DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1305 and 1311

[Docket No. DEA–217F]

RIN 1117–AA60

Electronic Orders for Controlled Substances

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final rule.

SUMMARY: DEA is revising 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 regulations will allow, but not require, registrants to order Schedule I and II substances electronically and maintain the records of these orders electronically. The regulations will reduce paperwork and transaction times for DEA registrants who handle, sell, or buy these controlled substances. This 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.

DATES: *Effective Date:* This rule is effective on May 31, 2005. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of May 31, 2005.

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SUPPLEMENTARY INFORMATION:

I. Background

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.

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.

Regulatory History

Although the paper-based regulatory structure limits diversion, it does not address or provide for the use of modern computer technologies. DEA issued more than six million individual order forms in fiscal year 2003. Because both the purchaser and supplier must maintain copies of the form for two years, the order system requires the maintenance of more than 24 million forms. Many, if not most, of the registrants using Form 222 place all their orders for Schedules III–V controlled substances 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.

DEA Pilot Project

Industry asked DEA to provide an electronic means to satisfy the legal requirements for order forms. DEA began discussions with the regulated industry regarding CSOS standards in 1999. On January 11, 2002, DEA published a notice in the **Federal Register** expressing its intent to conduct a pilot project to conduct performance verification testing of public key infrastructure enabled controlled substances orders. This pilot project was conducted in partnership with two industry associations—the Health Care Distribution Management Association and the National Association of Chain Drug Stores. A total of 22 DEA registrants were listed as initial pilot participants. Initial pilot objectives were to ascertain the level of compatibility and usability of CSOS standards for electronic controlled substances ordering applications and to test industry's ability to deploy these systems. All technical test objectives were successfully realized in early phases of the pilot with registrants demonstrating the ability to retrieve and manage their CSOS digital certificates. Where participants expressed difficulty or reported undue burden with processes (*e.g.*, with initial notarization requirements for enrollment) proposed technical standards were reviewed and modified, where possible, without compromising necessary nonrepudiation and security services objectives.

In August 2002, pilot participants began using CSOS certificates in simulated environments with DEA providing access to a test suite of CSOS certificates. Pilot participants demonstrated the ability to send, receive and validate digitally signed controlled substances orders in a test environment, and also demonstrated the ability to accurately reject orders, as appropriate. Pilot outcomes allowed DEA to identify and resolve potential challenges before the controlled substances ordering system was proposed. DEA continues to provide test resources to industry through the use of its pilot system, allowing continued refinement of CSOS applications.

Summary of Proposed Rule

On June 27, 2003, DEA issued a Notice of Proposed Rulemaking (NPRM) in which DEA proposed revisions to its regulations to allow electronic orders if those orders were signed using an electronic signature that met three criteria—authentication, non-repudiation, and record integrity (68 FR 38558). Because only digital signatures based on certificates issued by a Certification Authority as part of a public key infrastructure (PKI) meet all three criteria, DEA proposed requirements that apply to obtaining and using digital certificates.

DEA proposed allowing regulated entities who are eligible to order Schedule I and II controlled substances to issue and process electronic orders if those orders are signed using a digital certificate issued by a Certification Authority run by DEA; the approach is called the Controlled Substance Ordering System or CSOS. Use of electronic orders is optional; registrants may continue to issue orders on Form 222.

DEA proposed minor organizational revisions to the existing requirements in Part 1305 to create subparts. Subpart A includes those requirements that apply to all orders. Subpart B covers the requirements for handling Form 222 orders. Other than minor editorial changes to make the regulations easier to read, the existing requirements for paper orders are unchanged. A new subpart C was proposed to cover the requirements for issuing and filling electronic orders. These requirements parallel those for Form 222 orders, but include some differences based on the different constraints on the two systems. For example, the regulation specifies the data elements required on an electronic order; because these elements are part of the Form 222, they are not specified for paper orders. Orders submitted on paper must be filled by a single registered location because the original order form must be maintained at the distribution location in support of the distribution; electronic orders may be divided and filled from separate registered locations owned by the same company, since the order can be retrieved directly in verifiable form at each distributing location.

In addition to its revision of Part 1305, DEA proposed a new Part 1311 that includes the requirements for obtaining, storing, using, and renewing digital certificates. Registrants and people granted power of attorney by registrants to sign orders will be eligible to obtain digital certificates. A registrant must appoint a CSOS coordinator who will serve as that registrant's recognized agent regarding issues pertaining to issuance of, revocation of, and changes to digital certificates issued under that registrant's DEA registration. These individuals serve as knowledgeable liaisons between one or more DEA registered locations and the CSOS Certification Authority (CA). The coordinators will collect applications, ensure that they include all of the required information, and send them to the CA. Part 1311 also specifies the requirements that the digital signature software will have to meet to ensure that it is capable of creating and validating digitally signed orders.

Procedures for Obtaining a Digital Certificate

Procedures for enrolling to obtain a digital certificate are available on the DEA Diversion Control Program Web site, *http://www.deadiversion.usdoj.gov,* and on the DEA E-Commerce Web site at *http://www.deaecom.gov.* Applicants can download the Diversion PKI CSOS Enrollment document and the CSOS Subscriber's Manual for guidance on enrollment procedures. DEA will begin accepting applications to obtain digital certificates May 31, 2005. Upon receiving a completed application DEA estimates that it will take the Certification Authority 10 business days to process the application. DEA's Certification Authority will maintain a support line to assist applicants and subscribers with issues pertaining to certificate enrollment, issuance, revocation, and renewal.

PKI and Digital Certificates

A public key infrastructure is comprised of a Certification Authority, which must verify the identity of applicants before issuing digital certificates, and public-private key pairs. PKI systems are based on asymmetric cryptography: the holder of the digital certificate has a private key, which only the certificate holder can access, and a public key, which is available to anyone. What one key encrypts, only the other key can decrypt. It is computationally infeasible for the two keys to be derived from each other. Only one public key will validate signatures made using its corresponding private key. Because the private key is held by only one person, it is that person's responsibility to ensure that it is not divulged or compromised.

The DEA Certification Authority (CA) will issue digital certificates, which will serve as an electronic equivalent of the Form 222. DEA must serve as the CA because a digital certificate is the functional equivalent of a Form 222 that the CSA requires DEA to issue. In the same manner as DEA pre-prints the registration information on the paper order forms that are issued to registrants, DEA will enter the registration information in extensions within the certificates that are issued to registrants and those granted power of attorney by registrants.

As DEA explained in the NPRM, the process of digitally signing an order is technically complicated (the software uses several complex algorithms to create an encrypted digest of the text), but the user needs only to activate the key and then enter one or two key strokes to sign an order or validate it. Existing electronic order systems will have to be PKI-enabled, which can be done with commercially available toolkits. DEA has been working with industry to develop systems and procedures that allow PKI-enabling existing systems to reduce the cost of implementation.

CSOS Certificates

All of the information currently preprinted on the Form 222 will be part of the extension data of the CSOS digital certificate, which will be included with each order that is digitally signed. Attaching the digital certificate, with the registration information in the extension data, to an electronic order signed with the digital signature is the functional equivalent to DEA pre-printing the registrant information on the paper forms, thus creating an electronic equivalent of the Form 222.

A CSOS certificate will be valid until the DEA registration under which it is issued expires or until the CSOS CA is notified that the certificate should be revoked. Certificates will be revoked if the certificate holder is no longer authorized to sign Schedule I and II orders for the registrant, if the information on which the certificate is based changes, or if access to the private key has been compromised or lost.

II. Discussion of Comments on the NPRM

DEA received 11 comments on its proposed rule. Commenters included the major trade associations representing pharmacies and distributors as well as individual companies and one vendor. This section summarizes the comments and provides DEA's response.

Listed schedules. Several commenters were concerned with proposed rule language that implied that the digital certificate would include extension data that indicated the schedules the certificate holder rather than the registrant was authorized to order. The commenters stated that it would be an additional burden on suppliers if they had to verify the eligibility of the signer, as well as the registrant, to order specific schedules.

DEA has revised the rule language to clarify that only the registrant's authorized schedules will be included in the extension data. If a registrant limits an individual's signing authority, it is incumbent on the registrant to ensure that the individual does not sign orders for schedules he/she is not authorized to order. The supplier is not required to verify information on schedules beyond confirming that the

registrant is authorized to order the schedules.

Attaching the digital certificate. One commenter expressed concern about the statements in the preamble that a digital certificate be attached to each order.

Because the digital certificate serves as the equivalent of the CSA-mandated form, the certificate, with its extension data, must be attached to each order. Including the certificate with each order ensures that, just as with the paper forms, an accurate copy of the DEA registration information for the customer is with the order. It should be noted that the requirement that the digital certificate be attached to the order applies to when the order is transmitted by the purchaser to the supplier. Once orders have been archived, each order does not have to have the specific digital certificate attached, as long as the certificate is associated with the order. Thus, an archive may have one copy of a specific certificate that is associated with a number of orders that have been archived, provided that retrieval of an order includes a copy of the certificate.

FIPS 140–1. Commenters noted that the proposed rule referenced FIPS 140–2, but did not mention FIPS 140–1, causing concern that systems validated and approved under 140–1 might not be allowed under the new standard. They were further concerned because the rule did not specify the security level required. Commenters stated that requiring a standard beyond security level 1 would cause difficulties for participants.

FIPS 140–2 grandfathers FIPS 140–1; any system validated and approved under FIPS 140–1 is considered to be approved and validated under FIPS 140–2. Therefore, the regulatory provision that implementations be certified under FIPS 140–2 incorporates, by reference, any implementations previously certified under FIPS 140–1. With respect to the security level required, DEA agrees with comments that Security Level 1 is appropriate and has included it in the final rule.

Commenters objected to the requirement that the private keys be stored on a FIPS-approved module. As DEA explained in the NPRM, government agencies must adopt FIPS requirements for any federal system, such as CSOS. DEA, therefore, must require that storage of keys be on FIPS-approved systems. While DEA encourages the use of smartcards, biometrics, or other secure hardware devices for private key storage within the CSOS architecture, use of such devices is voluntary. The regulations only require that the private key be stored on a FIPS-approved cryptographic module.

