§ 1304.40  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) An online pharmacy that is in operation at the time Public Law 110–425 becomes effective (April 13, 2009) must make the notifications required in this section on or before May 13, 2009. However, in accordance with section 401(h) of the Act (21 U.S.C. 841(h)), as of April 13, 2009, it is unlawful for any online pharmacy to deliver, distribute, or dispense a controlled substance by means of the Internet unless such online pharmacy 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 the notifications to the DEA 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.
Drug Enforcement Administration, Justice

§ 1304.50 Disclosure requirements for Web sites of nonpharmacy practitioners that dispense controlled substances by means of the Internet.

For a Web site to identify itself as being exempt from the definition of an online pharmacy by virtue of section 102(52)(B)(ii) of the Act (21 U.S.C. 802(52)(B)(ii)) and §1300.04(h)(2) of this chapter, the Web site shall post in a visible and clear manner on its homepage, a list of the DEA-registered nonpharmacy practitioners who are affiliated with the Web site. Any nonpharmacy practitioner affiliated with such a Web site is responsible for compliance with this section. An institutional practitioner that otherwise complies with the requirements of the Act and this chapter will be deemed to meet the requirements of this section if, in lieu of posting the names of each affiliated individual practitioner, it posts its name (as it appears on its Certificate of Registration) in a visible and clear manner.