

Online Pharmacies Subject to Heightened Scrutiny and Requirements

by Jason B. Caron and Lee H. Rosebush, PharmD

November 2008

On October 15, 2008, President Bush signed into law the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Pub. L. No. 110-425) (the “**Ryan Haight Act**” or “**Act**”) which amends the Controlled Substances Act (“**CSA**”) and related sentencing guidelines. Among other things the Ryan Haight Act subjects online pharmacies to a host of new requirements. Significantly and with limited exceptions, effective April 2009, online pharmacies will only be allowed to fill prescriptions for controlled substances if the prescribing physician has conducted an in-person medical evaluation of the patient. In addition, online pharmacies will be required to make a number of disclosures to the government, including the number of controlled substances the pharmacies dispense to the extent that certain dispensing thresholds are triggered (i.e., 100 prescriptions or 5,000 units). Therefore, pharmacies with online operations need to review the Ryan Haight Act to ensure compliance with the law.

More specifically, the Ryan Haight Act prohibits the distributing, dispensing or delivery of controlled substances by means of the “Internet” (a broadly defined term) without a “valid prescription”.¹ The Act defines a “valid prescription” as a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by: (i) a practitioner who has conducted at least one in-person medical evaluation of the patient; or (ii) a “covering practitioner” (defined as, with respect to a patient, a practitioner who conducts a medical evaluation (other than an in-person evaluation) at the request of a practitioner who (i) has conducted at least one in-person medical evaluation of the patient or an evaluation of the patient through the practice of telemedicine, with the previous 24-months, and (ii) is temporarily unavailable to conduct the evaluation of the patient).

Among other provisions, the Ryan Haight Act also:

- Modifies the Drug Enforcement Administration (“**DEA**”) pharmacy registration requirements to authorize pharmacies to dispense controlled substances by means of the Internet, while at the same time requiring certain notifications to the U.S.

Attorney General and applicable state boards of pharmacy of the pharmacy's intent to sell, deliver, distribute or dispense controlled substances over the Internet and to report to the U.S. Attorney General when the pharmacies trigger certain dispensing thresholds (i.e., 100 prescriptions or 5,000 units);

- Requires an "online pharmacy" to meet certain website content requirements, including a Ryan Haight Act compliance statement and the posting of specific information about the pharmacy, pharmacist-in-charge and certain contractual relationships with health care practitioners²;
- Requires compliance with state laws for the licensure of pharmacies in each state from which and to which the pharmacies deliver, distribute, or dispense or offer to deliver, distribute, or dispense controlled substances;
- Authorizes the U.S. Attorney General to issue a special registration for telemedicine practitioners that are not subject to the new in-person medical evaluation requirement;
- Increases criminal penalties for CSA violations involving controlled substances in Schedules III, IV and V and creates specific penalties for offenses involving dispensing controlled substances by means of the Internet; and
- Provides the state Attorney Generals with the ability to bring a civil action in a Federal court when the state has reason to believe that an interest of the residents of that state has been or is being threatened or adversely affected by the action of person, entity, or Internet site that violates certain provisions of the Act. The states may seek to enjoin the conduct, enforce compliance, obtain damages, restitution or other compensation, including civil penalties and obtain such other legal or equitable relief as the court may find appropriate. However, the states must serve prior written notice on the Attorney General of the United States, giving the Attorney General the opportunity to intervene in the litigation.

In connection with the passage of the Ryan Haight Act, the DEA released the following statement about the importance of this new act: "Cyber-criminals illegally peddling controlled substances over the Internet have invaded households and threatened America's youth for far too long by supplying pharmaceuticals with a few clicks of a mouse and a credit card number [.] This landmark piece of legislation will bring rogue pharmacy operators out of the shadows by establishing a clear standard for legitimate online pharmaceutical sales. The legislation will allow customers to know they are doing business with a trusted, legitimate pharmacy, and give law enforcement the tools we need to identify illegitimate online pharmacies."

Although this Act is intended to target "rogue pharmacies", legitimate online pharmacies will also need to review the Ryan Haight Act with their legal counsel in order to ensure compliance with the law by April of 2009. In addition, we expect that the Department of Justice will issue implementing regulations in connection with the Act and, therefore, we suggest that interested parties continue to monitor developments related to the Act.

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For questions regarding this alert and topic, please contact:

Jason B. Caron
Washington, DC
202/861-4190
jcaron@ebglaw.com

Lee H. Rosebush, PharmD
Washington, DC
202/861-1812
lrosebush@ebglaw.com

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Lynn Shapiro Snyder, Esq.
EDITOR

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Endnotes:

- ¹ 21 U.S.C. §829. The Ryan Haight Act specifically excludes (1) the delivery, distribution, and dispensing of a controlled substance by a practitioner engaged in the “practice of telemedicine” (a specifically defined term), and (2) the dispensing or selling of a controlled substance pursuant to practices as determined with the U.S. Attorney General by regulation, which shall be consistent with effective controls against diversion.
- ² We note that contractual relationships between pharmacies and health care practitioners may raise health care fraud and abuse issues. Therefore, we suggest that pharmacies also carefully review these relationships with legal counsel.