Power of Attorney. A number of commenters raised issues related to the power of attorney (POA) provisions. Several suggested that the existing requirement that the POA letter be signed by the person who signed the most recent registration application is impractical for companies that have national or regional distribution operations. Other commenters suggested that the application for a digital certificate, handled through the CSOS coordinator, could replace the POA letter and process.

The intent of this rulemaking is to establish an electronic means of satisfying the order form requirements—not to change the existing order form requirements. DEA did not propose to change the POA requirement or process, which was established to ensure that all activities by a registrant with respect to order forms be under the ultimate control of one responsible individual within the registrant. Any concerns regarding existing requirements with respect to POA will have to be considered in a separate action; they are beyond the scope of this CSOS rulemaking.

With respect to the suggestion that application for a digital certificate serve as a substitute for granting power of attorney, DEA wishes to note that the granting of power of attorney is an explicit legal act of assignment of authority from an authorized individual to another; accepting the application for a digital certificate as a substitution would make the assignment implicit, which would not be acceptable to DEA. Any assignment of the authority to obtain and execute order forms on behalf of a registrant must be an explicit legal act.

One commenter noted that the language in § 1305.12(d) that states that orders must be signed by a person authorized to sign an application for registration was wrong and should state that orders must be signed either by a person who is authorized to sign a registration application or a person granted POA to sign orders. DEA agrees and has changed the rule.

Tracking number. Several commenters stated that the format of the unique tracking number that a registrant assigns to an order was incorrect, that the last two digits of the year should come first. DEA agrees and has corrected the rule.

Order contents. Commenters suggested several changes to the requirements for order contents. DEA agrees that the complete address of the supplier could be provided by either the purchaser or the supplier and has changed the rule. Similarly, DEA agrees that the order could include either the National Drug Code (NDC) number or the drug name. DEA emphasizes that the system used to view the orders must provide the drug description if the NDC code is used in the order.

Linked records. Commenters objected to the use of the phrase ''electronically linked'' records because they think that links could be electronic or manual. In technical discussions with DEA, industry clarified that their concern was that DEA might interpret ''electronically linked'' to require active rather than passive links, where all order data are linked automatically. Passive links would allow the data to be stored in separate databases linked by one or more data elements common to all records.

DEA emphasizes that it is not requiring any specific type of link; DEA's only concern is that if it requests copies of orders (*e.g.*, for a particular customer or substance), the registrant must be able to produce the requested records (*i.e.*, both the electronic orders and the linked distribution records) upon request in a format that an agent can read and understand. DEA has revised the rule to clarify that ''readable format'' means that a person, not a computer, can easily read the documents.

Corrections. Several commenters identified changes needed to correct regulatory language. In § 1305.22(c)(1), DEA proposed that suppliers should verify the signature and order by ''having'' software that complies with Part 1311. The commenter recommended ''using'' instead of ''having.'' DEA agrees and has made the change.

Commenters stated that the proposed language in § 1305.25(b) and (c) that requires the supplier to provide a reason for not filling the order was inconsistent with the existing rule. DEA agrees and has changed the language to clarify that a supplier must notify a purchaser that an order will not be filled, however, the supplier does not need to provide a reason for refusing to fill an order.

Commenters asked DEA to make the definition of digital certificate specific to CSOS. DEA disagrees. The definition is intended to be general and will cover more than CSOS certificates. In the regulatory text, however, DEA has added ''CSOS'' before digital certificate wherever the certificate is limited to the CSOS certificate.

One commenter asked whether ''a registrant's recognized agent'' was different from a CSOS coordinator. The two are the same; DEA has revised the

rule to replace registrant's recognized agent with CSOS coordinator.

Central Ordering. A commenter asked whether the § 1305.22(f) requirement to ship to the registered location of the purchaser allowed for shipment to a different registered location if the order was issued by a central ordering facility. A number of firms issue orders for all their registered locations from a central location which may not, itself, be registered. Each order, however, can be for only one specific registered location and the supplier must ship to that location. If the registered location identified within the order deviates from that identified within the digital certificate, the supplier cannot fill the order; a new order must be requested from the purchaser.

Commenters also recommended that for central processing of orders that DEA allow either the central location or the location filling part of the order to create the record. DEA agrees that either location may create the record and has revised the rule. DEA's concern is not with the creation of the record, but with its maintenance. The registrant that distributes a controlled substance must maintain a full record of the order and make it available for DEA on request.

One commenter raised the issue of linking a single certificate to multiple locations. As DEA explained in the NPRM, DEA understands the concern and has taken steps to reduce the burden for individuals who hold keys for many locations, but to serve as an equivalent of a Form 222, each digital certificate must be specific to a single registered location.

Endorsed, lost, and canceled orders. Commenters questioned whether the proposed rule for endorsing electronic orders could be implemented, noting that the requirements were confusing and cumbersome. DEA has reviewed this issue and agrees with the commenters that endorsing electronic orders in a manner that provides adequate safeguards may be technically too complicated. Consequently, DEA has decided to not allow endorsement of electronic orders. Because orders are rarely endorsed and the almost instantaneous communication of electronic orders and confirmations mean that a purchaser will learn that the supplier cannot fill all or part of an order shortly after the order is submitted, DEA does not expect this to pose any significant problem for registrants. The purchaser can quickly issue a new electronic order to another supplier for any items the first supplier cannot fill. Finally, if the order is originally submitted to a firm that processes orders centrally, the central processing supplier can fill the order from multiple locations without endorsement.

Commenters also stated that the meaning of § 1305.26 on lost orders was confusing and requested that only the purchaser maintain records of lost orders. DEA agrees and has revised the rule to specify that a supplier need maintain only those orders that the supplier fills.

Commenters stated that suppliers should not be required to maintain records of orders that are canceled. DEA agrees. Suppliers are only required to maintain records of orders that they fill. Suppliers need not return the electronic order to the purchaser, however, the supplier must notify the purchaser of the cancellation of the order. Commenters also said that purchasers should be able to use any method to notify the supplier that an order was canceled. DEA disagrees. Notification of an order cancellation must be written so that the purchaser can maintain a verifiable record. Written notification includes paper, facsimile, or electronically transmitted notifications such as e-mail; notification by telephone is not allowed.

Validity of a signature. Commenters asked whether it was feasible to determine whether a signature was valid at the time of signing. Commenters were particularly concerned that, if there was a delay in processing an order, they should be able to reject an order if the signature was no longer valid at the time of shipping.

The purpose of the requirement for consistent time systems is to allow suppliers to determine whether a signature was valid at the time of signing. If a digital signature was valid on Friday when the order was signed, but expired on Monday, DEA considers that the order is valid. Unless DEA or the purchaser has notified a supplier that orders issued by a specific person should not be filled, an order signed with a digital certificate that was valid at the time of signing is a valid order. A registrant may choose not to fill the order for any reason; if registrants want to require that the signature still be valid at the time of filling, they may do so. Suppliers have the option of imposing more stringent standards. As a secondary note, DEA wishes to stress that once a supplier has validated a signature on an order, it is not necessary to re-validate the signature prior to actually shipping the order to the purchaser.

Time period for reporting key compromise or loss of privilege. Commenters objected to the requirement that they report loss, theft, or compromise of the key within 24 hours of such loss, theft, or compromise, and that they report a certificate holder's loss of signing privilege within six hours. They also stated that they wanted to be able to report loss of signing privilege in advance (*e.g.*, when they learn an employee will be leaving the firm on a certain date). They stated that the 24-hour and 6-hour time frames were unrealistic and could result in notifications filed outside of business hours.

Registrants may notify the CA in advance of revocations. DEA agrees that the 24-hour period should be within 24 hours of substantiation of key compromise, etc., and has changed the rule. On the 6-hour notification, DEA disagrees with the commenters. DEA believes it is important that the CA be notified as soon as someone's signing privileges are revoked. The digital certificate is the equivalent of a Form 222—a former employee still in possession of their digital certificate and keys would have all they needed to generate orders that would be otherwise indistinguishable from legitimate orders. In the paper world, this concern does not exist since a former employee would no longer have access to the order forms and, thus, could not engage in any mischief. DEA notes that the CA will be staffed 24/7 so there is no need to wait until the next business day. An e-mail to the CA that is digitally signed by the coordinator or registrant will be sufficient notification.

Certification Authority. Commenters raised concerns about the DEA CA being run by a contractor and asked about the safety of information. DEA emphasizes that although a contractor may be used to carry out the day-to-day operations of the CA, the contractor will operate under direct DEA supervision and control. All Federal contractors are subject to the same legal requirements as government employees in regard to protection of information. DEA may use information submitted in its investigations, but the information would not be released for other purposes.

Reports to DEA. Commenters objected to the requirement that suppliers file reports on orders with DEA every other business day. They stated that this frequency of filing would not provide them with an opportunity to review and correct minor discrepancies. With paper orders, DEA knows which registrants have executed Form 222, which provides a control on the system. DEA needs frequent reports on electronic orders because it has no other means of determining who is ordering and in what volume. DEA recognizes that some

of the data may be imprecise due to changes in orders, but DEA needs frequent submissions of reports to account for all orders generated by a given purchasing registrant and as a means to identify and account for all outstanding orders for a given registrant.

Commenters also recommended changes to the information provided in the daily reports to make the data elements consistent with ARCOS data elements and to add four elements on the substances ordered. DEA agrees with the commenters. DEA will specify a format for the report that is consistent with the ARCOS reports plus the data fields on what was ordered. DEA notes that ARCOS is preparing to allow electronic filing of reports; when this occurs, DEA plans to develop a process by which the summary reports can be accepted as a substitute for ARCOS reporting for Schedule I and II substances, with the usual ARCOS provisions for filing corrections.

