supplier, the purchaser must electronically link the statement of nonacceptance to the original order. The original order and the statement must be retained in accordance with §1305.27.

(d) Neither a purchaser nor a supplier may correct a defective order; the purchaser must issue a new order for the order to be filled.

§1305.26 Lost electronic orders.

(a) If a purchaser determines that an unfilled electronic order has been lost before or after receipt, the purchaser must provide, to the supplier, a signed statement containing the unique tracking number and date of the lost order and stating that the goods covered by the first order were not received through loss of that order.

(b) If the purchaser executes an order to replace the lost order, the purchaser must electronically link an electronic record of the second order and a copy of the statement with the record of the first order and retain them.

(c) If the supplier to whom the order was directed subsequently receives the first order, the supplier must indicate that it is ''Not Accepted'' and return it to the purchaser. The purchaser must link the returned order to the record of that order and the statement.

§1305.27 Preservation of electronic orders.

(a) A purchaser must, for each order filled, retain the original signed order and all linked records for that order for two years. The purchaser must also retain all copies of each unaccepted or defective order and each linked statement.

(b) A supplier must retain each original order filled and the linked records for two years.

(c) If electronic order records are maintained on a central server, the records must be readily retrievable at the registered location.

§1305.28 Canceling and voiding electronic orders.

(a) A supplier may void all or part of an electronic order by notifying the purchaser of the voiding. If the entire order is voided, the supplier must make an electronic copy of the order, indicate on the copy ''Void,'' and return it to the purchaser. The supplier is not required to retain a record of orders that are not filled.

(b) The purchaser must retain an electronic copy of the voided order.

(c) To partially void an order, the supplier must indicate in the linked record that nothing was shipped for each item voided.

§1305.29 Reporting to DEA.

A supplier must, for each electronic order filled, forward either a copy of the electronic order or an electronic report of the order in a format that DEA specifies to DEA within two business days.

PART 1306—PRESCRIPTIONS

GENERAL INFORMATION

Sec.

CONTROLLED SUBSTANCES LISTED IN SCHEDULE II

CONTROLLED SUBSTANCES LISTED IN SCHEDULES III, IV, AND V

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 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 handprinted on it, as well as the signature of the officer.

[75 FR 16307, Mar. 31, 2010]

§ 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.

[68 FR 37410, June 24, 2003, as amended at 70 FR 36343, June 23, 2005]

§ 1306.07 Administering or dispensing of narcotic drugs.

(a) A practitioner may administer or dispense directly (but not prescribe) a narcotic drug listed in any schedule to a narcotic dependant person for the

purpose of maintenance or detoxification treatment if the practitioner meets both of the following conditions:

(1) The practitioner is separately registered with DEA as a narcotic treatment program.

(2) The practitioner is in compliance with DEA regulations regarding treatment qualifications, security, records, and unsupervised use of the drugs pursuant to the Act.

(b) Nothing in this section shall prohibit a practitioner, who is not specifically registered to conduct a narcotic treatment program, from dispensing (but not prescribing) narcotic drugs, in accordance with applicable Federal, State, and local laws relating to controlled substances, to one person or for one person's use at one time for the purpose of initiating maintenance treatment or detoxification treatment (or both). Not more than a three-day supply of such medication may be dispensed to the person or for the person's use at one time while arrangements are being made for referral for treatment. Such emergency treatment may not be renewed or extended.

(c) This section is not intended to impose any limitations on a physician or authorized hospital staff to administer or dispense narcotic drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction, or to administer or dispense narcotic drugs to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts.

(d) A practitioner may administer or dispense (including prescribe) any Schedule III, IV, or V narcotic drug approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment to a narcotic dependent person if the practitioner complies with the requirements of § 1301.28 of this chapter.

(e) [Reserved]

(f) Notwithstanding the definition of dispense under section 102(10) of the Act (21 U.S.C 802(10)), a pharmacy may deliver a controlled substance to a practitioner, pursuant to a prescription that meets the requirements under § 1306.04 for the purpose of administering the controlled substance by the practitioner if:

(1) The controlled substance is delivered by the pharmacy to the prescribing practitioner or the practitioner administering the controlled substance, as applicable, at the location, listed on the practitioner's certificate of registration;

(2) The controlled substance is to be administered for the purpose of maintenance or detoxification treatment under section 303(g)(2)(G)(iii) of the Act (21 U.S.C. 823(g)(2)(G)(iii)); and

(i) The practitioner who issued the prescription is a qualifying practitioner as defined in section 303(g) of the Act (21 U.S.C. 823(g)); and

(ii) The controlled substance is to be administered by injection or implantation;

(3) The pharmacy and the practitioner are authorized to conduct such activities specified in this paragraph (f) under the law of the State in which such activities take place;

(4) The prescription is not issued to supply any practitioner with a stock of controlled substances for the purpose of general dispensing to patients;

(5) The controlled substance is to be administered only to the patient named on the prescription not later than 14 days after the date of receipt of the controlled substance by the practitioner; and

(6) Notwithstanding any exceptions under section 307 of the Act (21 U.S.C. 827), the prescribing practitioner, and the practitioner administering the controlled substance, as applicable, shall maintain complete and accurate records of all controlled substances delivered, received, administered, or otherwise disposed of, under this paragraph (f), including the persons to whom the controlled substances were delivered and such other information as may be required under this chapter.

[39 FR 37986, Oct. 25, 1974, as amended at 70 FR 36344, June 23, 2005; 85 FR 69167, Nov. 2, 2020; 88 FR 53382, Aug. 8, 2023]

§ 1306.08 Electronic prescriptions.

