

PART 1306—PRESCRIPTIONS

GENERAL INFORMATION

Sec.

- 1306.01 Scope of part 1306.
- 1306.02 Definitions.
- 1306.03 Persons entitled to issue prescriptions.
- 1306.04 Purpose of issue of prescription.
- 1306.05 Manner of issuance of prescriptions.
- 1306.06 Persons entitled to fill prescriptions.
- 1306.07 Administering or dispensing of narcotic drugs.
- 1306.08 Electronic prescriptions.
- 1306.09 Prescription requirements for online pharmacies.

CONTROLLED SUBSTANCES LISTED IN SCHEDULE II

- 1306.11 Requirement of prescription.
- 1306.12 Refilling prescriptions; issuance of multiple prescriptions.
- 1306.13 Partial filling of prescriptions.
- 1306.14 Labeling of substances and filling of prescriptions.
- 1306.15 Provision of prescription information between retail pharmacies and central fill pharmacies for prescriptions of Schedule II controlled substances.

CONTROLLED SUBSTANCES LISTED IN SCHEDULES III, IV, AND V

- 1306.21 Requirement of prescription.
- 1306.22 Refilling of prescriptions.
- 1306.23 Partial filling of prescriptions.
- 1306.24 Labeling of substances and filling of prescriptions.
- 1306.25 Transfer between pharmacies of prescription information for Schedules III, IV, and V controlled substances for refill purposes.
- 1306.26 Dispensing without prescription.
- 1306.27 Provision of prescription information between retail pharmacies and central fill pharmacies for initial and refill prescriptions of Schedule III, IV, or V controlled substances.

AUTHORITY: 21 U.S.C. 821, 823, 829, 829a, 831, 871(b) unless otherwise noted.

SOURCE: 36 FR 7799, Apr. 24, 1971; 36 FR 13386, July 21, 1971, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 24, 1973.

GENERAL INFORMATION

§ 1306.01 Scope of part 1306.

Rules governing the issuance, filling and filing of prescriptions pursuant to section 309 of the Act (21 U.S.C. 829) are set forth generally in that section and specifically by the sections of this part.

§ 1306.02 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 13964, Mar. 24, 1997]

§ 1306.03 Persons entitled to issue prescriptions.

(a) A prescription for a controlled substance may be issued only by an individual practitioner who is:

(1) Authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession and

(2) Either registered or exempted from registration pursuant to §§ 1301.22(c) and 1301.23 of this chapter.

(b) A prescription issued by an individual practitioner may be communicated to a pharmacist by an employee or agent of the individual practitioner.

[36 FR 7799, Apr. 24, 1971, as amended at 36 FR 18732, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, as amended at 62 FR 13966, Mar. 24, 1997]

§ 1306.04 Purpose of issue of prescription.

(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

(b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for

§ 1306.05

21 CFR Ch. II (4–1–23 Edition)

the purpose of general dispensing to patients.

(c) A prescription may not be issued for “detoxification treatment” or “maintenance treatment,” unless the prescription is for a Schedule III, IV, or V narcotic drug approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment and the practitioner is in compliance with requirements in § 1301.28 of this chapter.

(d) A prescription may be issued by a qualifying practitioner, as defined in section 303(g)(2)(G)(iii) of the Act (21 U.S.C. 823(g)(2)(G)(iii)), in accordance with § 1306.05 for a Schedule III, IV, or V controlled substance for the purpose of maintenance or detoxification treatment for the purposes of administration in accordance with section 309A of the Act (21 U.S.C. 829a) and § 1306.07(f). Such prescription issued by a qualifying practitioner shall not be used to supply any practitioner with a stock of controlled substances for the purpose of general dispensing to patients.

[36 FR 7799, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 39 FR 37986, Oct. 25, 1974; 70 FR 36343, June 23, 2005; 85 FR 69167, Nov. 2, 2020]

§ 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.

(b) A prescription for a Schedule III, IV, or V narcotic drug approved by FDA specifically for “detoxification treatment” or “maintenance treatment” must include the identification number issued by the Administrator under § 1301.28(d) of this chapter or a written notice stating that the practitioner is acting under the good faith exception of § 1301.28(e) of this chapter.

(c) 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.

(d) A practitioner may sign a paper 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, paper prescriptions shall be written with ink or indelible pencil, typewriter, or printed on a computer printer and shall be manually signed by the practitioner. A computer-generated prescription that is printed out or faxed by the practitioner must be manually signed.

(e) Electronic prescriptions shall be created and signed using an application that meets the requirements of part 1311 of this chapter.

(f) A prescription 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.

(g) An individual practitioner exempted from registration under § 1301.22(c) of this chapter shall include on all prescriptions issued by him the registration number of the hospital or other institution and the special internal code number assigned to him by the hospital or other institution as provided in § 1301.22(c) of this chapter, in lieu of the registration number of the practitioner required by this section. Each paper prescription shall have the name of the practitioner stamped, typed, or handprinted on it, as well as the signature of the practitioner.

(h) An official exempted from registration under § 1301.23(a) of this chapter must include on all prescriptions issued by him his branch of service or agency (e.g., “U.S. Army” or “Public Health Service”) and his service identification number, in lieu of the registration number of the practitioner required by this section. The service identification number for a Public Health Service employee is his Social Security identification number. Each paper prescription shall have the name of the officer stamped, typed, or