

Drug Enforcement Administration, Justice

§ 1307.11

attempts must be recorded in accordance with the VA's internal policies and recordkeeping requirements.

(c) The controlled substance prescription(s) must be otherwise in conformity with the requirements of the Controlled Substances Act and this chapter.

EFFECTIVE DATE NOTE: At 90 FR 6522, Jan. 17, 2025, §1306.52 was added and delayed at 90 FR 9841, Feb. 19, 2025 and at 90 FR 13410, Mar. 24, 2025 further delayed to Dec. 31, 2025.

PART 1307—MISCELLANEOUS

GENERAL INFORMATION

Sec.

1307.01 Definitions.

1307.02 Application of State law and other Federal law.

1307.03 Exceptions to regulations.

SPECIAL EXCEPTIONS FOR MANUFACTURE AND DISTRIBUTION OF CONTROLLED SUBSTANCES

1307.11 Distribution by dispenser to another practitioner.

1307.13 Incidental manufacture of controlled substances.

DISPOSAL OF CONTROLLED SUBSTANCES

1307.22 Delivery of surrendered and forfeited controlled substances.

SPECIAL EXEMPT PERSONS

1307.31 Native American Church.

SPECIAL EXCEPTIONS RELATED TO TELEMEDICINE

1307.41 Temporary extension of certain COVID-19 telemedicine flexibilities for prescription of controlled medications.

AUTHORITY: 21 U.S.C. 821, 822(d), 871(b), unless otherwise noted.

SOURCE: 36 FR 7801, Apr. 24, 1971, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 24, 1973.

GENERAL INFORMATION

§ 1307.01 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 13966, Mar. 24, 1997]

§ 1307.02 Application of State law and other Federal law.

Nothing in this chapter shall be construed as authorizing or permitting

any person to do any act which such person is not authorized or permitted to do under other Federal laws or obligations under international treaties, conventions or protocols, or under the law of the State in which he/she desires to do such act nor shall compliance with such parts be construed as compliance with other Federal or State laws unless expressly provided in such other laws.

[62 FR 13966, Mar. 24, 1997]

§ 1307.03 Exceptions to regulations.

Any person may apply for an exception to the application of any provision of this chapter by filing a written request with the Office of Diversion Control, Drug Enforcement Administration, stating the reasons for such exception. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address. The Administrator may grant an exception in his discretion, but in no case shall he/she be required to grant an exception to any person which is otherwise required by law or the regulations cited in this section.

[75 FR 10678, Mar. 9, 2010]

SPECIAL EXCEPTIONS FOR MANUFACTURE AND DISTRIBUTION OF CONTROLLED SUBSTANCES

§ 1307.11 Distribution by dispenser to another practitioner.

(a) A practitioner who is registered to dispense a controlled substance may distribute (without being registered to distribute) a quantity of such substance to—

(1) Another practitioner for the purpose of general dispensing by the practitioner to patients, provided that—

(i) The practitioner to whom the controlled substance is to be distributed is registered under the Act to dispense that controlled substance;

(ii) The distribution is recorded by the distributing practitioner in accordance with §1304.22(c) of this chapter and by the receiving practitioner in accordance with §1304.22(c) of this chapter;

(iii) If the substance is listed in Schedule I or II, an order form is used

§ 1307.13

as required in part 1305 of this chapter; and

(iv) The total number of dosage units of all controlled substances distributed by the practitioner pursuant to this section and §1301.25 of this chapter during each calendar year in which the practitioner is registered to dispense does not exceed 5 percent of the total number of dosage units of all controlled substances distributed and dispensed by the practitioner during the same calendar year.

(2) [Reserved]

(b) If, during any calendar year in which the practitioner is registered to dispense, the practitioner has reason to believe that the total number of dosage units of all controlled substances which will be distributed by him pursuant to paragraph (a)(1) of this section and §1301.25 of this chapter will exceed 5 percent of this total number of dosage units of all controlled substances distributed and dispensed by him during that calendar year, the practitioner shall obtain a registration to distribute controlled substances.

(c) The distributions that a registered retail pharmacy makes to automated dispensing systems at long term care facilities for which the retail pharmacy also holds registrations do not count toward the 5 percent limit in paragraphs (a)(1)(iv) and (b) of this section.

[68 FR 41229, July 11, 2003, as amended at 70 FR 25466, May 13, 2005; 79 FR 53565, Sept. 9, 2014]

§ 1307.13 **Incidental manufacture of controlled substances.**

Any registered manufacturer who, incidentally but necessarily, manufactures a controlled substance as a result of the manufacture of a controlled substance or basic class of controlled substance for which he is registered and has been issued an individual manufacturing quota pursuant to part 1303 of this chapter (if such substance or class is listed in Schedule I or II) shall be exempt from the requirement of registration pursuant to part 1301 of this chapter and, if such incidentally manufactured substance is listed in Schedule I or II, shall be exempt from the requirement of an individual manufacturing quota pursuant to part 1303 of this

21 CFR Ch. II (4–1–25 Edition)

chapter, if such substances are disposed of in accordance with part 1317 of this chapter.

