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 plaintext 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:
§ 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.

Subpart C—Electronic Prescriptions

§ 1311.100 General.

(a) This subpart addresses the requirements that must be met to issue and process Schedule II, III, IV, and V controlled substance prescriptions electronically.

(b) A practitioner may issue a prescription for a Schedule II, III, IV, or V controlled substance electronically if all of the following conditions are met:

(1) The practitioner is registered as an individual practitioner or exempt from the requirement of registration under part 1301 of this chapter and is authorized under the registration or