(a) An individual practitioner may sign and transmit electronic prescriptions for controlled substances provided the practitioner meets all of the following requirements:

(1) The practitioner must comply with all other requirements for issuing controlled substance prescriptions in this part;

(2) The practitioner must use an application that meets the requirements of part 1311 of this chapter; and

(3) The practitioner must comply with the requirements for practitioners in part 1311 of this chapter.

(b) A pharmacy may fill an electronically transmitted prescription for a controlled substance provided the pharmacy complies with all other requirements for filling controlled substance prescriptions in this part and with the requirements of part 1311 of this chapter.

(c) To annotate an electronic prescription, a pharmacist must include all of the information that this part requires in the prescription record.

(d) If the content of any of the information required under §1306.05 for a controlled substance prescription is altered during the transmission, the prescription is deemed to be invalid and the pharmacy may not dispense the controlled substance.

(e) The transfer for initial dispensing of an electronic prescription for a controlled substance in Schedule II–V is permissible between retail pharmacies, upon request from the patient, on a one-time basis only. If the transferred prescription is for a controlled substance in Schedule III, IV, or V and includes authorized refills, the refills are transferred with the initial prescription to the pharmacy receiving the transfer.

(f) The transfer of an electronic prescription for a controlled substance in Schedule II–V between retail pharmacies for the purpose of initial dispensing is subject to the following requirements:

(1) The prescription must be transferred from one retail pharmacy to another retail pharmacy in its electronic form. At no time may an intermediary convert an electronic prescription to another form (*e.g.*, facsimile) for transmission.

(2) The contents of the prescription required by this part must not be altered during transfer between retail pharmacies. Any change to the content during transfer, including truncation or removal of data, will render the electronic prescription invalid.

(3) The transfer must be communicated directly between two licensed pharmacists.

(4) The transferring pharmacist must add the following to the electronic prescription record:

(i) Information that the prescription has been transferred.

(ii) The name, address, and DEA registration number of the pharmacy to which the prescription was transferred and the name of the pharmacist receiving the prescription information.

(iii) The date of the transfer and the name of the pharmacist transferring the prescription information.

(5) The receiving pharmacist must do the following:

(i) Add the word ''transfer'' to the electronic prescription record at the receiving pharmacy.

(ii) Annotate the prescription record with the name, address, and DEA registration number of the pharmacy from which the prescription was transferred and the name of the pharmacist who transferred the prescription.

(iii) Record the date of the transfer and the name of the pharmacist receiving the prescription information.

(6) In lieu of manual data entry, the transferring or receiving pharmacy's prescription processing software may, if capable, capture the information required, as outlined in this paragraph (f), from the electronic prescription and automatically populate the corresponding data fields to document the transfer of an electronic controlled substance prescription between pharmacies. The transferring or receiving pharmacist, as applicable, must ensure that the populated information is complete and accurate.

(g) The transfer of an electronic prescription for a controlled substance in Schedule II–V for the purpose of initial dispensing is permissible only if allowable under existing State or other applicable law.

(h) The electronic records documenting the transfer of the electronic prescription must be maintained for a period of two years from the date of the transfer by both the pharmacy transferring the electronic prescription

and the pharmacy receiving the electronic prescription.

(i) A pharmacy may transfer electronic prescription information for a controlled substance in Schedule III, IV, and V to another pharmacy for the purpose of refill dispensing pursuant to §1306.25.

[75 FR 16307, Mar. 31, 2010, as amended at 88 FR 48379, July 27, 2023]

§1306.09 Prescription requirements for online pharmacies.

(a) No controlled substance that is a prescription drug may be delivered, distributed, or dispensed by means of the Internet without a valid prescription.

(b) In accordance with the Act, it is unlawful for any person to knowingly or intentionally fill a prescription for a controlled substance that was issued in a manner that constitutes dispensing by means of the Internet unless such person is a pharmacist who is acting in the usual course of his professional practice and is acting on behalf of a pharmacy whose registration has been modified under sections 1301.13 and 1301.19 of this chapter to authorize it to operate as an online pharmacy.

(c) Any online pharmacy that participates in the transfer between pharmacies of prescription information must do so in accordance with the requirements of §§1306.15 and 1306.25 of this part.

[74 FR 15624, Apr. 6, 2009]

CONTROLLED SUBSTANCES LISTED IN SCHEDULE II

§1306.11 Requirement of prescription.

(a) A pharmacist may dispense directly a controlled substance listed in Schedule II that is a prescription drug as determined under section 503 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)) only pursuant to a written prescription signed by the practitioner, except as provided in paragraph (d) of this section. A paper prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy via facsimile equipment, provided that the original manually signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except as noted in paragraph (e), (f), or (g) of this section. The original prescription shall be maintained in accordance with §1304.04(h) of this chapter.

(b) An individual practitioner may administer or dispense directly a controlled substance listed in Schedule II in the course of his professional practice without a prescription, subject to §1306.07.

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule II only pursuant to a written prescription signed by the prescribing individual practitioner or to an order for medication made by an individual practitioner that is dispensed for immediate administration to the ultimate user.

