Increasing Supply Chain Efficiency With CSOS

by Steve Bruck

Since 1999, the Drug Enforcement Administration (DEA) has been working on a new electronic ordering alternative to the traditional paper 222 order form. On April 1, 2005, DEA published the final rule allowing the Controlled Substance Ordering System (CSOS), as an option to paper for Schedule II drugs The potential cost savings from this new program are generating significant interest. Wholesalers are enhancing their systems to comply with the DEA CSOS regulations, to ease the CII ordering process for their pharmacy customers. This early adoption of CSOS is a direct result of DEA's successful collaboration with industry during the development of the new regulations. Even more important, there are a number of commercial, EDI-based CSOS solutions now on the market.

As a result, pharmacists should expect that the way CII drugs are ordered will change sooner rather than later. Pharmacy owners need to be aware of the impact CSOS will have on their operational processes and start planning now to ensure compliance. What follows is a brief overview of the DEA's new regulations, identifying those areas where pharmacy owners and pharmacists in particular need to pay special attention.

A New Process

By DEA's last count of 222 forms, there are approximately 7 million CII orders sent annually. The anticipated cost savings will be realized by eliminating the time spent by pharmacists filling out paper forms, by overnight shipping of the forms to suppliers, and by supplier keying of the order. In addition, many suppliers already receive electronic orders for Schedule II controlled substances, pre-allocate inventory for the order, and then let the inventory sit until the completed paper form 222 is received. Add to all of this the three-year cost of storing 21 million pieces of paper (each 222 is a triplicate form) and CSOS is an obvious next step for the industry.

The new CSOS model also allows for a very exciting business process redesign for order fulfillment. Wholesalers that were unable to fill an order from multiple distribution locations due to restrictions imposed by the paper process are now free to do so using the new electronic system. This gives suppliers much-needed flexibility to deal with situations where a particular distribution center may be out of stock, but the drug is on hand and could be shipped from another of the supplier's distribution centers. This is significant because it should cut down on the number of controlled-substance backorders and reduce inventories levels at the pharmacy.

CSOS Basics

Within the pharmaceutical supply chain, electronic data interchange (EDI)-based systems are used for the vast majority of product orders. CSOS is designed to enable those same EDI systems

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(and other transaction formats) to handle CII orders with modifications that ensure DEA regulatory compliance.

The DEA's approach is based on the issuance of digital certificates to those individuals who are responsible for ordering controlled substances. In a small pharmacy, this may be the pharmacy owner who is the registrant, while in larger chains there may be many employees who have been granted powers of attorney (POA) to enable them to sign orders for CIIs digitally on behalf of the registrant.

Under CSOS, the individuals who have applied to the DEA for a CSOS digital certificate, which will include those granted POA, will use this certificate and a DEA-compliant and independently audited ordering system to generate electronic orders for controlled substances. Orders must be digitally signed using a PKI-enabled system. This cryptographically based process satisfies three key DEA requirements. First, the digital signature allows for the identity of the person placing the order to be authenticated. Second, it makes it "computationally infeasible" for anyone to alter the order after it has been signed, which is called message integrity. And third, it directly links the signer to the transaction, making it difficult for the signer to convincingly deny having signed the transaction, which is called nonrepudiation. These properties make PKI technology very attractive to DEA, since they not only improve the supplier's ability to validate a transaction, but also ensure the integrity of the electronic order, regardless of where it is stored.

Coordinating the Process

CSOS enrollment must ensure that only authorized individuals get DEA CSOS IDs. Initially DEA considered requiring that all applications be notarized, but backed away from this after pilot tests showed this approach to be too complicated. DEA finally settled on the concept of a "coordinator." Associated with one or more ordering locations, the coordinator is responsible for reviewing and submitting to DEA all POA applications. Each participating location must have a CSOS coordinator — for small pharmacies the owner or certificate applicant, such as the staff pharmacist who handles CII orders, could perform this function, and in some situations the registrant and the CSOS coordinator will be the same person. The key documents that specify the provisions that DEA CSOS certificate holders must follow are the DEA final regulations, the certificate policy, and the CSOS subscriber agreement, which is provided by the DEA certificate authority to each certificate holder and documents CSOS subscriber responsibilities.

