Drug Enforcement Administration, Justice

§ 1311.305

and the number of refills as required by § 1306.22 of this chapter, cannot be consistently and accurately recorded, stored, and transmitted, the third-party auditor or certification organization must indicate that the application does not meet the requirements of this part.

(2) If other information required under this chapter cannot be consistently and accurately recorded, stored, and transmitted, the third-party auditor or certification organization must indicate that the application has failed to meet the requirements for the specific information and should not be used to create, sign, and transmit prescriptions that require the additional information.

(i) For pharmacy 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 § 1311.205(b)(6), and the number of refills as required by § 1306.22 of this chapter, cannot be consistently and accurately imported, stored, and displayed, the third-party auditor or certification organization must indicate that the application does not meet the requirements of this part.

(2) If the pharmacy application accepts prescriptions with the practitioner’s digital signature, the third-party auditor or certification organization must indicate that the application does not meet the requirements of this part.

(3) If other information required under this chapter cannot be consistently and accurately imported, stored, and displayed, the third-party auditor or certification organization must indicate that the application has failed to meet the requirements for the specific information and should not be used to process electronic prescriptions that require the additional information.

§ 1311.302 Additional application provider requirements.

(a) If an application provider identifies or is made aware of any issue with its application that makes the application non-compliant with the requirements of this part, the application provider must notify practitioners or pharmacies that use the application as soon as feasible, but no later than five business days after discovery, that the application should not be used to issue or process electronic controlled substance prescriptions.

(b) When providing practitioners or pharmacies with updates to any issue that makes the application non-compliant with the requirements of this part, the application provider must indicate that the updates must be installed before the practitioner or pharmacy may use the application to issue or process electronic controlled substance prescriptions.

§ 1311.305 Recordkeeping.

(a) If a prescription is created, signed, transmitted, and received electronically, all records related to that prescription must be retained electronically.

(b) Records required by this subpart must be maintained electronically for two years from the date of their creation or receipt. This record retention requirement shall not pre-empt any longer period of retention which may be required now or in the future, by any other Federal or State law or regulation, applicable to practitioners, pharmacists, or pharmacies.

(c) Records regarding controlled substances prescriptions must be readily retrievable from all other records. Electronic records must be easily readable or easily rendered into a format that a person can read.

(d) Records required by this part must be made available to the Administrator upon request.

(e) If an application service provider ceases to provide an electronic prescription application or an electronic pharmacy application or if a registrant ceases to use an application service provider, the application service provider must transfer any records subject to this part to the registrant in a format that the registrant’s applications are capable of retrieving, displaying, and printing in a readable format.

(f) If a registrant changes application providers, the registrant must ensure that any records subject to this part