Adoption of new technologies. Commenters stated that it was unclear how DEA would evaluate new technologies and recommended that DEA develop a rapid means for evaluating and approving new technologies. DEA understands the commenters' concern, but approval of any new technology would be subject to the Administrative Procedure Act requirements for public notice and comment prior to adoption. Beyond the statutory mandates, DEA thinks it is vital that the regulated community have an opportunity to consider and discuss new methods to ensure that any new rules can be accommodated by existing systems. Although the development of this rule took several years, DEA believes that the time was well spent because discussions that DEA and industry held made it possible for all parties to identify potential problems and find solutions prior to publishing a regulation. DEA does not anticipate that review and recognition of suitable alternative technologies should take that long.

Audits. Comments expressed concern about the scope of the third-party audits and DEA audits. They specifically stated that the reports to DEA should not be included in the third-party audits.

DEA agrees with the commenters that the reports to DEA would not be part of third-party audits. The independent third-party audit is intended to ensure that the digital signature system functions properly for both the supplier and purchaser.

Reverse Distributors. Several commenters asked how the electronic order system will work for reverse distributors. DEA recognizes that the ordering system has different characteristics in reverse distribution and intends to address issues related to those distributions in a separate rulemaking.

Other Issues. Commenters objected to the mention of biometrics and smart cards. DEA notes that certificate holders may want to consider using biometric passwords or smart cards, but DEA is not requiring them to do so. Keys may be stored on any secure system provided that the storage module is approved under FIPS 140–2.

Commenters questioned the use of ''system.'' DEA agrees with commenters that systems for creating and processing digitally signed orders may be one or more software systems. As noted above, DEA's concern is the integrity and availability of the records of orders, not the technologies and software used to create and store the information.

Commenters asked that DEA include a definition or description of the subscriber agreement. DEA does not believe that it is necessary to define the subscriber agreement. The DEA CA will provide the agreement, appropriately titled, to each certificate holder.

Commenters objected to the statement in the NPRM that the practical implementation of PKI systems is simple. DEA understands and explained in the NPRM that the technologies involved in PKI systems are complex, but from the user's standpoint, digital signatures are simple because so much of the work is actually done by machine. After authenticating themselves to the system and activating the key, the signer generally digitally ''signs'' the document with a single key stroke.

One commenter raised issues related to digital certificates for pharmacists for use in the electronic prescription system. This issue is beyond the scope of this notice; DEA will address the issue when it proposes its rule for electronic prescriptions.

A commenter noted that the five-year transition period used in the economic analysis may be optimistic. DEA recognizes that the electronic orders may phase in at a different rate; some registrants may continue to use Forms 222 indefinitely, as the rule allows. The five-year period was simply used to estimate costs to avoid understating those costs.

One commenter supported the proposed rule, but expressed the hope that pharmacies would not bear the cost of implementation. DEA notes that use of electronic orders is voluntary. DEA believes that the system will provide cost savings to both purchasers and suppliers, but no registrant is required to adopt electronic orders.

One vendor recommended that DEA adopt an approach more consistent with the vendor's technology. DEA is not dictating a particular technology or PKI implementation. Any approved system that meets the criteria for authentication, non-repudiation, and record integrity may be used.

Special Note Regarding Certificate Extension Data

Finally, following publication of the proposed rule, DEA modified the specification for the certificate extensions. Certain registrants had expressed concerns regarding using the certificates for other health care purposes because their DEA registration number appeared in plain text in the certificate, thus making it easily accessible to the recipient. To address this concern, DEA has modified the certificate profile to allow that, in lieu of listing the plain text DEA number, the DEA number extension will contain a hash value generated from the DEA number and the specific certificate subject distinguished name serial number using the SHA–1 hashing algorithm. Because the DEA number will no longer be available in plain text in the certificate, DEA is modifying the order format requirement in Section 1305.21 to require that the purchaser include their DEA registration number in the body of the order. Further, Section 1311.55 is being amended to require that a supplier must verify that the DEA number listed in the body of the order is the same as the DEA number associated with the certificate. The verification is necessary to avoid circumstances where a person who has been granted POA for multiple registered locations does not inadvertently sign an order with the wrong certificate/private key.

III. Discussion of the Final Rule

Except for the changes discussed above, DEA is adopting the rule as proposed. Part 1305 has been reorganized to place requirements that apply to all Schedule I and II orders in subpart A; these include old §§ 1305.01, 1305.02, 1305.03, 1305.04, which retain their numbers, old § 1305.07 (power of attorney), which is redesignated as § 1305.05, old § 1305.08 (persons entitled to fill orders), which is redesignated as § 1305.06, and old § 1305.16 (special procedures for filling certain orders), which is redesignated as § 1305.07. The remainder of old Part 1305 is subpart B, which covers the requirements for obtaining, executing, and filling orders on Form 222. Subpart B includes old §§ 1305.05 and 1305.06 (procedures for obtaining and executing

Forms 222), which are redesignated as §§ 1305.11 and 1305.12, and old §§ 1305.09–1305.15, which are redesignated as §§ 1305.13–1305.19. These sections include specific references to orders on Form 222.

Subpart C covers the requirements for electronic orders.

Section 1305.21 specifies that an electronic order must be signed with a CSOS digital certificate and that the order may include substances other than Schedule I and II controlled substances. The section specifies the data fields that must be included in electronic orders.

Section 1305.22 specifies procedures for filling electronic orders.

Section 1305.23 covers endorsing electronic orders. As discussed above, endorsement of electronic orders will not be allowed.

Section 1305.24 covers central processing of orders. These requirements are also different for electronic orders because with electronic orders, the supplier may have multiple registered locations fill parts of an order provided that the supplying company owns and operates all of the locations filling an order.

Sections 1305.25 and 1305.26 specify the requirements for handling unaccepted and defective electronic orders and lost orders.

Section 1305.27 covers preservation of electronic orders.

Section 1305.28 covers canceling and voiding electronic orders.

Section 1305.29 specifies the requirements for reporting electronic orders to DEA. Suppliers may submit either a copy of the order and its linked records or a report in a format DEA specifies. DEA intends that the report will be identical to the ARCOS report in format with four additional data elements: the NDC number, quantity, unit, and strength ordered.

New Part 1311 covers the requirements for digital certificates. Subpart A includes the scope, definitions, standards for electronic orders, and incorporations by reference. Subpart B covers the requirements for obtaining and using CSOS digital certificates.

Section 1311.10 specifies who is eligible to obtain a CSOS certificate; § 1311.15 covers the limitation of certificates to the schedules authorized for the DEA registration under which the certificate is issued. The revised section states that the registrant is responsible for ensuring that any person whose signing authority the registrant limits abides by those limits.

Section 1311.20 specifies the requirements for CSOS coordinators.

Section 1311.25 specifies the requirements for obtaining a CSOS certificate.

Section 1311.30 provides the requirements for using and storing a digital certificate.

Section 1311.35 specifies the number of certificates needed.

Section 1311.40 specifies when a new certificate must be obtained.

Section 1311.45 specifies requirements for registrants that grant power of attorney authority.

Section 1311.50 specifies requirements for recipients handling electronic orders prior to filling them.

Section 1311.55 specifies software requirements for handling electronic orders.

Section 1311.60 specifies recordkeeping requirements.

PART 1305.—DISTRIBUTION TABLE

Old section	New section
1305.01—Scope of part 1305	1305.01—Scope of part 1305.
1305.02—Definitions	1305.02—Definitions.
1305.03—Distributions requiring order forms	1305.03—Distributions requiring order forms.
1305.04—Persons entitled to obtain and execute order forms	1305.04—Persons entitled to obtain and execute order forms.
1305.05—Procedure for obtaining order forms	1305.11—Procedure for obtaining DEA Forms 222.
1305.06—Procedure for executing order forms	1305.12—Procedure for executing DEA Forms 222.
1305.07—Power of attorney	1305.05—Power of attorney.
1305.08—Persons entitled to fill order forms	1305.06—Persons entitled to fill DEA Forms 222.
1305.09—Procedure for filling order forms	1305.13—Procedure for filling DEA Forms 222.
1305.10—Procedure for endorsing order forms	1305.14—Procedure for endorsing DEA Forms 222.
1305.11—Unaccepted and defective order forms	1305.15—Unaccepted and defective DEA Forms 222.
1305.12—Lost and stolen order forms	1305.16—Lost and stolen DEA Forms 222.
1305.13—Preservation of order forms	1305.17—Preservation of DEA Forms 222.
1305.14—Return of unused order forms	1305.18—Return of unused DEA Forms 222.
1305.15—Cancellation and voiding of order forms	1305.19—Cancellation and voiding of DEA Forms 222.
1305.16—Special procedure for filling certain order forms	1305.07—Special procedure for filling certain DEA Forms 222.

Incorporation by Reference

The following standards are incorporated by reference:

- FIPS 140–2, Security Requirements for Cryptographic Modules.
- FIPS 180–2, Secure Hash Standard.
- FIPS 186–2, Digital Signature Standard.

These standards are available from the National Institute of Standards and Technology, Computer Security Division, Information Technology Laboratory, National Institute of Standards and Technology, 100 Bureau Drive, Gaithersburg, MD 20899–8930 and are available at *http://csrc.nist.gov/.*

V. Required Analyses

Executive Order 12866

This regulation has been drafted and reviewed in accordance with Executive Order 12866, ''Regulatory Planning and Review'', Section 1(b), Principles of Regulation. It has been determined that this is a ''significant regulatory action'' under Executive Order 12866, Section 3(f), Regulatory Planning and Review, and accordingly this rule has been reviewed by the Office of Management and Budget.

DEA has conducted a cost-benefit analysis of the rule, which the Office of Management and Budget has reviewed. The Economic Impact Analysis for the proposed rule was posted on the Diversion Control Program Web site. That analysis has been updated to account for the number of orders expected in 2004 (6,561,000), the first year of implementation, and to adjust registrant estimates based on data from DEA's ARCOS reporting system. DEA estimates that about 98,000 registrants order Schedule I and II controlled substances and will apply for about 145,000 digital certificates. Over ten years, DEA estimates that electronic orders will reduce the annualized cost of Schedule I and II orders by $284 million; the annualized costs of digital

certificates are estimated to be $20 million. The annualized net benefit of the rule, therefore, is $264 million.

