

common or contract carriers to retrieve filled prescriptions from a central fill pharmacy, the retail pharmacy is responsible for reporting in-transit losses upon discovery of such loss by use of a DEA Form 106.

#### **PART 1304—[AMENDED]**

- 1. The authority citation for part 1304 continues to read as follows:

**Authority:** 21 U.S.C. 821, 827, 871(b), 958(e), 965, unless otherwise noted.

- 2. Section 1304.05 is added to read as follows:

##### **§ 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.

#### **PART 1305—[AMENDED]**

- 1. The authority citation for part 1305 continues to read as follows:

**Authority:** 21 U.S.C. 821, 828, 871(b), unless otherwise noted.

- 2. Section 1305.03 is revised to read as follows:

##### **§ 1305.03 Distributions requiring order forms.**

An order form (DEA Form 222) is required for each distribution of a Schedule I or II controlled substance except to persons exempted from registration under part 1301 of this chapter; which are exported from the United States in conformity with the Act; for delivery to a registered analytical laboratory, or its agent approved by DEA; or for delivery from a central fill pharmacy, as defined in § 1300.01(b)(43), to a retail pharmacy.

#### **PART 1306—[AMENDED]**

- 1. The authority citation for part 1306 continues to read as follows:

**Authority:** 21 U.S.C. 821, 829, 871(b), unless otherwise noted.

- 2. Section 1306.05 is amended by revising paragraph (a) to read as follows:

##### **§ 1306.05 Manner of issuance of prescriptions.**

(a) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the name, address and registration number of the practitioner. A practitioner may sign a prescription in the same manner as he would sign a check or legal document (e.g., J.H. Smith or John H. Smith). Where an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typewriter and shall be manually signed by the practitioner. The prescriptions may be prepared by the secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist, including a pharmacist employed by a central fill pharmacy, who fills a prescription not prepared in the form prescribed by these regulations.

\* \* \* \* \*

- 3. Section 1306.06 is revised to read as follows:

##### **§ 1306.06 Persons entitled to fill prescriptions.**

A prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice and either registered individually or employed in a registered pharmacy, a registered central fill pharmacy, or registered institutional practitioner.

- 4. Section 1306.11 is amended by adding a new paragraph (d)(5) to read as follows:

##### **§ 1306.11 Requirement of prescription.**

\* \* \* \* \*

(d) \* \* \*

(5) Central fill pharmacies shall not be authorized under this paragraph to prepare prescriptions for a controlled substance listed in Schedule II upon receiving an oral authorization from a retail pharmacist or an individual practitioner.

\* \* \* \* \*

- 5. Section 1306.14 is amended by redesignating existing paragraphs (b) and (c) as paragraphs (c) and (d), and by

adding a new paragraph (b) to read as follows:

##### **§ 1306.14 Labeling of substances and filling of prescriptions.**

\* \* \* \* \*

(b) If the prescription is filled at a central fill pharmacy, the central fill pharmacy shall affix to the package a label showing the retail pharmacy name and address and a unique identifier, (i.e. the central fill pharmacy's DEA registration number) indicating that the prescription was filled at the central fill pharmacy, in addition to the information required under paragraph (a) of this section.

\* \* \* \* \*

- 6. Section 1306.15 is added to read as follows:

##### **§ 1306.15 Provision of prescription information between retail pharmacies and central fill pharmacies for prescriptions of Schedule II controlled substances.**

Prescription information may be provided to an authorized central fill pharmacy by a retail pharmacy for dispensing purposes. The following requirements shall also apply:

(a) Prescriptions for controlled substances listed in Schedule II may be transmitted electronically from a retail pharmacy to a central fill pharmacy including via facsimile. The retail pharmacy transmitting the prescription information must:

(1) Write the word "CENTRAL FILL" on the face of the original prescription and record the name, address, and DEA registration number of the central fill pharmacy to which the prescription has been transmitted and, the name of the retail pharmacy pharmacist transmitting the prescription, and the date of transmittal;

(2) Ensure that all information required to be on a prescription pursuant to Section 1306.05 of this part is transmitted to the central fill pharmacy (either on the face of the prescription or in the electronic transmission of information);

(3) Maintain the original prescription for a period of two years from the date the prescription was filled;

(4) Keep a record of receipt of the filled prescription, including the date of receipt, the method of delivery (private, common or contract carrier) and the name of the retail pharmacy employee accepting delivery.

(b) The central fill pharmacy receiving the transmitted prescription must:

(1) Keep a copy of the prescription (if sent via facsimile) or an electronic record of all the information transmitted by the retail pharmacy, including the name, address, and DEA registration