessary to ensure record integrity and accessibility of records.

Section 104(a) of E-Sign provides that, subject to the requirements of the Government Paperwork Elimination Act of 1998 (GPEA), “* * * nothing in this title limits or supersedes any requirement by a Federal regulatory agency, self-regulatory organization, or State regulatory agency that records be filed with such agency or organization in accordance with specified standards or formats.” The CSA and regulations require that distributions involving Schedule I or II controlled substances may be accomplished only when the orders are made on forms that DEA issued in triplicate to the purchaser and upon which DEA has imprinted the name of the purchaser (21 U.S.C. 828(d)(1) and 21 CFR 1305.05(a)). The law further provides that “* * * 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.” (21 U.S.C. 828(d)(1)). Of the three copies of the form issued, the purchaser and the supplier must each maintain a copy, and the supplier must provide a copy to DEA following completion of the transaction (21 CFR 1305.13). The CSA and implementing regulations clearly establish a specified standard and format that must be adhered to in filing records of distributions of Schedule I and II controlled substances with DEA, which are not superseded by E-Sign. It should be noted that the filing requirement is subject to the requirements of GPEA, which requires, in part, that for certain governmental filings, an electronic means to satisfy the requirement must be established, to the extent practicable, by October, 2003.

DEA does anticipate that the electronic means to satisfy the order form requirement that is being proposed in this rule will be in place by the GPEA deadline.

II. Proposed Approach

What Is DEA's Objective With This Proposed Rule?

DEA's objective is to develop an approach for electronic orders that takes advantage of computer technology without compromising the effectiveness of the existing system to limit diversion of controlled substances.

How Did DEA Develop Its Approach?

Before selecting an approach, DEA developed a set of basic performance standards that any electronic signature system would have to meet to serve as an electronic equivalent of the DEA Form 222 and reviewed all of the existing electronic signature technologies. DEA also met with representatives from a mix of manufacturers, distributors, pharmacies, and other interested parties to identify issues with the DEA Form 222 and to identify the information technologies (IT) registrants currently use in their ordering process. If the proposed rule is to provide the benefits that DEA and industry seek, the system should be compatible with existing information technology architectures and configurations. The results of DEA's meetings are summarized in two documents: Public Key Infrastructure Certificate Policy Requirements Analysis and Public Key Infrastructure Existing Network Infrastructure Analysis, which are available at <http://www.deadiversion.usdoj.gov>. Throughout the project, DEA has continued to meet with industry to discuss the requirements and to obtain more detailed technical input on how the proposed approach could be integrated with existing IT systems.

What Approach Has DEA Selected?

DEA is proposing to include in the rule three performance standards that are necessary to ensure that the electronic system is substantially equivalent to the DEA Form 222: message/record integrity, authentication, and nonrepudiation. DEA has determined that of the existing electronic signature technologies, only digital signatures using certificates issued through a public key infrastructure (PKI) system, operated by DEA, provide for record integrity and can serve as the functional equivalent of the form that the CSA mandates DEA to provide. If other technologies are