As discussed in the NPRM, DEA developed estimates of the time required for each step in the process of issuing and processing an order and used weighted wage rates based on the number of orders registrant groups are estimated to issue. DEA estimates that issuing and processing a Form 222 order costs purchasers about $26 and suppliers about $13. In contrast, issuing and processing a digitally signed order will cost about $2.60 for purchasers and $3.00 for suppliers. (These costs do not include the cost of obtaining a digital certificate or installing software, most of which are one-time costs.) The costs for a single registrant vary depending on the number of orders issued and filled. DEA estimates that annual costs for Form 222 orders range from $26 for a registrant who issues a single order to more than $184,000 for distributors who both issue and fill orders. The annual costs for electronic orders range from $2.60 to about $40,000. The initial registrant costs of obtaining a digital certificate range from $156 to about $600, varying with the number of applicants a registrant has.

Table 1 presents the total annual hours and costs for the Form 222 system for 2004 orders. Tables 2–4 present the total annual hours and costs for obtaining digital certificates, issuing electronic orders, and developing and installing software, if these activities occurred in a single year.

TABLE 1.—TOTAL ANNUAL HOURS AND COSTS FOR THE FORM 222 SYSTEM

[2004 orders]

	Hours	Labor	Capital	O&M	Total
Purchaser:					
Complete and send order	1,640,250	$139,323,000	.....	$7,355,000	$146,677,000
Requisition order	3,124	265,000	.....	23,000	288,000
Annotate order	328,050	27,865,000	.....	.....	27,865,000
File orders	109,350	3,087,000	$129,700	2,668,000	4,472,000
Supplier:					
Enter order	1,640,250	58,770,000	.....	.....	58,770,000
Annotate order	328,050	21,212,000	.....	.....	21,212,000
Compile and send to DEA	90,936	3,258,000	.....	174,000	3,433,000
File orders	109,350	3,918,000	129,700	2,668,000	5,303,000
Total	4,249,360	257,698,000	259,000	12,887,000	270,844,000

TABLE 2.—TOTAL HOURS AND COSTS FOR DIGITAL CERTIFICATES

	Hours	Labor	O&M	Total
Purchaser:				
Complete application	58,950	$5,007,000	.....	$5,007,000
Complete application—coordinator	78,755	6,689,000	$638,000	7,328,000
Generate keys	12,116	1,029,000	.....	1,029,000
Learn to use signature	20,778	1,765,000	.....	1,765,000
Renewal—one year	1,234	105,000	.....	105,000
Renewal—3 year-annual	3,627	308,000	.....	308,000
Supplier:				
Complete application	3,311	214,000	.....	214,000
Complete application—coordinator	345	22,000	2,790	25,000
Generate keys	406	26,000	.....	26,000
Learn to use signature	2,032	131,000	.....	131,000
Renewal	406	26,000	.....	26,000
Total	181,960	15,324,000	641,000	15,965,000

TABLE 3.—TOTAL HOURS AND COSTS FOR ELECTRONIC ORDERS

	Hours	Activities	Total cost
Purchaser:			
Sign orders	36,450	6,561,000	$3,096,000
Edit and archive	164,025	6,561,000	13,932,000
Supplier:			
Validate orders	27,338	6,561,000	1,768,000
Collect and send to DEA	5,473	109,460	354,000
Edit and archive	273,375	6,561,000	17,676,000
Total	506,661	.....	36,826,000

TABLE 4.—TOTAL HOURS AND COSTS FOR THE ELECTRONIC ORDER SOFTWARE

	Hours	Labor	O&M	Total
Purchaser:				
Install—chains	8,680	$666,000		$666,000
Install software—other	314,408	13,010,000		13,010,000
Install—practitioner	43,940	1,818,000		1,818,000
Supplier:				
Install software	280	11,600		11,600
Software Developer:				
Development	103,600	9,700,000		9,700,000
Maintenance	89,000	3,683,000		3,683,000
Upgrades	17,800	1,367,000		1,367,000
Audit	2,314	96,000	$593,000	689,000
Total	580,022	30,352,000	593,000	30,945,000

To estimate costs over the first ten years, DEA assumed that implementation would be phased in over the first five years (*i.e.*, it would be five years before all registrants were using the electronic order system). Based on discussions with industry, the phase-in was estimated to occur at 20 percent in the first year, 40 percent in the second, 20 percent in the third, and 10 percent each in the fourth and fifth years. DEA made the conservative estimate that orders would phase in at the same rate as digital certificates. Because a few distributors and large chain drug stores supply and order a large proportion of the drugs, it is likely that orders will phase in more quickly than digital certificates will. A faster phase-in will increase the net benefits; a slower rate would lower the benefits.

DEA also assumed that the number of orders would increase seven percent annually. The seven percent increase is based on the average annual increase in orders over the last seven years. The total cost of both systems was estimated using a seven percent and a three percent discount rate. Table 5 presents the ten-year total cost of orders under the Form 222 system, the electronic system, and the combined systems as the electronic system is phased in over the first five years as well as the annualized cost of the three systems over ten years. Table 6 presents the costs of digital certificates and software needed to create digitally signed orders.

TABLE 5.—TOTAL COST OF ORDERS OVER TEN YEARS

[Present value]

	Paper system	Electronic system	Combined phase-in
Total (7%)	$2,699,913,000	$298,086,000	$704,112,000
Annualized (7%)	384,407,000	42,441,000	100,250,000
Total (3%)	3,223,440,000	363,653,000	781,438,000
Annualized (3%)	377,886,000	42,631,000	91,608,000

TABLE 6.—TOTAL COSTS OF DIGITAL CERTIFICATES AND SOFTWARE OVER 10 YEARS

[Present value]

	New costs
Total (7%)	$149,308,000
Annualized (7%)	21,258,000
Total (3%)	172,093,000
Annualized (3%)	20,275,000

In addition to the cost savings, electronic orders will also provide a number of other benefits that cannot be quantified. Purchasers will be able to create and send single unified controlled substance orders to their suppliers. With Forms 222, purchasers must create the separate Form 222 for the Schedule I and II controlled substances and complete other orders for all other controlled substance purchases from a particular supplier. If a purchaser needs more than 10 Schedule I or II substances, multiple Forms 222 must be completed because the form is limited to ten items. With the electronic orders, they will be able to submit a single order covering all controlled substance and other prescription drugs being purchased from the supplier. The combined orders should reduce the orders that need to be logged, tracked, and handled by both purchasers and suppliers.

Electronic orders should also bring faster receipt of controlled substances. Under the present system, the purchaser has the choice of sending the order by overnight service at considerable cost, mailing it and waiting several days, or sending the order back with the delivery truck, which may not be returning directly to the distributor. In most cases, the purchaser is likely to have to wait at least two days and possibly four or five days when the order is mailed or is shipped back by truck. If the distributor that receives the order cannot fill it, the distributor may endorse it to another distributor and ship it on to another distribution point, further delaying the final shipment. Electronic orders will be received almost instantly and can be shipped the same day. This speed may allow purchasers to order only when they need an item and limit the quantity of controlled substances that they stock. Limiting the quantity of Schedule I and II controlled substances in stock reduces the possibility of diversion and the cost of security.

With the Form 222, if a supplier cannot fill all of an order, the supplier may endorse the entire order over to another supplier. The order cannot be divided and filled in part by one supplier and in part by a second, even if both suppliers belong to the same company. Because each location holds a separate registration, a distributor with multiple locations must maintain stocks of all Schedule I and II controlled substances at each location to be able to fill orders for these substances from that location. Some distributors have created centralized systems where all orders are

processed through the central distribution office, which then transmits parts of the orders to the warehouses that hold specific items. The Form 222 system cannot take advantage of this arrangement because the paper must accompany the order. With electronic orders, DEA will allow a distributor with a central distribution system to divide an order and ship parts of the order from different distribution points. New orders will not need to be generated because the central computer system can track each item in the order and ensure that it is shipped to the appropriate registrant only once. DEA and the supplier will have the records necessary to maintain the closed system of control while allowing the supplier to take advantage of its own system of distribution.

A copy of the Economic Impact Analysis of the Electronic Orders Rule is available on the Diversion Control Program's Web site.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601–612) requires Federal agencies to determine whether regulations have a significant economic impact on a substantial number of small entities or have a disproportionate effect on small entities. DEA, as part of its economic analysis, considered the costs of the existing system and the electronic system on small entities. The annualized costs of the Form 222 system for the smallest entities (Narcotic Treatment Programs with less than $100,000 in revenues), are 1.66 percent of annual revenues; for these registrants, the annual costs of the electronic orders are about 0.24 percent of annual revenues. For most small entities affected by the rule, the cost of the electronic system will be less than 0.1 percent of revenues or sales. Consequently, the Deputy Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation, and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities.

A copy of the small business analysis for this proposed rule, which is section 7 of the economic analysis, can be obtained from the Diversion Control Program web site or by contacting the Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307–7297.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule has been determined to be a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will result in an annual effect on the economy of $100,000,000 or more, but will not impose a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets. In fact, this rule will result in a significant reduction in the cost of ordering Schedule I and II controlled substances.

Paperwork Reduction Act

The Department of Justice (DOJ), Drug Enforcement Administration (DEA) submitted the following information collection requests to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. Under the Paperwork Reduction Act, DEA is required to estimate the burden hours and other costs of any requirement for recordkeeping and reporting over a three-year period. Therefore, DEA proposed the revision of an existing collection of information *U.S. Official Order Forms for Schedules I and II Controlled Substances (Accountable Forms), Order Form Requisition, (OMB Control # 1117–0010)*, and the creation of a new collection of information *Reporting and Recordkeeping for Digital Certificates* under the Paperwork Reduction Act of 1995. This process is conducted in accordance with 5 CFR 1320.11. The Information Collection Request was submitted to the Office of Management and Budget for review under section 307 of the Paperwork Reduction Act.

