

Controlled Substances Ordering System (CSOS)

ANTICIPATED STANDARDS FOR DEA CONTROLLED SUBSTANCES ORDERING SYSTEM

[September, 2002]

DEA is implementing a system to permit electronic transmission of orders for controlled substances. DEA will not issue a specific electronic form to serve as the electronic equivalent of the paper-based DEA Form 222. Rather, DEA will issue digital certificates to persons authorized to order controlled substances. These digital certificates will serve as authentication of a registrant's authority to order Schedule I and II controlled substances, and will be used by such individuals to digitally sign all orders for Schedule I and II controlled substances. While DEA is requiring that certain elements be present in orders created and processed by this system to fulfill regulatory requirements, DEA will permit the use of any electronic form for the ordering of controlled substances, provided the form is digitally signed using the digital certificate issued to the registrant by DEA.

THESE ARE DRAFT STANDARDS THAT ARE STILL IN DEVELOPMENT. IMPLEMENTATION OF ANY STANDARDS WILL REQUIRE PUBLICATION IN THE FEDERAL REGISTER WITH OPPORTUNITY FOR PUBLIC COMMENT.

Differences between DEA Form 222 and electronic controlled substance orders:

- Electronic order systems will need to be formatted to include all data on the DEA Form 222, except:
 - the line number and total number of lines are not required
 - purchaser information, i.e., name, address, DEA registration number, authorized schedules, and business activity, which are included in the digital certificate which must accompany the order.
 - Supplier address, i.e., street address and city and state, is not required on the initial order
 - Name of Item and Size of Package are not required if an NDC number is present, provided that both the purchaser's and supplier's record systems automatically include the physical description as part of the record of the transaction.
 - DEA preassigned order form serial number is not required and will be replaced with a unique purchaser assigned number in the following format: YYX999999 (first two characters are the year, followed by "X", followed by a

unique sequence assigned by the purchaser). This format must be compatible with the existing ARCOS reporting system.

- The registered shipping location of the supplier must have direct access to and be able to provide upon demand a full copy of a distribution record, including the original order (including digital signature) and all linked files relating to distributions made pursuant to the order.
- Orders may be fulfilled from multiple registrant locations of the same supplier. However, individual lines on an order must be filled by a single registered location - they cannot be split between two registered locations for filling.
- Unlike the paper form, which is limited to purchases of Schedule I and II substances, the digitally signed order system may also be used for Schedule III through V substances.
- The electronic orders and linked shipment information or a summary report thereof must be filed with DEA within two business days after shipment rather than every month. For purposes of this requirement business day is defined as Monday through Friday, exclusive of holidays.
- Electronic records of Schedule I and II substances may be retained with other records by the registrant provided they are readily retrievable by schedule and substance.

Elements of electronic orders, order fulfillment and order receipt:

Any computer system may be used to create electronic orders for controlled substances, provided that the following elements are included, either automatically or manually, in each order:

- (1) A unique number the purchaser generates to track the order in the following format: YYX999999 (first two characters are the year, followed by "X", followed by a unique sequence assigned by the purchaser). This format must be compatible with the existing ARCOS reporting system.
- (2) The name of the supplier from which the controlled substances are being ordered. (The order may be transmitted to a registered location of the supplier or to a separate office maintained by the supplier at which orders are processed and then transmitted to one or more registered locations, all of which are part of that supplier, for filling. In cases involving a shared database, the processing office does not have to transmit the original order to the registered location(s) that distributes, provided that the registered location(s) has direct access to and is able to provide upon demand a full copy of a distribution record, including the original order (including digital signature) and all linked files relating to distributions made pursuant to the order. In such a case, any instructions

regarding the filling of the order that are provided to the registered location(s) that distributes must be linked to the original order as a permanent part of the distribution record.)

- (3) The complete address of the supplier. (optional)
- (4) The supplier's DEA registration number (Optional).*
- (5) The date the order is signed by the purchaser.
- (6) The name (including strength, where appropriate) and quantity in a single package of the controlled substance product or the National Drug Code (NDC) number. Where the NDC number is provided in lieu of the product description, both the purchaser's and supplier's systems must automatically include, as part of the record of the order, the required physical description of the product.
- (7) The National Drug Code (NDC) number (If not present on the order, the supplier must complete)*
- (8) The number of packages or containers of each item ordered.
- (9) Number of packages shipped (completed by the supplier). *
- (10) Date shipped (completed by the supplier). *
- (11) Number of packages received (purchaser completes on receipt of order). *
- (12) Date received (purchaser completes on receipt of order). *

* For information added after signature of the order by the purchaser, such information must be maintained in an annotated, linked record containing the order information. Use of an annotated, linked record is required because the original order cannot be modified in any way after signature. The software system(s) must archive both the original order and the annotated, linked record. The original order and linked records constitute the complete order form.