(d) In the case of an emergency situation, as defined by the Secretary in §290.10 of this title, a pharmacist may dispense a controlled substance listed in Schedule II upon receiving oral authorization of a prescribing individual practitioner, provided that:

(1) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a paper or electronic prescription signed by the prescribing individual practitioner);

(2) The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required in §1306.05, except for the signature of the prescribing individual practitioner;

(3) If the prescribing individual practitioner is not known to the pharmacist, he must make a reasonable effort to determine that the oral authorization came from a registered individual practitioner, which may include a callback to the prescribing individual practitioner using his phone number as listed in the telephone directory and/or other good faith efforts to insure his identity; and

(4) Within 7 days after authorizing an emergency oral prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed to be

delivered to the dispensing pharmacist. In addition to conforming to the requirements of §1306.05, the prescription shall have written on its face ''Authorization for Emergency Dispensing,'' and the date of the oral order. The paper prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail it must be postmarked within the 7-day period. Upon receipt, the dispensing pharmacist must attach this paper prescription to the oral emergency prescription that had earlier been reduced to writing. For electronic prescriptions, the pharmacist must annotate the record of the electronic prescription with the original authorization and date of the oral order. The pharmacist must notify the nearest office of the Administration if the prescribing individual practitioner fails to deliver a written prescription to him; failure of the pharmacist to do so shall void the authority conferred by this paragraph to dispense without a written prescription of a prescribing individual practitioner.

(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.

(e) A prescription prepared in accordance with §1306.05 written for a Schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be transmitted by the practitioner or the practitioner's agent to the pharmacy by facsimile. The facsimile serves as the original written prescription for purposes of this paragraph (e) and it shall be maintained in accordance with §1304.04(h) of this chapter.

(f) A prescription prepared in accordance with §1306.05 written for Schedule II substance for a resident of a Long Term Care Facility may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The facsimile serves as the original written prescription for purposes of this paragraph (f) and it shall be maintained in accordance with §1304.04(h).

(g) A prescription prepared in accordance with §1306.05 written for a Schedule II narcotic substance for a patient enrolled in a hospice care program certified and/or paid for by Medicare under Title XVIII or a hospice program which is licensed by the state may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The practitioner or the practitioner's agent will note on the prescription that the patient is a hospice patient. The facsimile serves as the original written prescription for purposes of this paragraph (g) and it shall be maintained in accordance with §1304.04(h).

[36 FR 7799, Apr. 24, 1971, as amended at 36 FR 18733, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973 and amended at 53 FR 4964, Feb. 19, 1988; 59 FR 26111, May 19, 1994; 59 FR 30832, June 15, 1994; 62 FR 13964, Mar. 24, 1997; 65 FR 45713, July 25, 2000; 68 FR 37410, June 24, 2003; 75 FR 16307, Mar. 31, 2010]

§1306.12 Refilling prescriptions; issuance of multiple prescriptions.

(a) The refilling of a prescription for a controlled substance listed in Schedule II is prohibited.

(b)(1) An individual practitioner may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a Schedule II controlled substance provided the following conditions are met:

(i) Each separate prescription is issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice;

(ii) The individual practitioner provides written instructions on each prescription (other than the first prescription, if the prescribing practitioner intends for that prescription to be filled immediately) indicating the earliest date on which a pharmacy may fill each prescription;

(iii) The individual practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse;

(iv) The issuance of multiple prescriptions as described in this section is permissible under the applicable state laws; and

(v) The individual practitioner complies fully with all other applicable requirements under the Act and these regulations as well as any additional requirements under state law.

(2) Nothing in this paragraph (b) shall be construed as mandating or encouraging individual practitioners to issue multiple prescriptions or to see their patients only once every 90 days when prescribing Schedule II controlled substances. Rather, individual practitioners must determine on their own, based on sound medical judgment, and in accordance with established medical standards, whether it is appropriate to issue multiple prescriptions and how often to see their patients when doing so.

[72 FR 64929, Nov. 19, 2007]

§ 1306.13 Partial filling of prescriptions.

(a) The partial filling of a prescription for a controlled substance listed in Schedule II is permissible if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and he makes a notation of the quantity supplied on the face of the written prescription, written record of the emergency oral prescription, or in the electronic prescription record. The remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall notify the prescribing individual practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.

(b) Partial filling of a prescription for a schedule II controlled substance at the request of the prescribing practitioner or patient:

(1) *General requirements.* A prescription for a schedule II controlled substance may be partially filled if all of the following conditions are satisfied:

(i) It is not prohibited by State law;

(ii) The prescription is written and filled in accordance with the Act, this chapter, and State law.

(iii) The partial fill is requested by the patient, by one acting on behalf of the patient (parent or legal guardian of a minor patient, or caregiver of an adult patient named in a medical power of attorney), or by the practitioner who wrote the prescription; and

(iv) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed.

(2) *Time limitations on filling the remaining portions of a partially filled prescription for a schedule II controlled substance.* If all the conditions of paragraph (b)(1) of this section are satisfied, and the prescription is partially filled, remaining portions of a partially filled prescription for a schedule II controlled substance, if filled, must be filled not later than 30 days after the date on which the prescription is written, except that in the case of an emergency oral prescription, as described in subsection 309(a) of the Act (21 U.S.C. 829(a)), the remaining portions of a partially filled prescription for a schedule II controlled substance, if filled, must be filled not later than 72 hours after the prescription is issued.

(3) *How a practitioner may request that a prescription for a schedule II controlled substance be partially filled.* Where a practitioner issues a prescription for a schedule II controlled substance and wants the prescription to be partially filled, the practitioner must specify the quantity to be dispensed in each partial filling on the face of the written prescription, in the written record of the emergency oral prescription, or in the record for an electronic prescription. After consultation with a pharmacist, a practitioner may authorize a partial fill for the prescription at a date after which the prescription was initially issued; however, the prescription must be filled not later than 30 days after the date on which the prescription is written, except that in the case of an emergency oral prescription, as described in subsection 309(a) of the Act (21 U.S.C. 829(a)), the remaining portions of a partially filled prescription for a schedule II controlled substance, if filled, must be filled not later than 72 hours after the prescription is issued. The pharmacist must notate this subsequent request in accordance with paragraph (b)(5) of this section. All required information in this paragraph, except that of an authorization for partial filling at a later date, must be included on the prescription, along

with the other information required by §1306.05, at the time the practitioner signs the prescription, or in the case of an emergency oral prescription, this information must be communicated by the prescribing practitioner to the pharmacist at the time that the oral communication is taking place.