Overview of U.S. Official Order Forms for Schedules I and II Controlled Substances (Accountable Forms), Order Form Requisition Information Collection

(1) Type of information collection: Revision of existing collection.

(2) The title of the form/collection: U.S. Official Order Forms for Schedule I and II Controlled Substances (Accountable Forms), Order Form Requisition.

(3) The agency form number, if any, and the applicable component of the Department sponsoring the collection:

Form No.: DEA Form 222, U.S. Official Order Forms for Schedule I and II Controlled Substances (Accountable Forms)

DEA Form 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 are 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; both the supplier and purchaser must retain records for two years.

(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 rule will affect 98,000 registrants. The average time for requisitioning Form 222 is 0.05 hours. The average time for completing, annotating and filing paper orders for purchasers is 0.317 hours. It is estimated that suppliers spend, on average, 0.317 hours annotating, entering and filing the DEA Forms 222. 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 reports to DEA.

(6) An estimate of the total public burden (in hours) associated with the collection: As registrants adopt the electronic ordering, the annual burden hours would average 2.5 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, with a 7 percent 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.:

DEA Form 251: CSOS DEA Registrant Certificate Application.

DEA Form 252: CSOS Principal Coordinator/Alternate Coordinator Certificate Application.

DEA Form 253: CSOS Power of Attorney Certificate Application.

DEA Form 254: CSOS Certificate Application Registrant List Addendum.

CSOS Certificate Revocation.

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 and/or replaced when information on which the certificate is based changes.

(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 rule will affect 98,000 registrants and 145,000 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 electronic ordering, the annual burden hours would average 48,500 hours a year. During this period, DEA assumes that 80 percent of the certificate holders will apply for certificates.

If additional information is required regarding these collections of information, contact: Brenda E. Dyer, 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 $114,540,000 (inflation-adjusted to 2003) 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 Part 1305

Drug traffic control, Reporting requirements.

21 CFR Part 1311

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

■ For the reasons set out above, 21 CFR Part 1305 is revised, and Part 1311 is 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

Sec.

Subpart B—DEA Form 222

Subpart C—Electronic Orders

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

Subpart A—General Requirements

§ 1305.01 Scope of part 1305.

Procedures governing the issuance, use, and preservation of orders for Schedule I and II controlled substances are set forth generally by section 308 of the Act (21 U.S.C. 828) and specifically by the sections of this part.

§ 1305.02 Definitions.

Any term contained in this part shall have the definition set forth in the Act or part 1300 of this chapter.

§ 1305.03 Distributions requiring a Form 222 or a digitally signed electronic order.

Either a DEA Form 222 or its electronic equivalent as set forth in subpart C of this part and Part 1311 of this chapter is required for each distribution of a Schedule I or II controlled substance except for the following:

(a) Distributions to persons exempted from registration under Part 1301 of this chapter.

(b) Exports from the United States that conform with the requirements of the Act.

(c) Deliveries to a registered analytical laboratory or its agent approved by DEA.

(d) Delivery from a central fill pharmacy, as defined in § 1300.01(b)(44) of this chapter, to a retail pharmacy.

§ 1305.04 Persons entitled to order Schedule I and II controlled substances.

(a) Only persons who are registered with DEA under section 303 of the Act (21 U.S.C. 823) to handle Schedule I or II controlled substances, and persons who are registered with DEA under section 1008 of the Act (21 U.S.C. 958) to export these substances may obtain and use DEA Form 222 (order forms) or

issue electronic orders for these substances. Persons not registered to handle Schedule I or II controlled substances and persons registered only to import controlled substances are not entitled to obtain Form 222 or issue electronic orders for these substances.

(b) An order for Schedule I or II controlled substances may be executed only on behalf of the registrant named on the order and only if his or her registration for the substances being purchased has not expired or been revoked or suspended.

§ 1305.05 Power of attorney.

(a) A registrant may authorize one or more individuals, whether or not located at his or her registered location, to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual, if the power of attorney is retained in the files, with executed Forms 222 where applicable, for the same period as any order bearing the signature of the attorney. The power of attorney must be available for inspection together with other order records.

(b) A registrant may revoke any power of attorney at any time by executing a notice of revocation.

(c) The power of attorney and notice of revocation must be similar to the following format:

Power of Attorney for DEA Forms 222 and Electronic Orders

_____
(Name of registrant)

_____
(Address of registrant)

_____
(DEA registration number)

I, _____ (name of person granting power), the undersigned, who am authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act or Controlled Substances Import and Export Act, have made, constituted, and appointed, and by these presents, do make, constitute, and appoint _____ (name of attorney-in-fact), my true and lawful attorney for me in my name, place, and stead, to execute applications for Forms 222 and to sign orders for Schedule I and II controlled substances, whether these orders be on Form 222 or electronic, in accordance with 21 U.S.C. 828 and Part 1305 of Title 21 of the Code of Federal Regulations. I hereby ratify and confirm all that said attorney must lawfully do or cause to be done by virtue hereof.

_____
(Signature of person granting power)

I, _____ (name of attorney-in-fact), hereby affirm that I am the person named herein as attorney-in-fact and that the signature affixed hereto is my signature.

(signature of attorney-in-fact)

Witnesses:

1. _____
2. _____

Signed and dated on the _____ day of _____, (year), at _____ .

Notice of Revocation

The foregoing power of attorney is hereby revoked by the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act or the Controlled Substances Import and Export Act. Written notice of this revocation has been given to the attorney-in-fact _____ this same day.

_____
(Signature of person revoking power)

Witnesses:

1. _____
2. _____

Signed and dated on the _____ day of _____, (year), at _____.

(d) A power of attorney must be executed by the person who signed the most recent application for DEA registration or reregistration; the person to whom the power of attorney is being granted; and two witnesses.

(e) A power of attorney must be revoked by the person who signed the most recent application for DEA registration or reregistration, and two witnesses.

§ 1305.06 Persons entitled to fill orders for Schedule I and II controlled substances.

An order for Schedule I and II controlled substances, whether on a DEA Form 222 or an electronic order, may be filled only by a person registered with DEA as a manufacturer or distributor of controlled substances listed in Schedule I or II pursuant to section 303 of the Act (21 U.S.C. 823) or as an importer of such substances pursuant to section 1008 of the Act (21 U.S.C. 958), except for the following:

(a) A person registered with DEA to dispense the substances, or to export the substances, if he/she is discontinuing business or if his/her registration is expiring without reregistration, may dispose of any Schedule I or II controlled substances in his/her possession with a DEA Form 222 or an electronic order in accordance with § 1301.52 of this chapter.

(b) A purchaser who has obtained any Schedule I or II controlled substance by either a DEA Form 222 or an electronic order may return the substance to the supplier of the substance with either a DEA Form 222 or an electronic order from the supplier.

(c) A person registered to dispense Schedule II substances may distribute the substances to another dispenser with either a DEA Form 222 or an electronic order only in the circumstances described in § 1307.11 of this chapter.

(d) A person registered or authorized to conduct chemical analysis or research with controlled substances may distribute a Schedule I or II controlled substance to another person registered or authorized to conduct chemical analysis, instructional activities, or research with the substances with either a DEA Form 222 or an electronic order, if the distribution is for the purpose of furthering the chemical analysis, instructional activities, or research.

(e) A person registered as a compounder of narcotic substances for use at off-site locations in conjunction with a narcotic treatment program at the compounding location, who is authorized to handle Schedule II narcotics, is authorized to fill either a DEA Form 222 or an electronic order for distribution of narcotic drugs to off-site narcotic treatment programs only.

§ 1305.07 Special procedure for filling certain orders.

A supplier of carfentanil, etorphine hydrochloride, or diprenorphine, if he or she determines that the purchaser is a veterinarian engaged in zoo and exotic animal practice, wildlife management programs, or research, and is authorized by the Administrator to handle these substances, may fill the order in accordance with the procedures set forth in § 1305.17 except that:

(a) A DEA Form 222 or an electronic order for carfentanil, etorphine hydrochloride, and diprenorphine must contain only these substances in reasonable quantities.

(b) The substances must be shipped, under secure conditions using substantial packaging material with no markings on the outside that would indicate the content, only to the purchaser's registered location.

Subpart B—DEA Form 222

§ 1305.11 Procedure for obtaining DEA Forms 222.

(a) DEA Forms 222 are issued in mailing envelopes containing either seven or fourteen forms, each form containing an original, duplicate, and triplicate copy (respectively, Copy 1, Copy 2, and Copy 3). A limit, which is

based on the business activity of the registrant, will be imposed on the number of DEA Forms 222, which will be furnished on any requisition unless additional forms are specifically requested and a reasonable need for such additional forms is shown.

(b) Any person applying for a registration that would entitle him or her to obtain a DEA Form 222 may requisition the forms by so indicating on the application form; a DEA Form 222 will be supplied upon the registration of the applicant. Any person holding a registration entitling him or her to obtain a DEA Form 222 may requisition the forms for the first time by contacting any Division Office or the Registration Section of the Administration. Any person already holding a DEA Form 222 may requisition additional forms on DEA Form 222a, which is mailed to a registrant approximately 30 days after each shipment of DEA Forms 222 to that registrant, or by contacting any Division Office or the Registration Section of the Administration. All requisition forms (DEA Form 222a) must be submitted to the DEA Registration Section.

(c) Each requisition must show the name, address, and registration number of the registrant and the number of books of DEA Forms 222 desired. Each requisition must be signed and dated by the same person who signed the most recent application for registration or for reregistration, or by any person authorized to obtain and execute DEA Forms 222 by a power of attorney under § 1305.05.

(d) DEA Forms 222 will be serially numbered and issued with the name, address, and registration number of the registrant, the authorized activity, and schedules of the registrant. This information cannot be altered or changed by the registrant; any errors must be corrected by the Registration Section of the Administration by returning the forms with notification of the error.

