§ 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, or on a page directly linked thereto in which the hyperlink is also visible and clear on the 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 on its homepage and in a manner that identifies itself as being responsible for the operation of the Web site.

[74 FR 15623, Apr. 6, 2009]

§ 1304.55 Reports by online pharmacies.

(a) Each online pharmacy shall report to the Administrator the total quantity of each controlled substance that the pharmacy has dispensed each calendar month. The report must include the total quantity of such dispensing by any means, regardless of whether the controlled substances are dispensed by means of the Internet. Thus, such reporting shall include all controlled substances dispensed via Internet transactions, mail-order transactions, face-to-face transactions, or any other means. However, the pharmacy is not required to describe in its report to the Administrator such means of dispensing. Such reporting is required for every calendar month in which the total quantity of controlled substances dispensed by the pharmacy meets or exceeds one of the following thresholds:

(1) 100 or more prescriptions for controlled substances filled; or

(2) 5,000 or more dosage units dispensed of all controlled substances combined.

(b) Each online pharmacy shall report a negative response if, during a given calendar month, its total dispensing of controlled substances falls below both of the thresholds in paragraph (a) of this section.

(c) The reporting requirements of this section apply to every pharmacy that, at any time during a calendar month, holds a modified registration authorizing it to operate as an online pharmacy, regardless of whether the online pharmacy dispenses any controlled substances by means of the Internet during the month.

(d) Reports will be submitted to DEA electronically via online reporting.