(4) *How a patient or one acting on a patient's behalf may request that a prescription for a schedule II controlled substance be partially filled.* A patient may request that his/her prescription for a schedule II controlled substance be partially filled. A caregiver named in an adult patient's medical power of attorney may request the adult patient's prescription be partially filled. When a patient is a minor (under age 18), a parent or legal guardian of the minor may request the prescription be partially filled. Where a practitioner has requested the partial filling of a prescription in accordance with paragraph (b)(3) of this section, neither the patient, the parent or legal guardian (in the case of a minor), nor the caregiver of an adult patient named in a medical power of attorney may request a partial filling in an amount greater than that specified by the practitioner. A request by the patient, the adult patient's caregiver named in the medical power of attorney, or the parent/legal guardian of a minor patient may be made: in person; in writing if signed by the patient, the adult patient's caregiver named in the medical power of attorney, or the parent/legal guardian of a minor patient; or by a phone call to the pharmacist from the patient, the adult patient's caregiver named in the medical power of attorney, or the parent/legal guardian of a minor patient.

(5) *How a pharmacy must record the partial filling of a prescription for a schedule II controlled substance.* (i) Upon partially filling a prescription at the request of the prescribing practitioner, as requested when the prescriber issued the prescription, in accordance with paragraph (b)(3) of this section, the pharmacist must make a notation of the quantity dispensed on the face of the written prescription or in the pharmacy's electronic records, in the written record or the pharmacy's electronic records of the emergency oral prescription, or in the record of the electronic prescription. When the pharmacist partially fills a prescription, after the prescriber has conveyed this request in a consultation with a pharmacist in accordance with paragraph (b)(3), the pharmacist must note the following: ''Authorized by Practitioner to Partial Fill,'' the name of the practitioner, the date and time of the discussion, and the pharmacist's initials. In addition, for each such partial filling (whether requested by the prescriber on the prescription or after consultation with the pharmacist), the pharmacy must maintain a record of dispensing that includes the date of each dispensing, the name or initials of the individual who dispensed the substance, and all other information required by 21 CFR 1306.22(c) for schedule III and IV prescription refills. For electronic prescriptions specifically, such required information pertaining to the quantity dispensed, date dispensed, and the dispenser must be linked to each electronic controlled substance prescription record.

(ii) Upon partially filling a prescription at the request of the patient, the caregiver of an adult patient who is named in their medical power of attorney, or a parent or legal guardian of a minor patient, in accordance with paragraph (b)(4) of this section, the pharmacist must make a notation of the following on the face of the written prescription or in the pharmacy's electronic records, in the written record or the pharmacy's electronic records of the emergency oral prescription, or in the record of the electronic prescription: (I) ''The [patient, parent or legal guardian of a minor patient, or caregiver of an adult patient named in a medical power of attorney] requested partial fill on [date such request was made]'' and (II) the quantity dispensed. In addition, for each such partial filling, the pharmacy must maintain a record of dispensing that includes the date of each dispensing, the name or initials of the individual who dispensed the substance, and all other information required by 21 CFR 1306.22(c) for schedule III and IV prescriptions. For electronic prescriptions specifically, such required information pertaining to the quantity dispensed, date dispensed, and the dispenser must be

linked to each electronic controlled substance prescription record.

(c) A prescription for a Schedule II controlled substance written for a patient in a Long Term Care Facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist must contact the practitioner prior to partially filling the prescription. Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient. The pharmacist must record on the prescription whether the patient is ''terminally ill'' or an ''LTCF patient.'' A prescription that is partially filled and does not contain the notation ''terminally ill'' or ''LTCF patient'' shall be deemed to have been filled in violation of the Act. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. The total quantity of Schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed. Schedule II prescriptions for patients in a LTCF or patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of medication.

(d) Information pertaining to current Schedule II prescriptions for patients in a LTCF or for patients with a medical diagnosis documenting a terminal illness may be maintained in a computerized system if this system has the capability to permit:

(1) Output (display or printout) of the original prescription number, date of issue, identification of prescribing individual practitioner, identification of patient, address of the LTCF or address of the hospital or residence of the patient, identification of medication authorized (to include dosage, form, strength and quantity), listing of the partial fillings that have been dispensed under each prescription and the information required in §1306.13(c).

(2) Immediate (real time) updating of the prescription record each time a partial filling of the prescription is conducted.

(3) Retrieval of partially filled Schedule II prescription information is the same as required by §1306.22(b) (4) and (5) for Schedule III and IV prescription refill information.

(Authority: 21 U.S.C. 801, *et seq.*)

[36 FR 7799, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 45 FR 54330, July 15, 1980; 56 FR 25027, June 3, 1991; 62 FR 13965, Mar. 24, 1997; 75 FR 16308, Mar. 31, 2010; 88 FR 47001, July 21, 2023]

§1306.14 Labeling of substances and filling of prescriptions.

(a) The pharmacist filling a written or emergency oral prescription for a controlled substance listed in Schedule II shall affix to the package a label showing date of filling, the pharmacy name and address, the serial number of the prescription, the name of the patient, the name of the prescribing practitioner, and directions for use and cautionary statements, if any, contained in such prescription or required by law.

(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.