§ 1305.12 Procedure for executing DEA Forms 222.

(a) A purchaser must prepare and execute a DEA Form 222 simultaneously in triplicate by means of interleaved carbon sheets that are part of the DEA Form 222. DEA Form 222 must be prepared by use of a typewriter, pen, or indelible pencil.

(b) Only one item may be entered on each numbered line. An item must consist of one or more commercial or bulk containers of the same finished or bulk form and quantity of the same substance. The number of lines completed must be noted on that form at the bottom of the form, in the space provided. DEA Forms 222 for carfentanil, etorphine hydrochloride, and diprenorphine must contain only these substances.

(c) The name and address of the supplier from whom the controlled substances are being ordered must be entered on the form. Only one supplier may be listed on any form.

(d) Each DEA Form 222 must be signed and dated by a person authorized to sign an application for registration or a person granted power of attorney to sign a Form 222 under § 1305.05. The name of the purchaser, if different from the individual signing the DEA Form 222, must also be inserted in the signature space.

(e) Unexecuted DEA Forms 222 may be kept and may be executed at a location other than the registered location printed on the form, provided that all unexecuted forms are delivered promptly to the registered location upon an inspection of the location by any officer authorized to make inspections, or to enforce, any Federal, State, or local law regarding controlled substances.

§ 1305.13 Procedure for filling DEA Forms 222.

(a) A purchaser must submit Copy 1 and Copy 2 of the DEA Form 222 to the supplier and retain Copy 3 in the purchaser's files.

(b) A supplier may fill the order, if possible and if the supplier desires to do so, and must record on Copies 1 and 2 the number of commercial or bulk containers furnished on each item and the date on which the containers are shipped to the purchaser. If an order cannot be filled in its entirety, it may be filled in part and the balance supplied by additional shipments within 60 days following the date of the DEA Form 222. No DEA Form 222 is valid more than 60 days after its execution by the purchaser, except as specified in paragraph (f) of this section.

(c) The controlled substances must be shipped only to the purchaser and the location printed by the Administration on the DEA Form 222, except as specified in paragraph (f) of this section.

(d) The supplier must retain Copy 1 of the DEA Form 222 for his or her files and forward Copy 2 to the Special Agent in Charge of the Drug Enforcement Administration in the area in which the supplier is located. Copy 2 must be forwarded at the close of the month during which the order is filled. If an order is filled by partial shipments, Copy 2 must be forwarded at the close of the month during which the final shipment is made or the 60-day validity period expires.

(e) The purchaser must record on Copy 3 of the DEA Form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser.

(f) DEA Forms 222 submitted by registered procurement officers of the Defense Supply Center of the Defense Logistics Agency for delivery to armed services establishments within the United States may be shipped to locations other than the location printed on the DEA Form 222, and in partial shipments at different times not to exceed six months from the date of the order, as designated by the procurement officer when submitting the order.

§ 1305.14 Procedure for endorsing DEA Forms 222.

(a) A DEA Form 222, made out to any supplier who cannot fill all or a part of the order within the time limitation set forth in § 1305.13, may be endorsed to another supplier for filling. The endorsement must be made only by the supplier to whom the DEA Form 222 was first made, must state (in the spaces provided on the reverse sides of Copies 1 and 2 of the DEA Form 222) the name and address of the second supplier, and must be signed by a person authorized to obtain and execute DEA Forms 222 on behalf of the first supplier. The first supplier may not fill any part of an order on an endorsed form. The second supplier may fill the order, if possible and if the supplier desires to do so, in accordance with § 1305.13(b), (c), and (d), including shipping all substances directly to the purchaser.

(b) Distributions made on endorsed DEA Forms 222 must be reported by the second supplier in the same manner as all other distributions except that where the name of the supplier is requested on the reporting form, the second supplier must record the name, address, and registration number of the first supplier.

§ 1305.15 Unaccepted and defective DEA Forms 222.

(a) A DEA Form 222 must not be filled if either of the following apply:

(1) The order is not complete, legible, or properly prepared, executed, or endorsed.

(2) The order shows any alteration, erasure, or change of any description.

(b) If a DEA Form 222 cannot be filled for any reason under this section, the supplier must return Copies 1 and 2 to the purchaser with a statement as to the reason (*e.g.*, illegible or altered).

(c) A supplier may for any reason refuse to accept any order and if a supplier refuses to accept the order, a statement that the order is not accepted

is sufficient for purposes of this paragraph.

(d) When a purchaser receives an unaccepted order, Copies 1 and 2 of the DEA Form 222 and the statement must be attached to Copy 3 and retained in the files of the purchaser in accordance with § 1305.17. A defective DEA Form 222 may not be corrected; it must be replaced by a new DEA Form 222 for the order to be filled.

§ 1305.16 Lost and stolen DEA Forms 222.

(a) If a purchaser ascertains that an unfilled DEA Form 222 has been lost, he or she must execute another in triplicate and attach a statement containing the serial number and date of the lost form, and stating that the goods covered by the first DEA Form 222 were not received through loss of that DEA Form 222. Copy 3 of the second form and a copy of the statement must be retained with Copy 3 of the DEA Form 222 first executed. A copy of the statement must be attached to Copies 1 and 2 of the second DEA Form 222 sent to the supplier. If the first DEA Form 222 is subsequently received by the supplier to whom it was directed, the supplier must mark upon the face ''Not accepted'' and return Copies 1 and 2 to the purchaser, who must attach it to Copy 3 and the statement.

(b) Whenever any used or unused DEA Forms 222 are stolen or lost (other than in the course of transmission) by any purchaser or supplier, the purchaser or supplier must immediately upon discovery of the theft or loss, report the theft or loss to the Special Agent in Charge of the Drug Enforcement Administration in the Divisional Office responsible for the area in which the registrant is located, stating the serial number of each form stolen or lost.

(c) If the theft or loss includes any original DEA Forms 222 received from purchasers and the supplier is unable to state the serial numbers of the DEA Forms 222, the supplier must report the date or approximate date of receipt and the names and addresses of the purchasers.

(d) If an entire book of DEA Forms 222 is lost or stolen, and the purchaser is unable to state the serial numbers of the DEA Forms 222 in the book, the purchaser must report, in lieu of the numbers of the forms contained in the book, the date or approximate date of issuance.

(e) If any unused DEA Form 222 reported stolen or lost is subsequently recovered or found, the Special Agent in Charge of the Drug Enforcement Administration in the Divisional Office responsible for the area in which the registrant is located must immediately be notified.

§ 1305.17 Preservation of DEA Forms 222.

(a) The purchaser must retain Copy 3 of each executed DEA Form 222 and all copies of unaccepted or defective forms with each statement attached.

(b) The supplier must retain Copy 1 of each DEA Form 222 that it has filled.

(c) DEA Forms 222 must be maintained separately from all other records of the registrant. DEA Forms 222 are required to be kept available for inspection for a period of two years. If a purchaser has several registered locations, the purchaser must retain Copy 3 of the executed DEA Form 222 and any attached statements or other related documents (not including unexecuted DEA Forms 222, which may be kept elsewhere under § 1305.12(e)), at the registered location printed on the DEA Form 222.

(d) The supplier of carfentanil, etorphine hydrochloride, and diprenorphine must maintain DEA Forms 222 for these substances separately from all other DEA Forms 222 and records required to be maintained by the registrant.

§ 1305.18 Return of unused DEA Forms 222.

If the registration of any purchaser terminates (because the purchaser dies, ceases legal existence, discontinues business or professional practice, or changes the name or address as shown on the purchaser's registration) or is suspended or revoked under § 1301.36 of this chapter for all Schedule I and II controlled substances for which the purchaser is registered, the purchaser must return all unused DEA Forms 222 to the nearest office of the Administration.

§ 1305.19 Cancellation and voiding of DEA Forms 222.

(a) A purchaser may cancel part or all of an order on a DEA Form 222 by notifying the supplier in writing of the cancellation. The supplier must indicate the cancellation on Copies 1 and 2 of the DEA Form 222 by drawing a line through the canceled items and printing ''canceled'' in the space provided for number of items shipped.

(b) A supplier may void part or all of an order on a DEA Form 222 by notifying the purchaser in writing of the voiding. The supplier must indicate the voiding in the manner prescribed for cancellation in paragraph (a) of this section.

Subpart C—Electronic Orders

§ 1305.21 Requirements for electronic orders.

(a) To be valid, the purchaser must sign an electronic order for a Schedule I or II controlled substance with a digital signature issued to the purchaser, or the purchaser's agent, by DEA as provided in part 1311 of this chapter.

(b) The following data fields must be included on an electronic order for Schedule I and II controlled substances:

(1) A unique number the purchaser assigns to track the order. The number must be in the following 9-character format: the last two digits of the year, X, and six characters as selected by the purchaser.

(2) The purchaser's DEA registration number.

(3) The name of the supplier.

(4) The complete address of the supplier (may be completed by either the purchaser or the supplier).

(5) The supplier's DEA registration number (may be completed by either the purchaser or the supplier).

(6) The date the order is signed.

(7) The name (including strength where appropriate) of the controlled substance product or the National Drug Code (NDC) number (the NDC number may be completed by either the purchaser or the supplier).

(8) The quantity in a single package or container.

(9) The number of packages or containers of each item ordered.

(c) An electronic order may include controlled substances that are not in schedules I and II and non-controlled substances.

§ 1305.22 Procedure for filling electronic orders.

(a) A purchaser must submit the order to a specific supplier. The supplier may initially process the order (*e.g.*, entry of the order into the computer system, billing functions, inventory identification, etc.) centrally at any location, regardless of the location's registration with DEA. Following centralized processing, the supplier may distribute the order to one or more registered locations maintained by the supplier for filling. The registrant must maintain control of the processing of the order at all times.

(b) A supplier may fill the order for a Schedule I or II controlled substance, if possible and if the supplier desires to do so and is authorized to do so under § 1305.06.

(c) A supplier must do the following before filling the order:

(1) Verify the integrity of the signature and the order by using software that

complies with Part 1311 of this chapter to validate the order.

