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 Administration 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 are migrated to the new application or are stored in a format that can be retrieved, displayed, and printed in a readable format.

(g) If a registrant transfers its electronic prescription files to another registrant, both registrants must ensure that the records are migrated to the new application or are stored in a format that can be retrieved, displayed, and printed in a readable format.

(h) Digitally signed prescription records must be transferred or migrated with the digital signature.

PART 1312—IMPORTATION AND EXPORTATION OF CONTROLLED SUBSTANCES

Sec.

AUTHORITY: 21 U.S.C. 821, 871(b), 952, 953, 954, 957, 958.

SOURCE: 36 FR 7815, Apr. 24, 1971, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 24, 1973.

§ 1312.01 Scope of part 1312.

Procedures governing the importation, exportation, transshipment and intransit shipment of controlled substances pursuant to section 1002, 1003, and 1004 of the Act (21 U.S.C. 952, 953, and 954) are governed generally by those sections and specifically by the sections of this part.

§ 1312.02 Definitions.

Any term contained in this part shall have the definition set forth in section

102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

[62 FR 13969, Mar. 24, 1997]

§ 1312.03 Forms applicable to this part.

Form	Access/ submission
DEA Form 35, Permit to Import	electronic.
DEA Form 36, Permit to Export	electronic.
DEA Form 161, Application for Permit to Export Controlled Substances	electronic.
DEA Form 161R, Application for Permit to Export Controlled Substances For Subsequent Reexport	electronic.
DEA Form 161R–EEA, Application for Permit to Export Controlled Substances for Subsequent Reexport Among Members of the European Economic Area.	electronic.
DEA Form 236, Controlled Substances Import/Export Declaration	electronic.
DEA Form 357, Application for Permit to Import Controlled Substances for Domestic And/Or Scientific Purposes.	electronic.

[81 FR 97025, Dec. 30, 2016]

IMPORTATION OF CONTROLLED SUBSTANCES

§ 1312.11 Requirement of authorization to import.

(a) No person shall import, or cause to be imported, into the customs territory of the United States from any place outside thereof (but within the United States), or into the United States from any place outside thereof, any controlled substances listed in Schedule I or II, or any narcotic controlled substance listed in Schedule III, IV, or V, or any non-narcotic controlled substance listed in Schedule III which the Administrator has specifically designated by regulation in §1312.30 or any non-narcotic controlled substance listed in Schedule IV or V which is also listed in Schedule I or II of the Convention on Psychotropic Substances, 1971, unless and until such person is properly registered under the Act (or, in accordance with part 1301 of this chapter, exempt from registration) and the Administration has issued him or her a permit to do so in accordance with §1312.13.

(b) No person shall import, or cause to be imported, into the customs territory of the United States from any place outside thereof (but within the United States), or into the United States from any place outside thereof, any non-narcotic controlled substance listed in Schedule III, IV, or V, excluding those described in paragraph (a) of this section, unless and until such person is properly registered under the Act (or, in accordance with part 1301 of this chapter, exempt from registration) and has filed an import declaration to do so in accordance with §1312.18.

(c) A separate permit or declaration is required for each shipment of a controlled substance to be imported.

[81 FR 97026, Dec. 30, 2016]

§ 1312.12 Application for import permit; return information.

(a) Registered importers, other registrants authorized to import as a coincident activity of their registrations, and persons who in accordance with part 1301 of this chapter are exempt from registration, seeking to import a controlled substance in schedule I or II; any narcotic drug in schedule III, IV, or V; any non-narcotic drug in schedule III that has been specifically designated by regulation in §1312.30; or any non-narcotic substance listed in schedule IV or V that is also listed in schedule I or II of the Convention on Psychotropic Substances, 1971, must submit an application for a permit to import controlled substances on DEA Form 357. All applications and supporting materials must be submitted to the Administration through the DEA Diversion Control Division secure network application. The application must be signed and dated by the importer and must contain the importer's registered address to which the controlled substances will be imported.

(b) The applicant must include on the DEA Form 357 the registration number of the importer and a detailed description of each controlled substance to be imported including the drug name, dosage form, National Drug Code (NDC) number, the Administration Controlled Substance Code Number as set forth in