

must take steps to secure the controlled substances and the authorization to obtain and distribute or dispense the controlled substances. In this regard, it is important that the private key be properly secured, since it is the functional equivalent of both the paper DEA Form 222 and the registrant's valid signature on that form.

All certificate holders must provide secure storage for the private key. The private key may be stored on any electronic medium, with access controlled by at least a user ID and password. As noted before, DEA encourages certificate holders and registrants to use biometric passwords instead of user IDs and passwords. Although not a requirement, biometric passwords provide a higher level of assurance that a private key cannot be used by anyone except the certificate holder.

Although DEA is proposing that certificate holders could store private keys on any electronic medium, including a hard drive or a disk, DEA encourages registrants to use smart cards or other secure hardware devices whose cryptographic modules are FIPS 140-2 validated for storing private keys.

Only the individual to whom a digital certificate is issued may use it. The certificate holder must report any loss or compromise of the private key or password to the Certification Authority within 6 hours of the loss or theft. In addition, the certificate holder is responsible for ensuring that others do not have access to the private key. The certificate holder must not give any other person the password or user ID and must ensure that once the private key has been accessed and the system is activated, no one else uses the computer or work station until the system is deactivated.

What Are the Conditions That Would Lead DEA To Revoke a Certificate?

A number of circumstances would require the revocation of a digital certificate. The Certification Authority would automatically revoke a certificate upon notice that the smart card or other hardware storage device has been lost, stolen, or compromised in any fashion, the password has been forgotten, or the private key can no longer be accessed. The certificate would also be revoked if the CA is notified that any of the information in the certificate changed (e.g., name or address, or new schedules added). In addition, a registrant must notify the Certification Authority whenever a specific individual's power of attorney has been revoked, so that the certificate issued in connection with the power of attorney can be revoked.

If a DEA registration is revoked or terminated for any reason, all digital certificates linked to that registration would be revoked because the validity of the certificate is linked to the validity of the DEA registration.

Any disagreement regarding a certificate revocation may be appealed to the Certification Authority in writing. Revocation of a digital certificate in and of itself does not affect a registrant's authority to handle controlled substances; it only affects the ability to engage in electronic transactions that require a digital signature.

B. Orders

This section discusses the specific requirements that relate to electronic orders and how these requirements differ from the current rules for Forms 222.

What Is DEA Proposing for Electronic Orders?

In general, DEA is proposing that purchasers be able to digitally sign and transmit electronic orders for Schedule I and II controlled substances if they use a digital certificate issued by the DEA Certification Authority and comply with the other requirements of proposed part 1311 on software and safeguarding of private keys. Suppliers would be able to validate and fill electronic orders for Schedule I and II controlled substances if they comply with the requirements in proposed part 1311 on software.

Most of the current part 1305 requirements would not change. Orders for Schedule I and II substances must be issued only on Form 222 or an electronic order signed with a valid digital certificate that the DEA Certification Authority issues. The same registrants would be eligible to sign and fill orders. Each party to the transaction would retain a copy and suppliers would send a copy or a data extract to DEA. DEA Form 222 will still be available for use. DEA expects that over time most, if not all, parties placing and filling orders will choose to use electronic orders, but this is not mandatory. Current regulations with respect to DEA Form 222 are not changed by this proposed rule.

What Are the Differences Between DEA Form 222 and Electronic Orders?

There are a number of differences with electronic orders.

- Electronic order systems would need to include the data on the DEA Form 222, except the line numbers, total number of lines, and purchaser information, *i.e.*, name, address, DEA registration number, authorized schedules, and business activity, all of

which are included in the digital certificate which must accompany the order. (A discussion of the contents of an electronic order is provided in the next section.)

- 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 and non-controlled prescription drugs.

- The DEA Form 222 limits the number of line items ordered to 10; the number of line items on electronic orders is unlimited.

- As discussed later, copies of the electronic orders or a report on the orders must be filed with DEA every other business day rather than every month.

- Electronic records for Schedule I and II controlled substances must, by regulation, be maintained separately from other records. However, DEA considers electronic records of Schedule I and II controlled substances to be maintained separately so long as these records are readily retrievable by schedule and controlled substance.

Each of these differences is discussed in greater detail in subsequent sections.

What Data Must Be Included in an Electronic Order?

The proposed electronic orders would be required to include the following data fields:

- (1) A unique number generated by the purchaser to track the order. The number must be in the following 9-character format: the last two digits of the year, the character "x", and six numbers of the purchaser's choice.

- (2) The name of the supplier.

- (3) The complete address of the supplier.

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

- (5) The date the order is signed.

- (6) The name (including strength where appropriate) of the controlled substance product.

- (7) The National Drug Code (NDC) number (may be completed by the supplier or the purchaser).

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

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

The digital certificate attached to the order provides the purchaser's name, registered location, DEA registration number, business activity, and schedules.

How Can Electronic Orders Be Annotated?

Because the original order has been digitally signed, it cannot be altered.