[79 FR 53565, Sept. 9, 2014]

DISPOSAL OF CONTROLLED SUBSTANCES

§ 1307.22 **Delivery of surrendered and forfeited controlled substances.**

Any controlled substance surrendered by delivery to the Administration under part 1317 of this chapter or forfeited pursuant to section 511 of the Act (21 U.S.C. 881) may be delivered to any department, bureau, or other agency of the United States or of any State upon proper application addressed to the Office of Diversion Control, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address. The application shall show the name, address, and official title of the person or agency to whom the controlled drugs are to be delivered, including the name and quantity of the substances desired and the purpose for which intended. The delivery of such controlled drugs shall be ordered by the Administrator, if, in his opinion, there exists a medical or scientific need therefor.

[75 FR 10678, Mar. 9, 2010, as amended at 79 FR 53565, Sept. 9, 2014]

SPECIAL EXEMPT PERSONS

§ 1307.31 **Native American Church.**

The listing of peyote as a controlled substance in Schedule I does not apply to the nondrug use of peyote in bona fide religious ceremonies of the Native American Church, and members of the Native American Church so using peyote are exempt from registration. Any person who manufactures peyote for or distributes peyote to the Native American Church, however, is required to obtain registration annually and to comply with all other requirements of law.

SPECIAL EXCEPTIONS RELATED TO
TELEMEDICINE

§ 1307.41 Temporary extension of certain COVID-19 telemedicine flexibilities for prescription of controlled medications.

(a) This section is in effect until the end of the day December 31, 2025. The authorization granted in paragraph (b) of this section expires at the end of December 31, 2025.

(b) During the period May 12, 2023, through December 31, 2025, a DEA-registered practitioner is authorized to prescribe schedule II–V controlled substances via telemedicine, as defined in 21 CFR 1300.04(i), to a patient without having conducted an in-person medical evaluation of the patient if all of the conditions listed in paragraph (c) of this section are met.

(c) A practitioner is only authorized to issue prescriptions for controlled substances pursuant to paragraph (b) of this section if all of the following conditions are met:

(1) The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice;

(2) The prescription is issued pursuant to a communication between a practitioner and a patient using an interactive telecommunications system referred to in 42 CFR 410.78(a)(3);

(3) The practitioner is:

(i) Authorized under their registration under 21 CFR 1301.13(e)(1)(iv) to prescribe the basic class of controlled substance specified on the prescription; or

(ii) Exempt from obtaining a registration to dispense controlled substances under 21 U.S.C. 822(d); and

(4) The prescription is consistent with all other requirements of 21 CFR part 1306.

[88 FR 30042, May 10, 2023, as amended at 88 FR 69882, Oct. 10, 2023; 89 FR 91257, Nov. 19, 2024]

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

GENERAL INFORMATION

Sec.

1308.01 Scope of this part.
1308.02 Definitions.

1308.03 Administration Controlled Substances Code Number.

SCHEDULES

1308.11 Schedule I.
1308.12 Schedule II.
1308.13 Schedule III.
1308.14 Schedule IV.
1308.15 Schedule V.

EXCLUDED NONNARCOTIC SUBSTANCES

1308.21 Application for exclusion of a non-narcotic substance.
1308.22 Excluded substances.

EXEMPT CHEMICAL PREPARATIONS

1308.23 Exemption of certain chemical preparations; application.
1308.24 Exemption chemical preparations.

EXCLUDED VETERINARY ANABOLIC STEROID IMPLANT PRODUCTS

1308.25 Exclusion of a veterinary anabolic steroid implant product; application.
1308.26 Excluded veterinary anabolic steroid implant products.

EXEMPTED PRESCRIPTION PRODUCTS

1308.31 Application for exemption of a non-narcotic prescription product.
1308.32 Exempted prescription products.

EXEMPT ANABOLIC STEROID PRODUCTS

1308.33 Exemption of certain anabolic steroid products; application.
1308.34 Exempt anabolic steroid products.

EXEMPT CANNABIS PLANT MATERIAL, AND PRODUCTS MADE THEREFROM, THAT CONTAIN TETRAHYDROCANNABINOLS

1308.35 Exemption of certain cannabis plant material, and products made therefrom, that contain tetrahydrocannabinols.

HEARINGS

1308.41 Hearings generally.
1308.42 Purpose of hearing.
1308.43 Initiation of proceedings for rule-making.
1308.44 Request for hearing or appearance; waiver.
1308.45 Final order.
1308.46 Control required under international treaty.
1308.47 Control of immediate precursors.
1308.49 Temporary scheduling.
1308.50 Temporary and permanent scheduling of recently emerged anabolic steroids.

AUTHORITY: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

SOURCE: 38 FR 8254, Mar. 30, 1973, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 24, 1973.