(c) The requirements of paragraph (a) of this section do not apply when a controlled substance listed in Schedule II is prescribed for administration to an ultimate user who is institutionalized: *Provided,* That:

(1) Not more than 7-day supply of the controlled substance listed in Schedule II is dispensed at one time;

(2) The controlled substance listed in Schedule II is not in the possession of the ultimate user prior to the administration;

(3) The institution maintains appropriate safeguards and records regarding the proper administration, control, dispensing, and storage of the controlled substance listed in Schedule II; and

(4) The system employed by the pharmacist in filling a prescription is adequate to identify the supplier, the product, and the patient, and to set forth the directions for use and cautionary statements, if any, contained in the prescription or required by law.

(d) All written prescriptions and written records of emergency oral prescriptions shall be kept in accordance with requirements of §1304.04(h) of this chapter.

(e) Where a prescription that has been prepared in accordance with section 1306.12(b) contains instructions from the prescribing practitioner indicating that the prescription shall not be filled until a certain date, no pharmacist may fill the prescription before that date.

[36 FR 13368, July 21, 1971, as amended at 37 FR 15921, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, as amended at 62 FR 13965, Mar. 24, 1997; 68 FR 37410, June 24, 2003; 72 FR 64930, Nov. 19, 2007]

§ 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 words ''CENTRAL FILL'' on the face of the original paper prescription and record the name, address, and DEA registration number of the central fill pharmacy to which the prescription has been transmitted, the name of the retail pharmacy pharmacist transmitting the prescription, and the date of transmittal. For electronic prescriptions the name, address, and DEA registration number of the central fill pharmacy to which the prescription has been transmitted, the name of the retail pharmacy pharmacist transmitting the prescription, and the date of transmittal must be added to the electronic prescription record.

(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 number of the retail pharmacy transmitting the prescription;

(2) Keep a record of the date of receipt of the transmitted prescription, the name of the pharmacist filling the prescription, and the date of filling of the prescription;

(3) Keep a record of the date the filled prescription was delivered to the retail pharmacy and the method of delivery (*i.e.* private, common or contract carrier).

[68 FR 37410, June 24, 2003, as amended at 75 FR 16308, Mar. 31, 2010]

CONTROLLED SUBSTANCES LISTED IN SCHEDULES III, IV, AND V

§ 1306.21 Requirement of prescription.

(a) A pharmacist may dispense directly a controlled substance listed in Schedule III, IV, or V that is a prescription drug as determined under section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)) only pursuant to either a paper prescription signed by a practitioner, a facsimile of a signed paper prescription transmitted by the practitioner or the practitioner's agent to the pharmacy, an

electronic prescription that meets the requirements of this part and part 1311 of this chapter, or an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist containing all information required in §1306.05, except for the signature of the practitioner.

(b) An individual practitioner may administer or dispense directly a controlled substance listed in Schedule III, IV, or V in the course of his/her professional practice without a prescription, subject to §1306.07.

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule III, IV, or V only pursuant to a paper prescription signed by an individual practitioner, a facsimile of a paper prescription or order for medication transmitted by the practitioner or the practitioner's agent to the institutional practitioner-pharmacist, an electronic prescription that meets the requirements of this part and part 1311 of this chapter, or an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist (containing all information required in §1306.05 except for the signature of the individual practitioner), or pursuant to an order for medication made by an individual practitioner that is dispensed for immediate administration to the ultimate user, subject to §1306.07.

[62 FR 13965, Mar. 24, 1997, as amended at 75 FR 16308, Mar. 31, 2010]

§1306.22 Refilling of prescriptions.

(a) No prescription for a controlled substance listed in Schedule III or IV shall be filled or refilled more than six months after the date on which such prescription was issued. No prescription for a controlled substance listed in Schedule III or IV authorized to be refilled may be refilled more than five times.

(b) Each refilling of a prescription shall be entered on the back of the prescription or on another appropriate document or electronic prescription record. If entered on another document, such as a medication record, or electronic prescription record, the document or record must be uniformly maintained and readily retrievable.

(c) The following information must be retrievable by the prescription number:

(1) The name and dosage form of the controlled substance.

(2) The date filled or refilled.

(3) The quantity dispensed.

(4) The initials of the dispensing pharmacist for each refill.

(5) The total number of refills for that prescription.

(d) If the pharmacist merely initials and dates the back of the prescription or annotates the electronic prescription record, it shall be deemed that the full face amount of the prescription has been dispensed.

(e) The prescribing practitioner may authorize additional refills of Schedule III or IV controlled substances on the original prescription through an oral refill authorization transmitted to the pharmacist provided the following conditions are met:

(1) The total quantity authorized, including the amount of the original prescription, does not exceed five refills nor extend beyond six months from the date of issue of the original prescription.

(2) The pharmacist obtaining the oral authorization records on the reverse of the original paper prescription or annotates the electronic prescription record with the date, quantity of refill, number of additional refills authorized, and initials the paper prescription or annotates the electronic prescription record showing who received the authorization from the prescribing practitioner who issued the original prescription.

(3) The quantity of each additional refill authorized is equal to or less than the quantity authorized for the initial filling of the original prescription.

(4) The prescribing practitioner must execute a new and separate prescription for any additional quantities beyond the five-refill, six-month limitation.

(f) As an alternative to the procedures provided by paragraphs (a) through (e) of this section, a computer application may be used for the storage and retrieval of refill information for original paper prescription orders for controlled substances in Schedule III and IV, subject to the following conditions:

(1) Any such proposed computerized application must provide online retrieval (via computer monitor or hard-copy printout) of original prescription order information for those prescription orders that are currently authorized for refilling. This shall include, but is not limited to, data such as the original prescription number; date of issuance of the original prescription order by the practitioner; full name and address of the patient; name, address, and DEA registration number of the practitioner; and the name, strength, dosage form, quantity of the controlled substance prescribed (and quantity dispensed if different from the quantity prescribed), and the total number of refills authorized by the prescribing practitioner.