A Few CSOS Terms Defined

The final rule uses a very specific vocabulary to describe the ordering process, one with which many people may not be familiar. The following definitions, drawn from Section 1311.02, should help you understand what you read and hear about CSOS.

Certification authority (CA): 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. The CSOS CA will be run by DEA.

Certificate policy: 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.

Digital certificate: 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.
5. Contains a serial number and is digitally signed by the certification authority issuing it.

Key pair: 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.
2. Even knowing one key, it is computationally infeasible to discover the other key.

Private key: The key of a key pair that is used to create a digital signature.

Public key: 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): 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.

Digital Certificates

Once the enrollment application has been adjudicated by DEA, one-time activation information will be sent to both the coordinator and the certificate applicant. This information must then be used by the applicant to retrieve the digital certificate from the DEA's CSOS web site. Electronic ordering can begin once the digital certificate has been retrieved and entered into the pharmacy's electronic ordering sys-

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More on Ordering Requirements

The CSOS final rule contains details that you'll need to be familiar with when implementing CSOS. Excerpted here are the requirements for electronic orders, from Section 1305.21, and the standards for technologies for the electronic transmission of orders, from Section 1311.05. Everyone planning on implementing CSOS should read the entire final rule, which is only 20 pages and is available along with enrollment applications and other important information at DEA's CSOS website, www.deaecom.gov.

For an electronic Schedule I or II controlled-substance order to be valid, the purchaser must sign it with a digital signature issued to the purchaser, or the purchaser's agent, by DEA, according to the procedure outlined in the final rule. The order must include the following data fields:

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.

DEA has identified digital signatures using public key infrastructure (PKI) as one technology for electronically signing and transmitting order forms that meets all of the following standards, which are set out in the final rule.

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.

However, a registrant or POA may use any technology to sign and electronically transmit controlled-substance orders provided that it meets these three criteria.

tem. DEA CSOS certificates are issued for three years, with the expiration synchronized with the overarching DEA number registration.

Placing an Order

Once a person has a digital certificate, the certificate must be used for each electronically transmitted CII order. The ordering system must prompt the purchaser to activate his digital certificate and digitally sign the order. Certificates and the corresponding private key must be safeguarded by the user for security reasons. This is a critically important area of the regulations. In organizations where POAs have ordering authority for large numbers of locations, specialized private-key management solutions can simplify this process.

Upon receipt of an electronic order, suppliers are required to validate the integrity of the order to ensure that it has not been altered. Suppliers must also verify the pharmacy's authorization to order the schedules listed and the pharmacy's registration status. For CSOS transactions, the DEA requires that reporting be done within two business days. As with the paper system, original electronic records must be maintained and be readily retrievable. Since a supplier can fill an order from a number of different locations, the supplier must make records retrievable at all distribution centers involved with the CSOS order. To ensure that orders are always readily retrievable, companies should plan to build in system redundancy to guard against data loss or system failures that could cause noncompliance.

Ensuring Compliance

While CSOS promises to provide cost savings, it also demands that pharmacies and suppliers implement compliant solutions that effectively manage the associated liability. There are some basic steps that every CSOS implementation project should begin with for tracking and documenting how compliance will be achieved across all systems. This means that pharmacy owners moving to CSOS will need to create a document that lists all of the compliance requirements and tracks implementation so that, during development, they will be able to pinpoint areas where their CSOS program doesn't follow the DEA regulations, and make the necessary changes. Once development is complete, a CSOS test

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suite can be used to validate compliance. By combining compliance tracking with a comprehensive CSOS compliance validation test suite, pharmacy owners can start using CSOS with the confidence that their system is fully DEA compliant. For pharmacists who are keeping an eye on new ways to increase productivity and boost the bottom line, this is something to be excited about. It is only a matter of carefully following the appropriate steps to create a compliant and tested CSOS process in their stores and to start taking advantage of the cost and time savings available from this new electronic ordering method. Now is the time to get started. CT

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