

Justification for emergency action for DEA Form 332
Reports of Dispensing of Controlled Substances by Online Pharmacies
New DEA Information Collection

The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Pub. L. 110-425) was enacted on October 15, 2008. The Ryan Haight Act amended the Controlled Substances Act by adding various provisions to prevent the illegal distribution and dispensing of controlled substances by means of the Internet. The law becomes effective April 13, 2009.

The Ryan Haight Act requires DEA-registered pharmacies that fall within the definition of an online pharmacy (21 U.S.C. 802(52), 21 CFR 1300.04(h)) to report the total quantity of each controlled substance that the pharmacy has dispensed during each calendar month (21 U.S.C. 827(d)(2), 21 CFR 1304.55). Reports are required to be filed by every pharmacy that holds a modified registration authorizing it to operate as an online pharmacy.

The Ryan Haight Act requires online pharmacies to report to DEA when the total quantity of controlled substances dispensed meets or exceeds either 100 or more prescriptions for controlled substances filled, or 5,000 or more dosage units dispensed of all controlled substances combined, in the calendar month for which reporting is required. If a pharmacy fills fewer than 100 prescriptions for controlled substances, and dispenses fewer than 5,000 dosage units of all controlled substances combined, in the calendar month for which reporting is required, a negative response indicating that reporting is not required must be received by DEA. Thus, each online pharmacy will report every month to DEA, either by providing actual dispensing information or by providing a negative response.

DEA has developed an Internet-based application to allow online pharmacies to submit these reports electronically through the DEA Office of Diversion Control website. As the Act requires reports of dispensed controlled substances on a monthly basis, DEA must implement the online reporting process to allow online pharmacies to submit reports beginning May 1, 2009, to be in compliance with the law.

The requirement for online pharmacies to report the total quantity of each controlled substance that the pharmacy has dispensed during each calendar month is an essential aspect of the Ryan Haight Act and the rule promulgating the implementing regulations. Congress contemplated it would be necessary for DEA to issue regulations on an interim basis to implement the Act given the 180 days between enactment of the Act and its effective date. Congress recognized it would be contrary to the public interest to delay the promulgation of regulations in a manner that would prevent implementation of the Act upon its effective date.

As of April 13, 2009, all online pharmacies are required to report the total quantity of each controlled substance that the pharmacy has dispensed during each calendar month. It is essential that the online reporting capability (DEA-332) be fully operational as soon as possible to allow DEA to carry out its functions as a law enforcement agency, and to meet the statutory deadline of the Ryan Haight Act. Consequently, DEA is requesting this new information collection be considered on an emergency basis. A delay in the approval of this information collection will prevent the Reports of Dispensing of Controlled Substances by Online

Pharmacies (DEA-332) from being operational in the timeframe mandated by law. If DEA does not have DEA-332 in place prior to the statutory deadline, online pharmacies will not be able to submit reports of controlled substances dispensed as set forth by law.