(2) Any such proposed computerized application must also provide online retrieval (via computer monitor or hard-copy printout) of the current refill history for Schedule III or IV controlled substance prescription orders (those authorized for refill during the past six months). This refill history shall include, but is not limited to, the name of the controlled substance, the date of refill, the quantity dispensed, the identification code, or name or initials of the dispensing pharmacist for each refill and the total number of refills dispensed to date for that prescription order.

(3) Documentation of the fact that the refill information entered into the computer each time a pharmacist refills an original paper, fax, or oral prescription order for a Schedule III or IV controlled substance is correct must be provided by the individual pharmacist who makes use of such an application. If such an application provides a hard-copy printout of each day's controlled substance prescription order refill data, that printout shall be verified, dated, and signed by the individual pharmacist who refilled such a prescription order. The individual pharmacist must verify that the data indicated are correct and then sign this document in the same manner as he would sign a check or legal document (e.g., J.H. Smith, or John H. Smith). This document shall be maintained in a separate file at that pharmacy for a period of two years from the dispensing date. This printout of the day's controlled substance prescription order refill data must be provided to each pharmacy using such a computerized application within 72 hours of the date on which the refill was dispensed. It must be verified and signed by each pharmacist who is involved with such dispensing. In lieu of such a printout, the pharmacy shall maintain a bound log book, or separate file, in which each individual pharmacist involved in such dispensing shall sign a statement (in the manner previously described) each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by him and is correct as shown. Such a book or file must be maintained at the pharmacy employing such an application for a period of two years after the date of dispensing the appropriately authorized refill.

(4) Any such computerized application shall have the capability of producing a printout of any refill data that the user pharmacy is responsible for maintaining under the Act and its implementing regulations. For example, this would include a refill-by-refill audit trail for any specified strength and dosage form of any controlled substance (by either brand or generic name or both). Such a printout must include name of the prescribing practitioner, name and address of the patient, quantity dispensed on each refill, date of dispensing for each refill, name or identification code of the dispensing pharmacist, and the number of the original prescription order. In any computerized application employed by a user pharmacy the central record-keeping location must be capable of sending the printout to the pharmacy within 48 hours, and if a DEA Special Agent or Diversion Investigator requests a copy of such printout from the user pharmacy, it must, if requested to do so by the Agent or Investigator, verify the printout transmittal capability of its application by documentation (e.g., postmark).

(5) In the event that a pharmacy which employs such a computerized application experiences system downtime, the pharmacy must have an auxiliary procedure which will be used for documentation of refills of Schedule III

and IV controlled substance prescription orders. This auxiliary procedure must ensure that refills are authorized by the original prescription order, that the maximum number of refills has not been exceeded, and that all of the appropriate data are retained for online data entry as soon as the computer system is available for use again.

(g) When filing refill information for original paper, fax, or oral prescription orders for Schedule III or IV controlled substances, a pharmacy may use only one of the two applications described in paragraphs (a) through (e) or (f) of this section.

(h) When filing refill information for electronic prescriptions, a pharmacy must use an application that meets the requirements of part 1311 of this chapter.

[75 FR 16308, Mar. 31, 2010]

§ 1306.23 Partial filling of prescriptions.

The partial filling of a prescription for a controlled substance listed in Schedule III, IV, or V is permissible, provided that:

(a) Each partial filling is recorded in the same manner as a refilling,

(b) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed, and

(c) No dispensing occurs after 6 months after the date on which the prescription was issued.

[36 FR 18733, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 51 FR 5320, Feb. 13, 1986; 62 FR 13965, Mar. 24, 1997]

§ 1306.24 Labeling of substances and filling of prescriptions.

(a) The pharmacist filling a prescription for a controlled substance listed in Schedule III, IV, or V shall affix to the package a label showing the pharmacy name and address, the serial number and date of initial filling, the name of the patient, the name of the practitioner issuing the prescription, and directions for use and cautionary statements, if any, contained in such prescription as required by law.

(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.

(c) The requirements of paragraph (a) of this section do not apply when a controlled substance listed in Schedule III, IV, or V is prescribed for administration to an ultimate user who is institutionalized: Provided, That:

(1) Not more than a 34-day supply or 100 dosage units, whichever is less, of the controlled substance listed in Schedule III, IV, or V is dispensed at one time;

(2) The controlled substance listed in Schedule III, IV, or V is not in the possession of the ultimate user prior to administration;

(3) The institution maintains appropriate safeguards and records the proper administration, control, dispensing, and storage of the controlled substance listed in Schedule III, IV, or V; and

(4) The system employed by the pharmacist in filling a prescription is adequate to identify the supplier, the product and the patient, and to set forth the directions for use and cautionary statements, if any, contained in the prescription or required by law.

(d) All prescriptions for controlled substances listed in Schedules III, IV, and V shall be kept in accordance with §1304.04(h) of this chapter.

[62 FR 13965, Mar. 24, 1997, as amended at 68 FR 37411, June 24, 2003]

§ 1306.25 Transfer between pharmacies of prescription information for Schedules III, IV, and V controlled substances for refill purposes.

(a) The transfer of original prescription information for a controlled substance listed in Schedule III, IV, or V for the purpose of refill dispensing is permissible between pharmacies on a one-time basis only. However, pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization.

(b) Transfers are subject to the following requirements:

(1) The transfer must be communicated directly between two licensed pharmacists.

(2) The transferring pharmacist must do the following:

(i) Write the word ''VOID'' on the face of the invalidated prescription; for electronic prescriptions, information that the prescription has been transferred must be added to the prescription record.

