

Can a Digital Certificate be Used to Sign Orders for Schedule III through V Controlled Substances?

A digital certificate may be used to sign orders for other substances including Schedule III through V controlled substances. DEA encourages the use of the DEA digital certificate to sign all controlled substances orders. Using a DEA issued digital certificate to order Schedule III through V substances provides the supplier with confirmation of the customer's registration status in compliance with 21 CFR 1301.74(a).

IV. Section by Section Discussion of the Proposed Rule

How Is the Proposed Rule Structured?

DEA is proposing to revise part 1305 and add a new part for digital certificates, new Part 1311, as follows:

- DEA is proposing to revise the entire part 1305 to incorporate requirements for the use of electronic orders. Part 1305 requirements would be grouped into three subparts: Subpart A would include general requirements that apply to both Form 222 and electronic orders. Subpart B would include requirements for DEA Form 222

transactions. Subpart C would include requirements for electronic orders.

- Part 1311—DEA is proposing to add a new part that would provide the requirements for the following:

- Performance standards for electronic signatures and electronic transmission.
- Applications for digital certificates.
- Number of certificates required.
- Renewal of certificates.
- Safeguarding of certificates.
- Use of digital signatures.
- Software requirements for handling digital signatures.

In part 1305, Sections 1305.01 and 1305.02 remain unchanged.

Section 1305.03 is proposed to be revised to explain that either Form 222 or an electronic order that complies with part 1311 could be used.

Section 1305.04 is proposed to be revised to include the power of attorney requirements currently found in 21 CFR 1305.07.

Section 1305.05 is redesignated as 1305.11, and includes specific references to DEA Form 222.

Section 1305.06 is redesignated as 1305.12, and includes specific references to DEA Form 222.

Section 1305.07 is removed.

Section 1305.08 is redesignated as Section 1305.05, and includes specific references to DEA Form 222.

Sections 1305.09–1305.15 are redesignated as Sections 1305.13–1305.19, and include specific references to DEA Form 222.

Section 1305.16 is redesignated as Section 1305.06.

To accommodate the new electronic order requirements, Sections 1305.21–1305.28 are proposed to be added as follows:

Section 1305.21 discusses requirements for electronic orders.

Section 1305.22 discusses procedures for filling electronic orders.

Section 1305.23 discusses endorsing electronic orders.

Section 1305.24 discusses central processing of orders.

Section 1305.25 discusses unaccepted and defective electronic orders.

Section 1305.26 discusses lost electronic orders.

Section 1305.27 discusses preservation of electronic orders.

Section 1305.28 discusses canceling and voiding electronic orders.

Section 1305.29 discusses reporting electronic orders to DEA.

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 forms order form	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	1305.04(c)—Power of attorney.
1305.08—Persons entitled to fill order forms	1305.05—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	1305.06—Special procedure for filling certain DEA Forms 222.

New sections (added)

- 1305.21—Requirements for electronic orders.
- 1305.22—Procedure for filling electronic orders.
- 1305.23—Endorsing electronic orders.
- 1305.24—Central processing of orders.
- 1305.25—Unaccepted and defective electronic orders.
- 1305.26—Lost electronic orders.
- 1305.27—Preservation of electronic orders.
- 1305.28—Cancelling and voiding electronic orders.
- 1305.29—Reporting to DEA

Part 1311 is proposed to be added to provide requirements for obtaining, handling, and using digital certificates.

Note that DEA is proposing, in a separate notice, rules for obtaining, handling, and using digital certificates to sign controlled substance prescriptions. Because the requirements are the same in some instances, some of the proposed sections cover both orders and prescriptions.

Section 1311.01 discusses the scope of the new part.

Section 1311.02 is proposed to add definitions of the following:

- Biometric authentication.
- Cache
- Certification Authority
- Certificate policy
- Certificate revocation list

- Digital certificate
- Digital signature
- Electronic signature
- FIPS
- Key pair
- NIST
- Private key
- Public Key

The definitions are taken from other government documents that define these terms.

Section 1311.05 proposes to specify the performance standards required for electronic signatures and transmission.

Section 1311.08 proposes to incorporate by reference FIPS 140–2, FIPS 180–1, and FIPS 186–2.