(2) Verify that the digital certificate has not expired.

(3) Check the validity of the certificate holder's certificate by checking the Certificate Revocation List. The supplier may cache the Certificate Revocation List until it expires.

(4) Verify the registrant's eligibility to order the controlled substances by checking the certificate extension data.

(d) The supplier must retain an electronic record of every order, and, linked to each order, a record of the number of commercial or bulk containers furnished on each item and the date on which the supplier shipped the containers to the purchaser. The linked record must also include any data on the original order that the supplier completes. Software used to handle digitally signed orders must comply with part 1311 of this chapter.

(e) If an order cannot be filled in its entirety, a supplier may fill it in part and supply the balance by additional shipments within 60 days following the date of the order. No order is valid more than 60 days after its execution by the purchaser, except as specified in paragraph (h) of this section.

(f) A supplier must ship the controlled substances to the registered location associated with the digital certificate used to sign the order, except as specified in paragraph (h) of this section.

(g) When a purchaser receives a shipment, the purchaser must create a record of the quantity of each item received and the date received. The record must be electronically linked to the original order and archived.

(h) Registered procurement officers of the Defense Supply Center of the Defense Logistics Agency may order controlled substances for delivery to armed services establishments within the United States. These orders may be shipped to locations other than the registered location, and in partial shipments at different times not to exceed six months from the date of the order, as designated by the procurement officer when submitting the order.

§ 1305.23 Endorsing electronic orders.

A supplier may not endorse an electronic order to another supplier to fill.

§ 1305.24 Central processing of orders.

(a) A supplier that has one or more registered locations and maintains a central processing computer system in which orders are stored may have one or more of the supplier's registered locations fill an electronic order if the supplier does the following:

(1) Assigns each item on the order to a specific registered location for filling.

(2) Creates a record linked to the central file noting both which items a location filled and the location identity.

(3) Ensures that no item is filled by more than one location.

(4) Maintains the original order with all linked records on the central computer system.

(b) A company that has central processing of orders must assign responsibility for filling parts of orders only to registered locations that the company owns and operates.

§ 1305.25 Unaccepted and defective electronic orders.

(a) No electronic order may be filled if:

(1) The required data fields have not been completed.

(2) The order is not signed using a digital certificate issued by DEA.

(3) The digital certificate used had expired or had been revoked prior to signature.

(4) The purchaser's public key will not validate the digital signature.

(5) The validation of the order shows that the order is invalid for any reason.

(b) If an order cannot be filled for any reason under this section, the supplier must notify the purchaser and provide a statement as to the reason (*e.g.*, improperly prepared or altered). A supplier may, for any reason, refuse to accept any order, and if a supplier refuses to accept the order, a statement that the order is not accepted is sufficient for purposes of this paragraph.

(c) When a purchaser receives an unaccepted electronic order from the supplier, the purchaser must electronically link the statement of nonacceptance to the original order. The original order and the statement must be retained in accordance with § 1305.27.

(d) Neither a purchaser nor a supplier may correct a defective order; the purchaser must issue a new order for the order to be filled.

§ 1305.26 Lost electronic orders.

(a) If a purchaser determines that an unfilled electronic order has been lost before or after receipt, the purchaser must provide, to the supplier, a signed statement containing the unique tracking number and date of the lost order and stating that the goods covered by the first order were not received through loss of that order.

(b) If the purchaser executes an order to replace the lost order, the purchaser must electronically link an electronic record of the second order and a copy of the statement with the record of the first order and retain them.

(c) If the supplier to whom the order was directed subsequently receives the first order, the supplier must indicate that it is ''Not Accepted'' and return it to the purchaser. The purchaser must link the returned order to the record of that order and the statement.

§ 1305.27 Preservation of electronic orders.

(a) A purchaser must, for each order filled, retain the original signed order and all linked records for that order for two years. The purchaser must also retain all copies of each unaccepted or defective order and each linked statement.

(b) A supplier must retain each original order filled and the linked records for two years.

(c) If electronic order records are maintained on a central server, the records must be readily retrievable at the registered location.

§ 1305.28 Canceling and voiding electronic orders.

(a) A supplier may void all or part of an electronic order by notifying the purchaser of the voiding. If the entire order is voided, the supplier must make an electronic copy of the order, indicate on the copy ''Void,'' and return it to the purchaser. The supplier is not required to retain a record of orders that are not filled.

(b) The purchaser must retain an electronic copy of the voided order.

(c) To partially void an order, the supplier must indicate in the linked record that nothing was shipped for each item voided.

§ 1305.29 Reporting to DEA.

A supplier must, for each electronic order filled, forward either a copy of the electronic order or an electronic report of the order in a format that DEA specifies to DEA within two business days.

■ 2. Part 1311 is added to read as follows:

PART 1311 ''DIGITAL CERTIFICATES

Subpart A—General

Sec.

Subpart B—Obtaining and Using Digital Certificates for Electronic Orders

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

Subpart A—General

§ 1311.01 Scope.

This part sets forth the rules governing the use of digital signatures and the protection of private keys by registrants.

§ 1311.02 Definitions.

For the purposes of this chapter:

Biometric authentication means authentication based on measurement of the individual's physical features or repeatable actions where those features or actions are both unique to the individual and measurable.

Cache means to download and store information on a local server or hard drive.

Certificate Policy means a named set of rules that sets forth the applicability of the specific digital certificate to a particular community or class of application with common security requirements.

Certificate Revocation List (CRL) means a list of revoked, but unexpired certificates issued by a Certification Authority.

Certification Authority (CA) means an organization that is responsible for verifying the identity of applicants, authorizing and issuing a digital certificate, maintaining a directory of public keys, and maintaining a Certificate Revocation List.

CSOS means controlled substance ordering system.

Digital certificate means a data record that, at a minimum:

(1) Identifies the certification authority issuing it;

(2) Names or otherwise identifies the certificate holder;

(3) Contains a public key that corresponds to a private key under the sole control of the certificate holder;

(4) Identifies the operational period; and

(5) Contains a serial number and is digitally signed by the Certification Authority issuing it.

Digital signature means a record created when a file is algorithmically transformed into a fixed length digest that is then encrypted using an asymmetric cryptographic private key associated with a digital certificate. The combination of the encryption and algorithm transformation ensure that the signer's identity and the integrity of the file can be confirmed.

Electronic signature means a method of signing an electronic message that identifies a particular person as the source of the message and indicates the person's approval of the information contained in the message.

FIPS means Federal Information Processing Standards. These Federal standards, as incorporated by reference in § 1311.08, prescribe specific performance requirements, practices, formats, communications protocols, etc., for hardware, software, data, etc.

FIPS 140–2, as incorporated by reference in § 1311.08, means a Federal standard for security requirements for cryptographic modules.

FIPS 180–2, as incorporated by reference in § 1311.08, means a Federal secure hash standard.

FIPS 186–2, as incorporated by reference in § 1311.08, means a Federal standard for applications used to generate and rely upon digital signatures.

Key pair means two mathematically related keys having the properties that:

(1) One key can be used to encrypt a message that can only be decrypted using the other key; and

(2) Even knowing one key, it is computationally infeasible to discover the other key.

NIST means the National Institute of Standards and Technology.

Private key means the key of a key pair that is used to create a digital signature.

Public key means the key of a key pair that is used to verify a digital signature. The public key is made available to anyone who will receive digitally signed messages from the holder of the key pair.

Public Key Infrastructure (PKI) means a structure under which a Certification Authority verifies the identity of applicants, issues, renews, and revokes digital certificates, maintains a registry of public keys, and maintains an up-to-date Certificate Revocation List.

§ 1311.05 Standards for technologies for electronic transmission of orders.

(a) A registrant or a person with power of attorney to sign orders for Schedule I and II controlled substances may use any technology to sign and electronically transmit orders if the technology provides all of the following:

(1) *Authentication:* The system must enable a recipient to positively verify the signer without direct communication with the signer and subsequently demonstrate to a third party, if needed, that the sender's identity was properly verified.

(2) *Nonrepudiation:* The system must ensure that strong and substantial evidence is available to the recipient of the sender's identity, sufficient to prevent the sender from successfully denying having sent the data. This criterion includes the ability of a third party to verify the origin of the document.

(3) *Message integrity:* The system must ensure that the recipient, or a third party, can determine whether the contents of the document have been altered during transmission or after receipt.

(b) DEA has identified the following means of electronically signing and transmitting order forms as meeting all of the standards set forth in paragraph (a) of this section.

(1) Digital signatures using Public Key Infrastructure (PKI) technology.

(2) [Reserved]

§ 1311.08 Incorporation by reference.

(a) The following standards are incorporated by reference:

(1) FIPS 140–2, Security Requirements for Cryptographic Modules, May 25, 2001, as amended by Change Notices 2 through 4, December 3, 2002.

(i) Annex A: Approved Security Functions for FIPS PUB 140–2, Security Requirements for Cryptographic Modules, September 23, 2004.

(ii) Annex B: Approved Protection Profiles for FIPS PUB 140–2, Security Requirements for Cryptographic Modules, November 4, 2004.

(iii) Annex C: Approved Random Number Generators for FIPS PUB 140–2, Security Requirements for Cryptographic Modules, January 31, 2005.

(iv) Annex D: Approved Key Establishment Techniques for FIPS PUB 140–2, Security Requirements for Cryptographic Modules, February 23, 2004.

(2) FIPS 180–2, Secure Hash Standard, August 1, 2002, as amended by change notice 1, February 25, 2004.

(3) FIPS 186–2, Digital Signature Standard, January 27, 2000, as amended by Change Notice 1, October 5, 2001.

(b) These standards are available from the National Institute of Standards and Technology, Computer Security Division, Information Technology Laboratory, National Institute of Standards and Technology, 100

Bureau Drive, Gaithersburg, MD 20899–8930 and are available at *http://csrc.nist.gov/*.