(ii) Record on the reverse of the invalidated prescription the name, address, and DEA registration number of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information; for electronic prescriptions, such information must be added to the prescription record.

(iii) Record the date of the transfer and the name of the pharmacist transferring the information.

(3) For paper prescriptions and prescriptions received orally and reduced to writing by the pharmacist pursuant to §1306.21(a), the pharmacist receiving the transferred prescription information must write the word ''transfer'' on the face of the transferred prescription and reduce to writing all information required to be on a prescription pursuant to §1306.05 and include:

(i) Date of issuance of original prescription.

(ii) Original number of refills authorized on original prescription.

(iii) Date of original dispensing.

(iv) Number of valid refills remaining and date(s) and locations of previous refill(s).

(v) Pharmacy's name, address, DEA registration number, and prescription number from which the prescription information was transferred.

(vi) Name of pharmacist who transferred the prescription.

(vii) Pharmacy's name, address, DEA registration number, and prescription number from which the prescription was originally filled.

(4) For electronic prescriptions being transferred electronically, the transferring pharmacist must provide the receiving pharmacist with the following information in addition to the original electronic prescription data:

(i) The date of the original dispensing.

(ii) The number of refills remaining and the date(s) and locations of previous refills.

(iii) The transferring pharmacy's name, address, DEA registration number, and prescription number for each dispensing.

(iv) The name of the pharmacist transferring the prescription.

(v) The name, address, DEA registration number, and prescription number from the pharmacy that originally filled the prescription, if different.

(5) The pharmacist receiving a transferred electronic prescription must create an electronic record for the prescription that includes the receiving pharmacist's name and all of the information transferred with the prescription under paragraph (b)(4) of this section.

(c) The original and transferred prescription(s) must be maintained for a period of two years from the date of last refill.

(d) Pharmacies electronically accessing the same prescription record must satisfy all information requirements of a manual mode for prescription transferal.

(e) The procedure allowing the transfer of prescription information for refill purposes is permissible only if allowable under existing State or other applicable law.

[75 FR 16309, Mar. 31, 2010]

§1306.26 Dispensing without prescription.

A controlled substance listed in Schedules II, III, IV, or V 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 dispensing is made only by a pharmacist (as defined in part 1300 of this chapter), and not by a nonpharmacist employee even if under the supervision of a pharmacist (although after the pharmacist has fulfilled his professional and legal responsibilities set forth in this 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 controlled substance containing opium, nor more than 120 cc. (4 ounces) of any other such controlled substance nor more than 48 dosage units of any such controlled substance containing opium, nor more than 24 dosage units of any other such controlled substance may be dispensed 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 under this section not known to him to furnish suitable identification (including proof of age where appropriate);

(e) A bound record book for dispensing of controlled substances under this section 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 dispensed the substance to the purchaser (the book shall be maintained in accordance with the recordkeeping requirement of §1304.04 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.

(g) Central fill pharmacies may not dispense controlled substances to a purchaser at retail pursuant to this section.

[36 FR 7799, Apr. 24, 1971, as amended at 36 FR 18733, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and further redesignated and amended at 62 FR 13966, Mar. 24, 1997; 68 FR 37411, June 24, 2003]

§ 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.

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 III, IV or V 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 §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) Indicate in the information transmitted the number of refills already dispensed and the number of refills remaining;

(4) Maintain the original prescription for a period of two years from the date the prescription was last refilled;

(5) 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 number of the retail pharmacy transmitting the prescription;

(2) Keep a record of the date of receipt of the transmitted prescription, the name of the licensed pharmacist filling the prescription, and dates of filling or refilling of the prescription;

(3) Keep a record of the date the filled prescription was delivered to the retail pharmacy and the method of delivery (*i.e.* private, common or contract carrier).

[68 FR 37411, June 24, 2003]

§§1306.28–1306.49 [Reserved]

EFFECTIVE DATE NOTE: At 90 FR 6522, Jan. 17, 2025, §§1306.28–1306.49 were added and reserved and delayed at 90 FR 9841, Feb. 19, 2025 and at 90 FR 13410, Mar. 24, 2025 further delayed to Dec. 31, 2025.

SPECIAL CIRCUMSTANCES FOR TELEMEDICINE PRESCRIBING

§ 1306.51 Telemedicine prescribing of schedule III–V medications for the treatment of Opioid Use Disorder.

(a) For purposes of this section, terms defined in part 1300 of this chapter, elsewhere in this chapter, or in 21 U.S.C. 802 and 829 shall have the definitions set forth therein.

(b) A practitioner may issue a prescription for schedule III–V controlled substances listed in 42 CFR 8.12(h)(2) as approved by the Food and Drug Administration (FDA) for use in the treatment of Opioid Use Disorder (OUD), defined as the use of an effective medication such as buprenorphine to treat OUD, pursuant to a communication between the prescribing practitioner and the patient using an interactive telecommunications system, including an audio-only telecommunications system, as described in 42 CFR 410.78(a)(3), if the following conditions are met:

(1) *Prescription drug monitoring program review*. The prescribing practitioner must be authorized to access the applicable prescription drug monitoring program (PDMP) data of the state in which the patient is located at the time of the telemedicine encounter. The prescribing practitioner shall review such data regarding any controlled substance prescriptions issued to the patient in the last year, or, if less than one year of data is available, in the entire available period. The prescribing practitioner shall ensure the date and time of such a review is annotated in the patient's electronic health record (EHR) or paper record. This review, or attempted review, must be conducted prior to issuing a prescription in a manner authorized under this section.

