

stance listed in schedule V in the course of his professional practice without a prescription, subject to § 306.07.

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in schedule V only pursuant to a written prescription signed by the prescribing individual practitioner, or pursuant to an oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist (containing all information required in § 306.05 except for the signature of the prescribing individual practitioner), or pursuant to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user, subject to § 306.07.

§ 306.32 Dispensing without prescription.

A controlled substance listed in schedule V, and a controlled substance listed in schedule II, III, or IV which is not a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed by a pharmacist without a prescription to a purchaser at retail, provided that:

(a) Such distribution is made only by a pharmacist and not by a nonpharmacist employee even if under the direct supervision of a pharmacist (although after the pharmacist has fulfilled his professional and legal responsibilities set forth in his section, the actual cash, credit transaction, or delivery, may be completed by a nonpharmacist);

(b) Not more than 240 cc. (8 ounces) of any such substance containing opium, nor more than 120 cc. (4 ounces) of any other controlled substance listed in schedule V, may be distributed at retail to the same purchaser in any given 48-hour period;

(c) The purchaser is at least 18 years of age;

(d) The pharmacist requires every purchaser of a controlled substance listed in schedule V not known to him to furnish suitable identification (including proof of age where appropriate);

(e) A bound record book for distributions of controlled substances listed in schedule V (other than by prescription) is maintained by the pharmacist, which book shall contain the name and address of the purchaser, the name and quantity of controlled substance purchased, the date of each purchase, and the name or initials of the pharmacist who distributed the substance to the purchaser (the book shall be maintained in accordance with the recordkeeping requirement of § 304.04 of this chapter); and

(f) A prescription is not required for distribution or dispensing of the substance pursuant to any other Federal, State or local law.

Sec.
 307.03 Exceptions to regulations.

SPECIAL EXCEPTIONS FOR MANUFACTURE AND DISTRIBUTION CONTROLLED SUBSTANCES

- 307.11 Emergency distribution by a dispenser.
- 307.12 Distribution of aqueous or oleaginous solution by pharmacist.
- 307.13 Distribution to supplier.
- 307.14 Distribution upon discontinuance or transfer of business.
- 307.15 Incidental manufacture of controlled substances.

DISPOSAL OF CONTROLLED SUBSTANCES

- 307.21 Procedure for disposing of controlled substances.
- 307.22 Disposal of controlled substances by the Bureau.

SPECIAL EXEMPT PERSONS

- 307.31 Native American Church.

AUTHORITY: The provisions of this Part 307 issued under secs. 301, 302(d), 501(b), 84 Stat. 1253, 1271; U.S.C. 821, 822(d), 871(b).

GENERAL INFORMATION

§ 307.01 Definitions.

As used in this part, the following terms shall have the meanings specified:

(a) The term "Act" means the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801) and/or the Controlled Substances Import and Export Act (84 Stat. 1285; 21 U.S.C. 951).

(b) Any term not defined in this section shall have the definition set forth in sections 102 and 1001 of the Act (21 U.S.C. 802 and 951) and in § 301.02 of this chapter.

§ 307.02 Application of State law and other Federal law.

Nothing in Parts 301-308, 311, 312, or 316 of 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 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.

§ 307.03 Exceptions to regulations.

Any person may apply for an exception to the application of any provision of Parts 301-308, 311, 312, or 316 of this chapter by filing a written request stating the reasons for such exception. Requests shall be filed with the Director, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Washington, D.C. 20537. The Director may grant an exception in his discretion, but in no case shall he be required to grant an exception to any person which is not otherwise required by law or the regulations cited in this section.

SPECIAL EXCEPTIONS FOR MANUFACTURE AND DISTRIBUTION OF CONTROLLED SUBSTANCES

§ 307.11 Emergency distribution by a dispenser.

(a) In the event of an emergency, a dispenser may distribute (without being

registered to distribute) a controlled substance to a second dispenser in order for the second dispenser to dispense the substance, provided that:

(1) The amount distributed does not exceed to the amount required by the second dispenser for immediate dispensing;

(2) The distribution is recorded as a dispensing by the first dispenser, and the receipt as a distribution received by the second dispenser, and each dispenser retains a signed receipt of the distribution;

(3) The second dispenser is registered under the Act to dispense the controlled substance to be distributed to him; and

(4) If the substance is listed in schedule I or II, an order form is used as required in Part 305 of this chapter.

(b) For purposes of this section, an emergency shall mean a situation where a quantity of a controlled substance must be dispensed to a person who does not have an alternative source for such substance reasonably available to him and the dispenser cannot obtain such substance through normal distribution channels within the time required to meet the need of the person for such substance.

§ 307.12 Distribution of aqueous or oleaginous solutions by a pharmacist.

A pharmacist who is registered to dispense or is covered by another person's registration to dispense may distribute (without being registered to distribute) to a registered practitioner, an aqueous or oleaginous solution, in a quantity not exceeding 1 ounce at any one time, containing a narcotic controlled substance in a proportion not exceeding 20 percent of the complete solution, to be used by the practitioner in the course of his professional practice for administration to a patient, provided that a written record is maintained which indicates the date of the transaction, the name, form and quantity of the substance, the name, address, and registration number of the pharmacist (or other registered person), and the name, address, and registration number of the practitioner. In the case of a controlled substance listed in schedule I or II, an order form shall be used in the manner prescribed in Part 305 of this chapter and be maintained as the written record of the transaction.

§ 307.13 Distribution to supplier.

