

**Ryan Haight Online Pharmacy Consumer Protection Act of 2008
A Compliance Guide for Community Pharmacists**

April 2009

What is the Ryan Haight Act?

Amends the Controlled Substance Act (CSA) and the Controlled Substance Import and Export Act adding provisions to prevent illegal distribution and dispensing of controlled substances over the Internet. The Drug Enforcement Administration (DEA) issued an interim final rule with comment effective immediately with comments due on June 5, 2009. Internet pharmacies, defined as online pharmacies by the rule, may continue providing controlled substance prescriptions in federal Schedules III-V for legitimate medical purposes subject to certain registration reporting, and recordkeeping requirements. To prescribe controlled substances through entities that qualify as online pharmacies, practitioners must conduct at least one in-person medical evaluation. Finally, the law imposes additional federal and state criminal penalties for unlawful distributors and dispensers of controlled substances.

How does this legislation apply to community pharmacists/pharmacies?

Most community pharmacists will *not* have to comply with the additional registration requirements for online pharmacies. However, all community pharmacies must determine whether the provisions apply to their business and ensure compliance with new DEA requirements. All pharmacies must understand new restrictions for dispensing controlled substance prescriptions received through websites that provide access to practitioners who write prescriptions for consumers.

All pharmacies must also be aware of new maximum sentencing guidelines for violations associated with illegal sales of controlled substances applicable to all dispensers and prescribers. The maximum penalties are as follows:

Schedule III: Maximum sentence for first offenders from 5 years to 10 years; □ maximum sentence for second offenders from 10 years to 20 years

Schedule IV: Maximum sentence for first offenders from 3 years to 5 years □; maximum sentence for second offenders from 6 years to 10 years

Schedule V: Maximum sentence for second offenders from 2 years to 6 years.

Penalties for violations associated with Schedule II prescriptions have not changed.

What is the definition of online pharmacy?

Business entities in the United States or abroad that knowingly or intentionally sell or offer to sell controlled substances in federal schedules III-V over the Internet, including:

- Websites that sell or offer to sell any controlled substance prescription in the United States.
- Entities that pay pharmacies a fee to fill prescriptions from practitioners referred from the Internet.
- Pharmacies that knowingly or intentionally fill prescriptions for controlled substances issued to customers of a website.

What entities are excluded from the definition of online pharmacy?

- Pharmacies that fill or refill prescriptions in Schedules III-V transmitted via the Internet upon implementation of DEA rules permitting electronic prescribing.
- Retail pharmacies operating properly registered automated dispensing systems at long-term care facilities are excluded from this definition.
- DEA registered manufacturers or distributors that do not dispense controlled substances to unregistered individuals.
- Nonpharmacy practitioners who are registered under DEA to dispense, administer, or prescribe controlled substances.
- Federal and Indian health care facilities.
- Advertising that does not facilitate an actual transaction involving a controlled substance.

What steps must online pharmacies take to comply?

Pharmacies that meet the definition of online pharmacy must obtain modification of registration from DEA for all Internet business on or after April 13, 2009. Pharmacies that meet the definition of online pharmacies that have not received a modification of registration from DEA will not be able to continue delivering, dispensing, or distributing controlled substances via the Internet until the proper steps have been taken. Online pharmacies must post certain disclaimers and declarations on its website pursuant to the interim final rule. Pharmacies must ensure that all disclosures, declarations, and information are included in the modification request that may be submitted online. Information may be obtained through the DEA Office of Diversion Control, <http://www.deadiversion.usdoj.gov>.

Pharmacies that have modified DEA registrations that dispense 100 or more controlled substance prescriptions or 5,000 total dosage units in a month must report on a monthly basis all controlled substances dispensed not just those dispensed via the Internet. These reports will be submitted online using the NDC of the medications dispensed.

What must pharmacies that do not meet the definition of online pharmacy do to comply?

Beginning April 13, 2009, pharmacists must determine whether controlled substance prescriptions are issued through the Internet. If a pharmacist has *actual knowledge* that the prescription was issued by means of the Internet through an online pharmacy in violation of the Ryan Haight Act or in light of all the facts surrounding the issuance of the prescription, then he or she has a duty not to fill the prescription. If the pharmacist fills such a prescription, then this is considered an intentional violation of the Ryan Haight Act by both the pharmacy and the pharmacist that subjects both to criminal penalties.