

MORE REGULATION FOR PHARMACIES: NEW FEDERAL REQUIREMENTS FOR INTERNET SALES OF CONTROLLED SUBSTANCES AND PENALTIES FOR EVERYONE

CHICAGO
Citigroup Center
500 West Madison Street
Suite 3700
Chicago, IL 60661-2511
phone: (312) 715-5000
fax: (312) 715-5155

MADISON
33 East Main Street
Suite 900
Madison, WI 53703-3095
phone: (608) 251-5000
fax: (608) 251-9166

MILWAUKEE
411 East Wisconsin Avenue
Suite 2040
Milwaukee, WI 53202-4497
phone: (414) 277-5000
fax: (414) 271-3552

NAPLES
1395 Panther Lane
Suite 300
Naples, FL 34109-7874
phone: (239) 262-5959
fax: (239) 434-4999

PHOENIX
One Renaissance Square
Two North Central Avenue
Phoenix, AZ 85004-2391
phone: (602) 229-5200
fax: (602) 229-5690

TUCSON
One South Church Avenue
Suite 1700
Tucson, AZ 85701-1621
phone: (520) 770-8700
fax: (520) 623-2418

www.quarles.com

© 2008 Quarles & Brady LLP

This document provides information of a general nature. None of the information contained herein is intended as legal advice or opinion relative to specific matters, facts, situations or issues. Additional facts and information or future developments may affect the subjects addressed in this document. You should consult with a lawyer about your particular circumstances before acting on any of this information because it may not be applicable to you or your situation.

On October 15, President Bush signed the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 ("Act"), which amends the Controlled Substances Act ("CSA") to address problems of controlled substance abuse and availability. The Act creates new requirements for "online pharmacies" and increases penalties for all unlawful distributors/dispensers of controlled substances. The Act will take effect in April 2009.

New Requirements for Online Pharmacies

The centerpiece of the Act is a ban on the delivery, distribution or dispensing of controlled substances over the Internet without a "valid prescription." The new requirement for a valid prescription is intended to address rogue Internet pharmacies that operate with the aid of doctors who issue prescriptions to "patients" throughout the country with whom they do not have a preexisting, bona fide doctor-patient relationship. Telemedicine practitioners are not subject to the new requirement.

Under the Act, a "valid prescription" is defined as a prescription that is issued for a legitimate medical purpose in the usual course of professional practice, by a practitioner who has conducted at least one in-person medical evaluation of the patient. Alternatively, a "covering physician" may write a valid prescription at the request of a practitioner who has conducted an in-person or telemedicine examination within the previous 24 months and is temporarily unavailable to evaluate the patient.

Thirty days prior to offering a controlled substance for sale, delivery, distribution or dispensing, an online pharmacy must notify the United States attorney general and the state boards of pharmacy in any states where the online pharmacy offers

to sell, deliver, distribute or dispense controlled substances. The term "online pharmacy" means a person, entity or Internet site, whether in the United States or abroad, that knowingly or intentionally delivers, distributes or dispenses, or offers or attempts to deliver, distribute or dispense, a controlled substance by means of the Internet, with some exceptions, including but not limited to manufacturers or distributors, certain government or tribal health care facilities and certain practitioners registered under section 303(f) of the CSA (related to research on controlled substances). The Act also creates Web page design requirements for all online pharmacies and reporting requirements for a subset of them.

The Act will give the attorney general of each state the ability to bring a civil action in a federal district court to enjoin the actions of an online pharmacy or person which/who is operating in violation of the Act. To bring such an action, the state must have served prior written notice on the attorney general of the United States, giving the attorney general the opportunity to intervene in the litigation. Under current law, a state attorney general's enforcement authority against an online pharmacy is limited to the geographic boundaries of that state, which creates challenges when a case involves illegal activity over the Internet.

Increased Penalties for All Unlawful Distributors/Dispensers

For all unlawful distributors and dispensers of controlled substances — not just online pharmacies — the Act increases criminal penalties involving drugs in Schedules III, IV and V of the CSA. To provide a greater deterrent where illicit distribution is most prominent, the Act increases the statutory maximum penalties as follows:

- Schedule III: From 5 years to 10 years for first-time offenders (plus additional time if death or serious bodily injury results); from 10 years to 20 years for second-time offenders (plus additional time if death or serious bodily injury results); increased maximum penalties for first- and second-time offenders.
- Schedule IV: From 3 years to 5 years for first-time offenders; from 6 years to 10 years for second-time offenders.
- Schedule V: From 2 years to 6 years for second-time offenders.

* * *

For more details about the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, please contact [Amy Bradshaw](mailto:abradsha@quarles.com) at 608-283-2411 / abradsha@quarles.com, [Sarah Coyne](mailto:sec@quarles.com) at 608-283-2435 / sec@quarles.com or your local Quarles & Brady LLP attorney.