(c) Any prescription not signed in the manner required by this section shall not be transmitted.

§ 1311.145 Digitally signing the prescription with the individual practitioner's private key.

(a) An individual practitioner who has obtained a digital certificate as provided in §1311.105 may digitally sign a controlled substance prescription using the private key associated with his digital certificate.

(b) The electronic prescription application must require the individual practitioner to complete a two-factor authentication protocol as specified in §1311.140(a)(4) to use his private key.

(c) The electronic prescription application must digitally sign at least all information required under part 1306 of this chapter.

(d) The electronic prescription application must electronically archive the digitally signed record.

(e) A prescription that is digitally signed with a practitioner's private key may be transmitted to a pharmacy without the digital signature.

(f) If the electronic prescription is transmitted without the digital signature, the electronic prescription application must check the certificate revocation list of the certification authority that issued the practitioner's digital certificate. If the digital certificate is not valid, the electronic prescription application must not transmit the prescription. The certificate revocation list may be cached until the certification authority issues a new certificate revocation list.

(g) When the individual practitioner digitally signs a controlled substance prescription with the private key associated with his own digital certificate obtained as provided under §1311.105, the electronic prescription application is not required to digitally sign the prescription using the application's private key.

§ 1311.150 Additional requirements for internal application audits.

(a) The application provider must establish and implement a list of auditable events. Auditable events must, at a minimum, include the following:

(1) Attempted unauthorized access to the electronic prescription application, or successful unauthorized access where the determination of such is feasible.

(2) Attempted unauthorized modification or destruction of any information or records required by this part, or successful unauthorized modification or destruction of any information or records required by this part where the determination of such is feasible.

(3) Interference with application operations of the prescription application.

(4) Any setting of or change to logical access controls related to the issuance of controlled substance prescriptions.

(5) Attempted or successful interference with audit trail functions.

(6) For application service providers, attempted or successful creation, modification, or destruction of controlled substance prescriptions or logical access controls related to controlled substance prescriptions by any agent or employee of the application service provider.

(b) The electronic prescription application must analyze the audit trail at least once every calendar day and generate an incident report that identifies each auditable event.

(c) Any person designated to set logical access controls under §§1311.125 or 1311.130 must determine whether any identified auditable event represents a security incident that compromised or could have compromised the integrity of the prescription records. Any such incidents must be reported to the electronic prescription application provider and the Administration within one business day.

§ 1311.170 Transmission requirements.

(a) The electronic prescription application must transmit the electronic prescription as soon as possible after signature by the practitioner.

(b) The electronic prescription application may print a prescription that has been transmitted only if an intermediary or the designated pharmacy
§ 1311.200 Pharmacy responsibilities.

(a) Before initially using a pharmacy application to process controlled substance prescriptions, the pharmacy must determine that the third-party auditor or certification organization has found that the pharmacy application does the following accurately and consistently:

(1) Import, store, and display the information required for prescriptions under §1306.05(a) of this chapter.

(2) Import, store, and display the indication of signing as required by §1311.120(b)(17).

(3) Import, store, and display the number of refills as required by §1306.22 of this chapter.

(4) Import, store, and verify the practitioner’s digital signature, as provided in §1311.210(c), where applicable.

(b) If the third-party auditor or certification organization has found that a pharmacy application does not accurately and consistently import, store, and display other information required for prescriptions under this chapter, the pharmacy must not process electronic prescriptions for controlled substances that are subject to the additional information requirements.

(c) If a pharmacy application provider notifies a pharmacy that a third-party audit or certification report indicates that the application or the application provider no longer meets the requirements of this part or notifies it that the application provider has identified an issue that makes the application non-compliant, the pharmacy must immediately cease to process controlled substance prescriptions using the application.

(d) A pharmacy that receives a notification that the pharmacy application is not in compliance with the requirements of this part must not use the application to process controlled substance prescriptions until it is notified that the application is again compliant and all relevant updates to the application have been installed.

(e) The pharmacy must determine which employees are authorized to enter information regarding the dispensing of controlled substance prescriptions and annotate or alter records of these prescriptions (to the extent such alterations are permitted under this chapter). The pharmacy must ensure that logical access controls in the pharmacy application are set so that only such employees are granted access to perform these functions.