Any person lawfully in possession of a controlled substance listed in any schedule may distribute (without being registered to distribute) that substance to the person from whom he obtained it or to the manufacturer of the substance, provided that a written record is maintained which indicates the date of the transaction, the name, form and quantity of the substance, the name, address, and registration number, if any, of the person making the distribution, and the name, address, and registration number, if known, of the supplier or manufacturer. In the case of returning a controlled substance listed in schedule I or II, an order form shall be used in the manner prescribed in Part 305 of this

PART 307—MISCELLANEOUS

GENERAL INFORMATION

- Sec. 307.01 Definitions.
- 307.02 Application of State law and other Federal law.

chapter and be maintained as the written record of the transaction.

§ 307.14 Distribution upon discontinuance or transfer of business.

(a) Any registrant desiring to discontinue or transfer business activities altogether or with respect to controlled substances shall return his Certificate of Registration, and any unexecuted order forms in his possession, to the Registration Branch, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Post Office Box 28083, Central Station, Washington, D.C. 20005 for cancellation. Any controlled substances in his possession may be disposed of either in accordance with § 307.21 or by transfer to another registrant. If the registrant desires to transfer the substance to another registrant, he shall take an inventory of all controlled substances which he desires to transfer and submit this inventory, together with his name, address, and registration number, and the name, address, and registration number of the proposed transferee, to the Regional Director of the Bureau in the region in which he is doing business at least 15 days in advance of the date of the proposed transfer. If the Regional Director does not notify the registrant that the transfer should be postponed or canceled, the registrant may transfer the substances to the named transferee without being registered as a distributor. All controlled substances listed in schedule I or II must be transferred pursuant to order forms in accordance to Part 305 of this chapter. Schedule III, IV, and V substances will be transferred in accordance to the inventory prepared by the registrant and submitted to the Regional Director. If the Regional Director denies the registrant authority to make the proposed transfer, the registrant shall either dispose of the substance in accordance with § 307.21 or transfer the substances to another registrant in accordance with this section and/or the instructions of the Regional Director.

(b) In the case of registrants required to make reports pursuant to Part 304 of this chapter, a report marked "Final" will be prepared and submitted by the transferor registrant showing the disposition of all the controlled substances for which a report is required; no additional report will be required from him, provided that no further transactions involving controlled substances are consummated by him. The initial report of the transferee registrant shall account for transactions beginning with the day next succeeding the date of discontinuance or transfer of business by the transferor registrant, and the substances transferred to him shall be reported as receipts in his initial report.

§ 307.15 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 303 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 301 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 303 of this chapter, if such substances are disposed of in accordance with § 307.21.

DISPOSAL OF CONTROLLED SUBSTANCES

§ 307.21 Procedure for disposing of controlled substances.

(a) Any person in possession of any controlled substance and desiring or required to dispose of such substance may request the Regional Director of the Bureau in the region in which the person is located for authority and instructions to dispose of such substance. The request should be made as follows:

(1) If the person is a registrant required to make reports pursuant to Part 304 of this chapter, he shall list the controlled substance or substances which he desires to dispose of on the "b" subpart of the report normally filed by him, and submit three copies of that subpart to the Regional Director of the Bureau in his region;

(2) If the person is a registrant not required to make reports pursuant to Part 304 of this chapter, he shall list the controlled substance or substances which he desires to dispose of on BND Form 41, and submit three copies of that form to the Regional Director in his region; and

(3) If the person is not a registrant, he shall submit to the Regional Director a letter stating:

(1) The name and address of the person;

(2) The name and quantity of each controlled substance to be disposed of;

(3) How the applicant obtained the substance, if known; and

(4) The name, address, and registration number, if known, of the person who possessed the controlled substances prior to the applicant, if known.

(b) The Regional Director shall authorize and instruct the applicant to dispose of the controlled substance in one of the following manners:

(1) By transfer to person registered under the Act and authorized to possess the substance;

(2) By delivery to an agent of the Bureau or to the nearest office of the Bureau;

(3) By destruction in the presence of an agent of the Bureau or other authorized person; or

(4) By such other means as the Regional Director may determine to assure that the substance does not become available to unauthorized persons.

(c) This section shall not be construed as affecting or altering in any way the disposal of controlled substances through procedures provided in laws and regulations adopted by any State.

§ 307.22 Disposal of controlled substances by the Bureau.

Any controlled substance delivered to the Bureau under § 307.21 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 Director, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Washington, D.C. 20537. 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 Director, if, in his opinion, there exists a medical or scientific need therefor.

SPECIAL EXEMPT PERSONS

§ 307.31 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.

PART 308—SCHEDULES OF CONTROLLED SUBSTANCES

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308.02	Definitions.
308.03	Bureau Controlled Substances Code Number.

SCHEDULES

308.11	Schedule I.
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308.13	Schedule III.
308.14	Schedule IV.
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EXCLUDED NONNARCOTIC SUBSTANCES

308.21	Application for exclusion of a non-narcotic substance.
308.22	Excluded substances.

EXCEPTED STIMULANT OR DEPRESSANT COMPOUNDS

308.31	Application for exception of a stimulant or depressant compound.
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HEARINGS

308.41	Hearings generally.
308.42	Purpose of hearing.
308.43	Waiver or modification of rules.
308.44	Institution of proceeding; notice of propose rule making.
308.45	Notice of appearance; waiver.
308.46	Burden of proof.
308.47	Time and place of hearing.
308.48	Final order.
308.49	Control required under international treaty.
308.50	Control of immediate precursors.
308.51	Pending proceedings.

AUTHORITY: The provisions of this Part 308 issued under secs. 201, 202, 501(b), 84