

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 system by documentation (e.g., postmark).

(5) In the event that a pharmacy which employs such a computerized system experiences system down-time, 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 insure 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 is retained for on-line data entry as soon as the computer system is available for use again.

(c) When filing refill information for original prescription orders for Schedule III or IV controlled substances, a pharmacy may use only one of the two systems described in paragraphs (a) or (b) of this section.

[36 FR 7799, Apr. 24, 1971; 36 FR 13386, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 42 FR 28878, June 6, 1977; 45 FR 44266, July 1, 1980; 52 FR 3605, Feb. 5, 1987; 62 FR 13966, Mar. 24, 1997]

§ 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 filing 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 Schedules III, IV or V

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for the purpose of refill dispensing is permissible between pharmacies on a one time basis only. However, pharmacies electronically sharing a real-time, on-line database may transfer up to the maximum refills permitted by law and the prescriber's authorization. Transfers are subject to the following requirements:

(1) The transfer is communicated directly between two licensed pharmacists and the transferring pharmacist records the following information:

(i) Write the word "VOID" on the face of the invalidated prescription.

(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.

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

(b) The pharmacist receiving the transferred prescription information shall reduce to writing the following:

(1) Write the word "transfer" on the face of the transferred prescription.

(2) Provide all information required to be on a prescription pursuant to 21 CFR 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;

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

(c) Pharmacies electronically accessing the same prescription record must satisfy all information requirements of

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a manual mode for prescription transferral.

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

[46 FR 48919, Oct. 5, 1981. Redesignated and amended at 62 FR 13966, Mar. 24, 1997]

§ 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