

that distributes exclusively to (for dispensing by) agents, employees, or affiliated institutional practitioners of the registrant may be exempted from filing reports under this section by applying to the Pharmaceutical Investigations Section, Diversion Control Division, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

(2) Registrants that acquire recalled controlled substances from ultimate users pursuant to § 1317.85 of this chapter may report as a single transaction all recalled controlled substances of the same name and finished form (e.g., all 10-milligram tablets or all 5-milligram concentration per fluid ounce or milliliter) received from ultimate users for the purpose of reporting acquisition transactions.

(g) *Exemptions.* (1) Collectors that acquire controlled substances from ultimate users are exempt from the ARCOS reporting requirements only with respect to controlled substances collected through mail-back programs and collection receptacles for the purpose of disposal.

(2) Reverse distributors and distributors that acquire controlled substances pursuant to § 1317.55(a) or (b) of this chapter are exempt from the ARCOS reporting requirements in this section with regard to any controlled substances acquired pursuant to § 1317.55(a) or (b) of this chapter.

(Approved by the Office of Management and Budget under control number 1117-0003)

[62 FR 13962, Mar. 24, 1997, as amended at 68 FR 41229, July 11, 2003; 70 FR 294, Jan. 4, 2005; 75 FR 10678, Mar. 9, 2010; 79 FR 53564, Sept. 9, 2014; 81 FR 97020, Dec. 30, 2016]

#### ONLINE PHARMACIES

#### § 1304.40 Notification by online pharmacies.

(a) Thirty days prior to offering a controlled substance for sale, delivery, distribution, or dispensing by means of the Internet, an online pharmacy shall:

(1) Notify the Administrator of its intent to do so by submitting an application for a modified registration in accordance with §§ 1301.13 and 1301.19 of this chapter, with such application

containing the information required by this section; and

(2) Notify the State boards of pharmacy in any States in which the online pharmacy offers to sell, deliver, distribute, or dispense controlled substances.

(b) The following information must be included in the notification submitted under paragraph (a) of this section:

(1) The pharmacy's Internet Pharmacy Site Disclosure information required to be posted on the homepage of the online pharmacy's Internet site under section 311(c) of the Act (21 U.S.C. 831(c)) and § 1304.45 of this part.

(2) Certification that the information disclosed on its Internet site under the Internet Pharmacy Site Disclosure is true and accurate. The statement shall be in a form similar to the following: "The above-named pharmacy, a DEA registrant, certifies, under penalty of perjury, that the information contained in this statement is true and accurate."

(3) Each Internet site address utilized by the online pharmacy and a certification that the online pharmacy shall notify the Administrator of any change in any such Internet address at least 30 days in advance. In the event that a pharmacy delivers, distributes, or dispenses controlled substances pursuant to orders made on, through, or on behalf of, more than one Web site, the pharmacy shall provide, for purposes of complying with this paragraph, the Internet site address of each such site.

(4) The DEA registration numbers of:

(i) Every pharmacy that delivers, distributes, or dispenses controlled substances pursuant to orders made on, through, or on behalf of, each Web site referred to in paragraph (b)(3) of this section; and

(ii) Every practitioner who has a contractual relationship to provide medical evaluations or issue prescriptions for controlled substances, through referrals from the Web site or at the request of the owner or operator of the Web site, or any employee or agent thereof.

(c) It is unlawful for any online pharmacy to deliver, distribute, or dispense a controlled substance by means of the internet unless such online pharmacy

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is validly registered with a modification of such registration authorizing such activity.

(d) On and after the date an online pharmacy makes the notifications required under this section, each online pharmacy shall display on the homepage of its Internet site, a declaration that it has made such notifications to the Administrator in the following form: “In accordance with the Controlled Substances Act and the DEA regulations, this online pharmacy has made the notifications to the DEA Administrator required by 21 U.S.C. 831 and 21 CFR 1304.40.”

(e)(1) Except as provided in paragraphs (e)(2) and (e)(3) of this section, if any of the information required to be submitted under this section changes after the online pharmacy submits the notification to the Administrator, the online pharmacy shall notify the Administrator of the updated information no later than 30 days before the change becomes effective via the online process.

(2) If a pharmacy referred to in paragraph (b)(4)(i) of this section ceases to deliver, distribute, or dispense controlled substances pursuant to orders made on, through, or on behalf of, each Web site referred to in paragraph (b)(3) of this section, the online pharmacy shall notify the Administrator no later than 30 days after the change becomes effective via the online process.

(3) If a practitioner referred to in paragraph (b)(4)(ii) of this section ceases to have a contractual relationship with the online pharmacy, the online pharmacy shall notify the Administrator no later than 30 days after the change becomes effective via the online process.

[74 FR 15623, Apr. 6, 2009, as amended at 85 FR 61601, Sept. 30, 2020]

### § 1304.45 Internet Web site disclosure requirements.

(a) Each online pharmacy shall display, at all times and in a visible and clear manner, on its homepage a statement that it complies with the requirements of section 311 of the Act (21 U.S.C. 831) with respect to the delivery or sale or offer for sale of controlled substances. This statement must include the name of the pharmacy as it

appears on the DEA Certificate of Registration.

(b) Each online pharmacy shall clearly display the following information on the homepage of each Internet site it operates, or on a page directly linked to the homepage. If the information is displayed on a page directly linked to the homepage, that link on the homepage must be visible and clear. The information must be displayed for each pharmacy that delivers, distributes, or dispenses controlled substances pursuant to orders made on, through, or on behalf of that Web site.

(1) The name and address of the pharmacy as it appears on the pharmacy’s DEA Certificate of Registration.

(2) The pharmacy’s telephone number and e-mail address.

(3) The name, professional degree, and States of licensure of the pharmacist-in-charge, and a telephone number at which the pharmacist-in-charge can be contacted.

(4) A list of the States in which the pharmacy is licensed to dispense controlled substances.

(5) A certification that the pharmacy is registered under part 1301 of this chapter with a modification of its registration authorizing it to deliver, distribute, or dispense controlled substances by means of the Internet.

(6) The name, address, telephone number, professional degree, and States of licensure with State license number of any practitioner who has a contractual relationship to provide medical evaluations or issue prescriptions for controlled substances, through referrals from the Web site or at the request of the owner or operator of the Web site, or any employee or agent thereof.

(7) The following statement: “This online pharmacy is obligated to comply fully with the Controlled Substances Act and DEA regulations. As part of this obligation, this online pharmacy has obtained a modified DEA registration authorizing it to operate as an online pharmacy. In addition, this online pharmacy will only dispense a controlled substance to a person who has a valid prescription issued for a legitimate medical purpose based upon a medical relationship with a prescribing practitioner. This includes at