

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.

[75 FR 16307, Mar. 31, 2010]

§ 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

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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;