

§ 1311.140

agent to enter data for a controlled substance prescription, provided that only the registrant may sign the prescription in accordance with §§ 1311.120(b)(11) and 1311.140.

(b) If a practitioner holds multiple DEA registrations, the practitioner or his agent must select the appropriate registration number for the prescription being issued in accordance with the requirements of § 1301.12 of this chapter.

(c) If required by State law, a supervisor's name and DEA number may be listed on a prescription, provided the prescription clearly indicates who is the supervisor and who is the prescribing practitioner.

§ 1311.140 Requirements for signing a controlled substance prescription.

(a) For a practitioner to sign an electronic prescription for a controlled substance the following must occur:

(1) The practitioner must access a list of one or more controlled substance prescriptions for a single patient. The list must display the information required by § 1311.120(b)(9).

(2) The practitioner must indicate the prescriptions that are ready to be signed.

(3) While the prescription information required in § 1311.120(b)(9) is displayed, the following statement or its substantial equivalent is displayed: "By completing the two-factor authentication protocol at this time, you are legally signing the prescription(s) and authorizing the transmission of the above information to the pharmacy for dispensing. The two-factor authentication protocol may only be completed by the practitioner whose name and DEA registration number appear above."

(4) While the prescription information required in § 1311.120(b)(9) and the statement required by paragraph (a)(3) of this section remain displayed, the practitioner must be prompted to complete the two-factor authentication protocol.

(5) The completion by the practitioner of the two-factor authentication protocol in the manner provided in paragraph (a)(4) of this section will constitute the signing of the prescrip-

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tion by the practitioner for purposes of § 1306.05(a) and (e) of this chapter.

(6) Except as provided under § 1311.145, the practitioner's completion of the two-factor authentication protocol must cause the application to digitally sign and electronically archive the information required under part 1306 of this chapter.

(b) The electronic prescription application must clearly label as the signing function the function that prompts the practitioner to execute the two-factor authentication protocol using his credential.

(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 pro-

vider 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 notifies a practitioner that an electronic prescription was not successfully delivered to the designated pharmacy. If this occurs, the electronic prescription application may print the prescription for the practitioner's manual signature. The printed prescription must include information noting that the prescription was originally transmitted electronically to [name of the specific pharmacy] on [date/time] and that transmission failed.

(c) The electronic prescription application may print copies of the transmitted prescription if they are clearly labeled: "Copy only—not valid for dispensing." Data on the prescription may be electronically transferred to medical records, and a list of prescriptions written may be printed for patients if the list indicates that it is for informational purposes only and not for dispensing.

(d) The electronic prescription application must not allow the transmission of an electronic prescription if an original prescription was printed prior to attempted transmission.

(e) The contents of the prescription required by part 1306 of this chapter must not be altered during transmission between the practitioner and pharmacy. Any change to the content during transmission, including truncation or removal of data, will render the electronic prescription invalid. The electronic prescription data may be converted from one software version to another between the electronic prescription application and the pharmacy application; conversion includes altering the structure of fields or machine language so that the receiving pharmacy application can read the prescription and import the data.

(f) An electronic prescription must be transmitted from the practitioner to