

PART 1304—RECORDS AND REPORTS OF REGISTRANTS [AMENDED]

1. The authority citation for 21 CFR Part 1304 continues to read as follows:

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

2. Section 1304.22 is proposed to be amended by revising paragraph (c) to read as follows:

§ 1304.22 Records for manufacturers, distributors, dispensers, researchers, importers and exporters.

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(c) *Records for dispensers and researchers.* Each person registered or authorized to dispense or conduct research with controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraph (a)(2) (i), (ii), (iv), (vii), and (ix) of this section. In addition, records shall be maintained of the number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser. In addition to the requirements of this paragraph practitioners dispensing gamma-hydroxybutyric acid pursuant to a prescription must also comply with § 1304.26.

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3. Section 1304.26 is proposed to be added to read as follows:

§ 1304.26 Additional recordkeeping requirements applicable to drug products containing gamma-hydroxybutyric acid.

In addition to the recordkeeping requirements for dispensers and researchers provided in § 1304.22, practitioners dispensing gamma-hydroxybutyric acid that is manufactured or distributed in accordance with an application under section 505 of the Federal Food, Drug, and Cosmetic Act must maintain, and make available for inspection and copying by the Attorney General, all of the following records for each prescription:

(a) Name of the prescribing practitioner.

(b) Prescribing practitioner's Federal and State registration numbers, with the expiration dates of these registrations.

(c) Verification that the prescribing practitioner possesses the appropriate registration to prescribe this controlled substance.

(d) Patient's name and address.

(e) Patient's insurance provider, if available.

4. Section 1304.33 is proposed to be amended by revising paragraph (c) and the introductory text of paragraph (d)(1) to read as follows:

§ 1304.33 Reports to ARCOS.

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(c) *Persons reporting.* For controlled substances in Schedules I, II, narcotic controlled substances in Schedule III, and gamma-hydroxybutyric acid drug product controlled substances in Schedule III, each person who is registered to manufacture in bulk or dosage form, or to package, repack, label or relabel, and each person who is registered to distribute, including each person who is registered to reverse distribute, shall report acquisition/distribution transactions. In addition to reporting acquisition/distribution transactions, each person who is registered to manufacture controlled substances in bulk or dosage form shall report manufacturing transactions on controlled substances in Schedules I and II, each narcotic controlled substance listed in Schedules III, IV, and V, gamma-hydroxybutyric acid drug product controlled substances in Schedule III, and on each psychotropic controlled substance listed in Schedules III and IV as identified in paragraph (d) of this section.

(d) *Substances covered.* (1) Manufacturing and acquisition/distribution transaction reports shall include data on each controlled substance listed in Schedules I and II, on each narcotic controlled substance listed in Schedule III (but not on any material, compound, mixture or preparation containing a quantity of a substance having a stimulant effect on the central nervous system, which material, compound, mixture or preparation is listed in Schedule III or on any narcotic controlled substance listed in Schedule V), and on gamma-hydroxybutyric acid drug products listed in Schedule III. Additionally, reports on manufacturing transactions shall include the following psychotropic controlled substances listed in Schedules III and IV:

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PART 1306—PRESCRIPTIONS [AMENDED]

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

Authority: 21 U.S.C. 821, 829, 871(b).

2. Section 1306.05 is proposed to be 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. Where a prescription is for gamma-hydroxybutyric acid, the practitioner shall note on the face of the prescription the medical need of the patient for the prescription. 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 DEA regulations.

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PART 1310—RECORDS AND REPORTS OF LISTED CHEMICALS AND CERTAIN MACHINES [AMENDED]

1. The authority citation for part 1310 is revised to read as follows:

Authority: 21 U.S.C. 802, 827(h), 830, 871(b).

2. Section 1310.03 is proposed to be amended by revising paragraph (c) to read as follows:

§ 1310.03 Persons required to keep records and file reports.

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(c) Each regulated person who engages in a transaction with a nonregulated person or who engages in an export transaction that involves ephedrine, pseudoephedrine, or phenylpropanolamine, or gamma-hydroxybutyric acid, including drug products containing these chemicals, and uses or attempts to use the Postal Service or any private or commercial carrier must file monthly reports of each such transaction as specified in § 1310.05 of this part.