§ 1307.11

Distribution by dispenser to another practitioner or reverse distributor.

(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 as required in part 1305 of this chapter; and

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

(2) A reverse distributor who is registered to receive such controlled substances.

(b) Distributions referred to in paragraph (a) may be made through a freight forwarding facility operated by the person to whom the controlled substance is being returned provided that prior arrangement has been made for the return and the person making the distribution delivers the controlled substance directly to an agent or employee of the person to whom the controlled substance is being returned.

SPECIAL EXCEPTIONS FOR MANUFACTURE AND DISTRIBUTION OF CONTROLLED SUBSTANCES

§ 1307.12 Distribution to supplier or manufacturer.

(a) Any person lawfully in possession of a controlled substance listed in any schedule may distribute (without being registered to distribute) that substance to the person from whom he/she obtained it or to the manufacturer of the substance, or, if designated, to the manufacturer’s registered agent for accepting returns, provided that a written record is maintained which indicates the date of the transaction, the name, form and quantity of the substance, the name, address, and registration number, if any, of the person making the distribution, and the name, address, and registration number, if known, of the supplier or manufacturer. In the case of returning a controlled substance in Schedule I or II, an order form shall be used in the manner prescribed in part 1305 of this chapter and be maintained as the written record of the transaction. Any person not required to register pursuant to sections 302(c) or 1007(b)(1) of the Act (21 U.S.C. 822(c) or 957(b)(1)) shall be exempt from maintaining the records required by this section.

[b]VerDate Mar<15>2010 14:42 May 17, 2012 Jkt 226075 PO 00000 Frm 00112 Fmt 8010 Sfmt 8010 Y:\SGML\226075.XXX 226075pmangrum on DSK3VPTVN1PROD with CFR