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(12) The pharmacy application must allow downloading of prescription data into a database or spreadsheet that is readable and sortable.

(13) The pharmacy application must maintain an audit trail of all actions related to the following:

(i) The receipt, annotation, alteration, or deletion of a controlled substance prescription.

(ii) Any setting or changing of logical access control permissions related to the dispensing of controlled substance prescriptions.

(iii) Auditable events as specified in § 1311.215.

(14) The pharmacy application must record within each audit record the following information:

(i) The date and time of the event.

(ii) The type of event.

(iii) The identity of the person taking the action, where applicable.

(iv) The outcome of the event (success or failure).

(15) The pharmacy application must conduct internal audits and generate reports on any of the events specified in § 1311.215 in a format that is readable by the pharmacist. Such an internal audit may be automated and need not require human intervention to be conducted.

(16) The pharmacy application must protect the stored audit records from unauthorized deletion. The pharmacy application shall prevent modifications to the audit records.

(17) The pharmacy application must back up the controlled substance prescription records daily.

(18) The pharmacy application must retain all archived records electronically for at least two years from the date of their receipt or creation and comply with all other requirements of § 1311.305.

§ 1311.210 Archiving the initial record.

(a) Except as provided in paragraph (c) of this section, a copy of each electronic controlled substance prescription record that a pharmacy receives must be digitally signed by one of the following:

(1) The last intermediary transmitting the record to the pharmacy must digitally sign the prescription immediately prior to transmission to the pharmacy.

(2) The first pharmacy application that receives the electronic prescription must digitally sign the prescription immediately on receipt.

(b) If the last intermediary digitally signs the record, it must forward the digitally signed copy to the pharmacy.

(c) If a pharmacy receives a digitally signed prescription that includes the individual practitioner's digital signature, the pharmacy application must do the following:

(1) Verify the digital signature as provided in FIPS 186–3, as incorporated by reference in § 1311.08.

(2) Check the validity of the certificate holder's digital certificate by checking the certificate revocation list. The pharmacy may cache the CRL until it expires.

(3) Archive the digitally signed record. The pharmacy record must retain an indication that the prescription was verified upon receipt. No additional digital signature is required.

§ 1311.215 Internal audit trail.

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

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

(2) Attempted or successful 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 pharmacy application.

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

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

(6) For application service providers, attempted or successful annotation, alteration, 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 pharmacy application must analyze the audit trail at least once every calendar day and generate an incident report that identifies each auditable event.

(c) The pharmacy 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 pharmacy application service provider, if applicable, and the Administration within one business day.

§ 1311.300 Application provider requirements—Third-party audits or certifications.

(a) Except as provided in paragraph (e) of this section, the application provider of an electronic prescription application or a pharmacy application must have a third-party audit of the application that determines that the application meets the requirements of this part at each of the following times:

(1) Before the application may be used to create, sign, transmit, or process controlled substance prescriptions.

(2) Whenever a functionality related to controlled substance prescription requirements is altered or every two years, whichever occurs first.

(b) The third-party audit must be conducted by one of the following:

(1) A person qualified to conduct a SysTrust, WebTrust, or SAS 70 audit.

(2) A Certified Information System Auditor who performs compliance audits as a regular ongoing business activity.

(c) An audit for installed applications must address processing integrity and determine that the application meets the requirements of this part.

(d) An audit for application service providers must address processing integrity and physical security and determine that the application meets the requirements of this part.

(e) If a certifying organization whose certification process has been approved by DEA verifies and certifies that an electronic prescription or pharmacy application meets the requirements of this part, certification by that organization may be used as an alternative to the audit requirements of paragraphs (b) through (d) of this section, provided that the certification that determines that the application meets the requirements of this part occurs at each of the following times:

(1) Before the application may be used to create, sign, transmit, or process controlled substance prescriptions.

(2) Whenever a functionality related to controlled substance prescription requirements is altered or every two years, whichever occurs first.

(f) The application provider must make the audit or certification report available to any practitioner or pharmacy that uses the application or is considering use of the application. The electronic prescription or pharmacy application provider must retain the most recent audit or certification results and retain the results of any other audits or certifications of the application completed within the previous two years.

(g) Except as provided in paragraphs (h) and (i) of this section, if the third-party auditor or certification organization finds that the application does not meet one or more of the requirements of this part, the application must not be used to create, sign, transmit, or process electronic controlled substance prescriptions. The application provider must notify registrants within five business days of the issuance of the audit or certification report that they should not use the application for controlled substance prescriptions. The application provider must also notify the Administration of the adverse audit or certification report and provide the report to the Administration within one business day of issuance.

(h) For electronic prescription applications, the third-party auditor or certification organization must make the following determinations:

(1) If the information required in §1306.05(a) of this chapter, the indication that the prescription was signed as required by §1311.120(b)(17) or the digital signature created by the practitioner's private key, if transmitted,