

§ 1304.05

name, patient name, drug dispensed, and date filled.

(Authority: 21 U.S.C. 821 and 871(b); 28 CFR 0.100)

[36 FR 7790, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 39 FR 37985, Oct. 25, 1974; 45 FR 44266, July 1, 1980; 47 FR 41735, Sept. 22, 1982; 51 FR 5320, Feb. 13, 1986; 62 FR 13959, Mar. 24, 1997; 70 FR 25466, May 13, 2005; 75 FR 10677, Mar. 9, 2010; 75 FR 16306, Mar. 31, 2010; 79 FR 53562, Sept. 9, 2014; 86 FR 33885, June 28, 2021]

§ 1304.05 Records of authorized central fill pharmacies and retail pharmacies.

(a) Every retail pharmacy that utilizes the services of a central fill pharmacy must keep a record of all central fill pharmacies, including name, address and DEA number, that are authorized to fill prescriptions on its behalf. The retail pharmacy must also verify the registration for each central fill pharmacy authorized to fill prescriptions on its behalf. These records must be made available upon request for inspection by DEA.

(b) Every central fill pharmacy must keep a record of all retail pharmacies, including name, address and DEA number, for which it is authorized to fill prescriptions. The central fill pharmacy must also verify the registration for all retail pharmacies for which it is authorized to fill prescriptions. These records must be made available upon request for inspection by DEA.

[68 FR 37410, June 24, 2003]

§ 1304.06 Records and reports for electronic prescriptions.

(a) As required by §1311.120 of this chapter, a practitioner who issues electronic prescriptions for controlled substances must use an electronic prescription application that retains the following information:

(1) The digitally signed record of the information specified in part 1306 of this chapter.

(2) The internal audit trail and any auditable event identified by the internal audit as required by §1311.150 of this chapter.

(b) An institutional practitioner must retain a record of identity proofing and issuance of the two-factor au-

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thentication credential, where applicable, as required by §1311.110 of this chapter.

(c) As required by §1311.205 of this chapter, a pharmacy that processes electronic prescriptions for controlled substances must use an application that retains the following:

(1) All of the information required under §1304.22(c) and part 1306 of this chapter.

(2) The digitally signed record of the prescription as received as required by §1311.210 of this chapter.

(3) The internal audit trail and any auditable event identified by the internal audit as required by §1311.215 of this chapter.

(d) A registrant and application service provider must retain a copy of any security incident report filed with the Administration pursuant to §§1311.150 and 1311.215 of this chapter.

(e) An electronic prescription or pharmacy application provider must retain third party audit or certification reports as required by §1311.300 of this chapter.

(f) An application provider must retain a copy of any notification to the Administration regarding an adverse audit or certification report filed with the Administration on problems identified by the third-party audit or certification as required by §1311.300 of this chapter.

(g) Unless otherwise specified, records and reports must be retained for two years.

[75 FR 16306, Mar. 31, 2010]

INVENTORY REQUIREMENTS

§ 1304.11 Inventory requirements.

(a) *General requirements.* Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. An inventory taken by use of an oral recording device must be promptly transcribed. Controlled substances shall be deemed to be “on hand” if they are in the possession of or under the control of the registrant, including substances returned by a customer, ordered by a customer but not yet invoiced, stored in a