Transmitting digitally signed orders for Schedule I and II controlled substances:

Any system enabled to handle digital signatures may be used to transmit digitally signed orders for Schedule I and II controlled substances provided it meets the following requirements:

- The system must control the activation of the private key with an authentication mechanism which may include, but is not limited to, password, smart card, fingerprint scan, iris scan.

- The system must employ a ten-minute inactivity time period after which the certificate holder must re-authenticate to access the private key.
- 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.
- The system must digitally sign and transmit the electronic order.
- The system must communicate with the Certification Authority directory.
- The system must have a time system that is within five minutes of the official National Institute of Standards and technology (NIST) time source.
- The system must archive digitally signed files.

Receiving and processing digitally signed orders for Schedule I and II controlled substances:

Any system may be used to process an electronic order provided it has been enabled to handle digital signatures and that it meets the following requirements:

- The system must check the purchaser certificate extension data to ensure that the certificate is current and the purchaser is authorized to order the products.
- The system must validate that an order has not been altered in transmission.
- The system must check the certificate revocation list automatically and invalidate any order with a certificate listed on the CRL.
- The system must have a time system that is within five minutes of the official National Institute of Standards and technology time source.
- The system must archive the order and include the digital certificate linked to the order in the record of each order.

If the supplier intends to file a summary report of orders rather than copies of the actual orders, the system must create a report that includes, for each Schedule I and II order, The following:

- (1) The supplier's name.
- (2) The supplier's complete address.
- (3) The supplier's DEA registration number.
- (4) The Purchaser's name.

- (5) The purchaser's complete address,
- (6) The Purchaser's DEA registration number.
- (7) The schedules the purchaser is authorized to receive.
- (8) The purchaser's business activity.
- (9) The unique tracking number the purchaser assigned to the order.
- (10) The date the order was signed by the purchaser.
- (11) The name of the controlled substance product
- (12) The national Drug Code (NDC) number of the controlled substance.
- (13) The quantity in a single package.
- (14) The number of packages of containers of each item ordered.
- (15) The number of packages shipped.
- (16) The date shipped.

DEA will specify the formats in which information may be provided. This provision would allow for compliance with the current paper requirement that suppliers forward copy 2 of the DEA Form 222 to the nearest DEA office on a monthly basis.

Technical specifications:

The Federal Information Processing Standards (FIPS) are standards developed by the National Institute of Standards and Technology (NIST) and have been adopted by the U.S. government. These standards are required for all cryptographic-based security systems and digital signature systems that are used by, or approved by, Federal agencies to protect unclassified information. DEA, therefore, must require that the software modules used for digital signatures comply with these standards. Within each system used to transmit or process electronic orders for controlled substances:

- The cryptographic module must be FIPS 140-2 validated. FIPS 140-2 discusses general requirements for cryptographic modules for computer and telecommunications systems.
- The digital signature system must be FIPS 186-2 validated and use the RSA algorithm. FIPS 186-2 specifies algorithms for applications used to generate digital signatures.
- The hash function must be FIPS 180-1 validated. FIPS 180-1 is the Secure Hash Standard.

A list of vendors whose cryptographic modules have been validated as FIPS 140-2 compliant may be obtained from the NIST web site at <http://csrc.nist.gov/cryptval/140-1/1401vend.htm>. Information on FIPS 186-2 and FIPS 180-1 can be obtained from <http://csrc.nist.gov>.

- The modules that have been validated as compliant with these standards can be used to enable software to handle digital signatures. As long as the code in the compliant module is not altered, adding it to the software will not alter its validation.

System Operational Qualification Audits:

Before implementing an electronic system for Schedule I and II controlled substances orders, the system must be audited and certified as performing the required functions. Ensuring that this audit has been performed is the responsibility of the registrant implementing the order system and may entail an audit of that registrant's internally developed software or certification from a software vendor that the product being acquired has received the required audit. Audits must be performed by an independent third party qualified to perform such a function. After the initial audit, the developer or vendor would be required to have third-party audits whenever the signing or verifying functionality is changed to ensure that it is functioning as required. Registrants who implement order systems developed by third-party vendors to comply with this rule will be required to obtain and review a copy of the latest audit report (or summary of the report) from their vendors. In instances where suppliers provide their customers with ordering software for use in this system, it will be the supplier's responsibility to ensure this auditing requirement has been satisfied. Individual customers of that supplier will not be required to maintain a copy of the audit report.

**STANDARDS STILL IN DEVELOPMENT
NO IMPLEMENTATION PRIOR TO PROMULGATION OF APPLICABLE
REGULATIONS**