(2) *Time limit*. The practitioner may issue prescriptions to the patient pursuant to this section for a period not to exceed six calendar months beginning on the date the first prescription is issued. The practitioner may issue additional prescriptions to the patient for schedule III–V controlled substances approved by the FDA for use in the treatment of OUD either:

(i) After the prescribing practitioner has conducted at least one in-person medical evaluation of the patient, as defined in 21 U.S.C. 829(e)(2)(B); or

(ii) As otherwise authorized by 21 U.S.C. 829(e), including pursuant to any other form of telemedicine as defined in 21 U.S.C. 802(54) or pursuant to practices as determined by regulation issued pursuant to 21 U.S.C. 829(e)(3)(B).

(3) *PDMP inaccessible or unavailable*. If the PDMP data is inaccessible or unavailable for any reason, the prescribing practitioner shall annotate in the patient's EHR or paper record the date and time that an attempt to view the PDMP data was made and the reason the data could not be reviewed. A practitioner may prescribe a seven-day supply of medication and must perform another PDMP review before prescribing another seven-day supply. Each time the PDMP is reviewed or attempted to be reviewed, the date and time must be annotated in the patient's EHR. A seven-day supply prescribed pursuant to this paragraph (b)(3) counts toward the time limit described in paragraph (b)(2) of this section.

(4) *Pharmacy identification requirement*. The pharmacist shall verify the identity of the patient prior to filling a controlled substance prescription issued under the authority of this section. The pharmacist shall verify the identity of the patient with a state or Federal Government-issued photographic identification card or other form of identification. For the purposes of verifying the identity of the patient, the pharmacist may accept identification in the manner described herein from any qualifying ''ultimate user'' as defined in 21 U.S.C. 802(27) prior to filling the prescription.

(5) *Prescription only for treatment of OUD*. Controlled substance prescriptions issued pursuant to this section may only be issued for the treatment of OUD, and subject to the requirements of this section.

(6) *Authorization to prescribe*. The practitioner must be:

(i) Authorized under §§ 1301.11, 1301.12(a), and 1301.13(e)(1)(iv) of this chapter 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).

(7) *Consistent with general prescription requirements.* The issuance of the controlled substance prescription otherwise complies with the requirements set forth in this part.

EFFECTIVE DATE NOTE: At 90 FR 6522, Jan. 17, 2025, §1306.51 was added and delayed at 90 FR 9841, Feb. 19, 2025 and at 90 FR 13410, Mar. 24, 2025 further delayed until Dec. 31, 2025.

§1306.52 Other circumstances where Department of Veterans Affairs practitioners may prescribe controlled substances via the practice of telemedicine.

A practitioner may prescribe controlled substance(s) to a patient via the practice of telemedicine under §1300.04(i)(7) of this chapter if all the following conditions are met:

(a) The practitioner is:

(1) An employee or contractor of the Department of Veterans Affairs (VA) who is acting in the scope of such employment or contract, and registered under section 303(g) of the Act (21 U.S.C. 823(g)) (§1301.13 of this chapter) in any state or is utilizing the registration of a hospital or clinic operated by the VA registered under section 303(f);

(2) Prescribing to a VA patient who has previously received, at any time, an in-person medical evaluation by any VA practitioner who at the time of the in-person medical evaluation was acting within the scope of their VA employment or contract and had prescribing authority, or would reasonably be expected to have prescribing authority based on their credentials (*e.g.*, medical doctor) or organizational role (*e.g.*, primary care provider), as described in paragraph (a)(1) of this section;

(3) Not a contracted practitioner located outside a VA facility or clinic providing care via the community care network or conducting disability compensation evaluations; and

(4) Prescribing a controlled substance(s) for a legitimate medical purpose in the usual course of professional practice, and in accordance with applicable Federal and State law(s).

(b) Prior to prescribing, the practitioner must conduct a review of both the VA EHR, to include the VA's internal prescription database, and the PDMP data of the state in which the patient is located at the time of the telemedicine encounter (if the state has such a program) for controlled substance prescription(s) for the patient's previous twelve (12) months preceding the controlled substance prescription(s), or if less than a year of data is available, for the entire prescription period.

(1) Should either the patient's VA electronic health record, to include the VA's internal prescription database, or the PDMP of the state in which the patient is located at the time of the telemedicine encounter (if the state has such a program) be unavailable or non-operational, for any reason, the VA practitioner must limit the prescription to a 7-day supply. Once the VA's internal prescription database and the PDMP are available or operational, a review of the databases as outlined in this paragraph (b) must be completed to continue prescribing the controlled substance(s) to the VA patient.

(2) If no PDMP exists in the state in which the patient is located at the time of the telemedicine encounter, the VA practitioner must review the VA internal prescription database prior to issuing a controlled substance prescription. A prescription may extend beyond 7 days under this circumstance.

(3) The VA practitioner must annotate in the VA patient's EHR their attempts to access the PDMP data of the state in which the patient is located, and VA internal prescription database data. If no PDMP exists in the state in which the patient is located at the time of the telemedicine encounter, the prescribing practitioner must annotate that in the VA patient's EHR. If the prescribing VA practitioner fails to access the PDMP data of the state in which the patient is located or VA internal prescription database data as described in paragraph (b)(1) of this section, the VA practitioner must annotate in the VA patient's EHR the dates and times that the VA practitioner attempted to gain access, the reason why the VA practitioner was unable to gain access, and any follow-up attempts made to gain access to the system. The

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

SPECIAL EXCEPTIONS FOR MANUFACTURE AND DISTRIBUTION OF CONTROLLED SUBSTANCES

DISPOSAL OF CONTROLLED SUBSTANCES

SPECIAL EXEMPT PERSONS

SPECIAL EXCEPTIONS RELATED TO TELEMEDICINE

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