(c) These incorporations by reference were approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be inspected at the Drug Enforcement Administration, 600 Army Navy Drive, Arlington, VA 22202 or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

Subpart B—Obtaining and Using Digital Certificates for Electronic Orders

§ 1311.10 Eligibility to obtain a CSOS digital certificate.

The following persons are eligible to obtain a CSOS digital certificate from the DEA Certification Authority to sign electronic orders for controlled substances.

(a) The person who signed the most recent DEA registration application or renewal application and a person authorized to sign a registration application.

(b) A person granted power of attorney by a DEA registrant to sign orders for one or more schedules of controlled substances.

§ 1311.15 Limitations on CSOS digital certificates.

(a) A CSOS digital certificate issued by the DEA Certification Authority will authorize the certificate holder to sign orders for only those schedules of controlled substances covered by the registration under which the certificate is issued.

(b) When a registrant, in a power of attorney letter, limits a certificate applicant to a subset of the registrant's authorized schedules, the registrant is responsible for ensuring that the certificate holder signs orders only for that subset of schedules.

§ 1311.20 Coordinators for CSOS digital certificate holders.

(a) Each registrant, regardless of number of digital certificates issued, must designate one or more responsible persons to serve as that registrant's CSOS coordinator regarding issues pertaining to issuance of, revocation of, and changes to digital certificates issued under that registrant's DEA registration. While the coordinator will be the main point of contact between one or more DEA registered locations and the CSOS Certification Authority, all digital certificate activities are the responsibility of the registrant with whom the digital certificate is associated. Even when an individual registrant, *i.e.*, an individual practitioner, is applying for a digital certificate to order controlled substances a CSOS Coordinator must be designated; though in such a case, the individual practitioner may also serve as the coordinator.

(b) Once designated, coordinators must identify themselves, on a one-time basis, to the Certification Authority. If a designated coordinator changes, the Certification Authority must be notified of the change and the new responsibilities assumed by each of the registrant's coordinators, if applicable. Coordinators must complete the application that the DEA Certification Authority provides and submit the following:

(1) Two copies of identification, one of which must be a government-issued photographic identification.

(2) A copy of each current DEA Certificate of Registration (DEA form 223) for each registered location for which the coordinator will be responsible or, if the applicant (or their employer) has not been issued a DEA registration, a copy of each application for registration of the applicant or the applicant's employer.

(3) The applicant must have the completed application notarized and forward the completed application and accompanying documentation to the DEA Certification Authority.

(c) Coordinators will communicate with the Certification Authority regarding digital certificate applications, renewals and revocations. For applicants applying for a digital certificate from the DEA Certification Authority, and for applicants applying for a power of attorney digital certificate for a DEA registrant, the registrant's Coordinator must verify the applicant's identity, review the application package, and submit the completed package to the Certification Authority.

§ 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 or person with power of attorney for a registrant must complete the application that the DEA Certification Authority provides and submit the following:

(1) Two copies of identification, one of which must be a government-issued photographic identification.

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

(3) A copy of the power of attorney from the registrant, if applicable.

(4) An acknowledgment that the applicant has read and understands the Subscriber Agreement and agrees to the statement of subscriber obligations that DEA provides.

(b) The applicant must provide the completed application to the registrant's coordinator for CSOS digital certificate holders who will review the application and submit the completed application and accompanying documentation to the DEA Certification Authority.

(c) When the Certification Authority 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.

(d) 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.

§ 1311.30 Requirements for storing and using a private key for digitally signing orders.

(a) Only the certificate holder may access or use his or her digital certificate and private key.

(b) The certificate holder must provide FIPS-approved secure storage for the private key, as discussed by FIPS 140–2, 180–2, 186–2, and accompanying change notices and annexes, as incorporated by reference in § 1311.08.

(c) A certificate holder must ensure that no one else uses the private key. While the private key is activated, the certificate holder must prevent unauthorized use of that private key.

(d) A certificate holder must not make back-up copies of the private key.

(e) The certificate holder must report the loss, theft, or compromise of the private key or the password, via a revocation request, to the Certification Authority within 24 hours of substantiation of the loss, theft, or compromise. Upon receipt and verification of a signed revocation request, the Certification Authority will revoke the certificate. The certificate holder must apply for a new certificate under the requirements of § 1311.25.

§ 1311.35 Number of CSOS digital certificates needed.

A purchaser of Schedule I and II controlled substances must obtain a separate CSOS certificate for each registered location for which the purchaser will order these controlled substances.

§ 1311.40 Renewal of CSOS digital certificates.

(a) A CSOS certificate holder must generate a new key pair and obtain a new CSOS digital certificate when the registrant's DEA registration expires or whenever the information on which the certificate is based changes. This information includes the registered name and address, the subscriber's name, and the schedules the registrant is authorized to handle. A CSOS certificate will expire on the date on which the DEA registration on which the certificate is based expires.

(b) The Certification Authority will notify each CSOS certificate holder 45 days in advance of the expiration of the certificate holder's CSOS digital certificate.

(c) If a CSOS certificate holder applies for a renewal before the certificate expires, the certificate holder may renew electronically 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 documentation, as provided in § 1311.25.

§ 1311.45 Requirements for registrants that allow powers of attorney to obtain CSOS digital certificates under their DEA registration.

(a) A registrant that grants power of attorney must report to the DEA Certification Authority within 6 hours of either of the following (advance notice may be provided, where applicable):

(1) The person with power of attorney has left the employ of the institution.

(2) The person with power of attorney has had his or her privileges revoked.

(b) A registrant must maintain a record that lists each person granted power of attorney to sign controlled substances orders.

§ 1311.50 Requirements for recipients of digitally signed orders.

(a) The recipient of a digitally signed order must do the following before filling the order:

(1) Verify the integrity of the signature and the order by having the system validate the order.

(2) Verify that the certificate holder's CSOS digital certificate has not expired by checking the expiration date against the date the order was signed.

(3) Check the validity of the certificate holder's certificate by checking the Certificate Revocation List.

(4) Check the certificate extension data to determine whether the sender has the authority to order the controlled substance.

(b) A recipient may cache Certificate Revocation Lists for use until they expire.

§ 1311.55 Requirements for systems used to process digitally signed orders.

(a) A CSOS certificate holder and recipient of an electronic order may use any system to write, track, or maintain orders provided that the system has been enabled to process digitally signed documents and that it meets the requirements of paragraph (b) or (c) of this section.

(b) A system used to digitally sign Schedule I or II orders must meet the following requirements:

(1) The cryptographic module must be FIPS 140–2, Level 1 validated, as incorporated by reference in § 1311.08.

(2) The digital signature system and hash function must be compliant with FIPS 186–2 and FIPS 180–2, as incorporated by reference in § 1311.08.

(3) The private key must be stored on a FIPS 140–2 Level 1 validated cryptographic module using a FIPS-approved encryption algorithm, as incorporated by reference in § 1311.08.

(4) The system must use either a user identification and password combination or biometric authentication to access the private key. Activation data must not be displayed as they are entered.

(5) The system must set a 10-minute inactivity time period after which the certificate holder must reauthenticate the password to access the private key.

(6) For software implementations, when the signing module is deactivated, the system must clear the plain text private key from the system memory to prevent the unauthorized access to, or use of, the private key.

(7) The system must be able to digitally sign and transmit an order.

(8) The system must have a time system that is within five minutes of the official National Institute of Standards and Technology time source.

(9) The system must archive the digitally signed orders and any other records required in part 1305 of this chapter, including any linked data.

(10) The system must create an order that includes all data fields listed under § 1305.21(b) of this chapter.

(c) A system used to receive, verify, and create linked records for orders signed with a CSOS digital certificate must meet the following requirements:

(1) The cryptographic module must be FIPS 140–2, Level 1 validated, as incorporated by reference in § 1311.08.

(2) The digital signature system and hash function must be compliant with FIPS 186–2 and FIPS 180–2, as incorporated by reference in § 1311.08.

(3) The system must determine that an order has not been altered during transmission. The system must invalidate any order that has been altered.

(4) The system must validate the digital signature using the signer's public key. The system must invalidate any order in which the digital signature cannot be validated.

(5) The system must validate that the DEA registration number contained in the body of the order corresponds to the registration number associated with the specific certificate by separately generating the hash value of the registration number and certificate subject distinguished name serial number and comparing that hash value to the hash value contained in the certificate extension for the DEA registration number. If the hash values are not equal the system must invalidate the order.

(6) The system must check the Certificate Revocation List automatically and invalidate any order with a certificate listed on the Certificate Revocation List.

(7) The system must check the validity of the certificate and the Certification Authority certificate and invalidate any order that fails these validity checks.

(8) The system must have a time system that is within five minutes of the official National Institute of Standards and Technology time source.

(9) The system must check the substances ordered against the schedules that the registrant is allowed to order and invalidate any order that includes substances the registrant is not allowed to order.

(10) The system must ensure that an invalid finding cannot be bypassed or ignored and the order filled.

(11) The system must archive the order and associate with it the digital certificate received with the order.

(12) If a registrant sends reports on orders to DEA, the system must create a report in the format DEA specifies, as provided in § 1305.29 of this chapter.

(d) For systems used to process CSOS orders, the system developer or vendor must have an initial independent third-party audit of the system and an

additional independent third-party audit whenever the signing or verifying functionality is changed to determine whether it correctly performs the functions listed under paragraphs (b) and (c) of this section. The system developer must retain the most recent audit results and retain the results of any other audits of the software completed within the previous two years.

§ 1311.60 Recordkeeping.

(a) A supplier and purchaser must maintain records of CSOS electronic orders and any linked records for two years. Records may be maintained electronically. Records regarding controlled substances that are maintained electronically must be readily retrievable from all other records.

(b) Electronic records must be easily readable or easily rendered into a format that a person can read. They must be made available to the Administration upon request.

(c) CSOS certificate holders must maintain a copy of the subscriber agreement that the Certification Authority provides for the life of the certificate.

Dated: March 28, 2005.

Michele M. Leonhart,

Deputy Administrator.

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