

Drug Enforcement Administration, Justice

§ 1311.08

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

1311.302 Additional application provider requirements.

1311.305 Recordkeeping.

AUTHORITY: 21 U.S.C. 821, 828, 829, 871(b), 958(e), 965, unless otherwise noted.

SOURCE: 70 FR 16915, Apr. 1, 2005, unless otherwise noted.

Subpart A—General

§ 1311.01 Scope.

This part sets forth the rules governing the creation, transmission, and storage of electronic orders and prescriptions.

[75 FR 16310, Mar. 31, 2010]

§ 1311.02 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.

[75 FR 16310, Mar. 31, 2010]

§ 1311.05 Standards for technologies for electronic transmission of orders.

(a) A registrant or a person with power of attorney to sign orders for Schedule I and II controlled substances may use any technology to sign and electronically transmit orders if the technology provides all of the following:

(1) *Authentication*: The system must enable a recipient to positively verify the signer without direct communication with the signer and subsequently demonstrate to a third party, if needed, that the sender's identity was properly verified.

(2) *Nonrepudiation*: The system must ensure that strong and substantial evidence is available to the recipient of the sender's identity, sufficient to prevent the sender from successfully denying having sent the data. This criterion includes the ability of a third party to verify the origin of the document.

(3) *Message integrity*: The system must ensure that the recipient, or a third party, can determine whether the contents of the document have been altered during transmission or after receipt.

(b) DEA has identified the following means of electronically signing and transmitting order forms as meeting all of the standards set forth in paragraph (a) of this section.

(1) Digital signatures using Public Key Infrastructure (PKI) technology.

(2) [Reserved]

§ 1311.08 Incorporation by reference.

(a) These incorporations by reference were approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be inspected at the Drug Enforcement Administration, 600 Army Navy Drive, Arlington, VA 22202 or at the National Archives and Records Administration (NARA). For information on the availability of this material at the Drug Enforcement Administration, call (202) 307-1000. For information on the availability of this material at NARA, call (202) 741-6030 or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(b) These standards are available from the National Institute of Standards and Technology, Computer Security Division, Information Technology Laboratory, National Institute of Standards and Technology, 100 Bureau Drive, Gaithersburg, MD 20899-8930, (301) 975-6478 or TTY (301) 975-8295, inquiries@nist.gov, and are available at <http://csrc.nist.gov>. The following standards are incorporated by reference:

(1) Federal Information Processing Standard Publication (FIPS PUB) 140-2, Change Notices (12-03-2002), Security Requirements for Cryptographic Modules, May 25, 2001 (FIPS 140-2) including Annexes A through D; incorporation by reference approved for §§ 1311.30(b), 1311.55(b), 1311.115(b), 1311.120(b), 1311.205(b).

(i) *Annex A*: Approved Security Functions for FIPS PUB 140-2, Security Requirements for Cryptographic Modules, September 23, 2004.

(ii) *Annex B*: Approved Protection Profiles for FIPS PUB 140-2, Security Requirements for Cryptographic Modules, November 4, 2004.

(iii) *Annex C*: Approved Random Number Generators for FIPS PUB 140-2, Security Requirements for Cryptographic Modules, January 31, 2005.