

**APhA Summary of
S.980: Ryan Haight Online Pharmacy Consumer Protection Act of 2008
As Passed by the Senate on April 1, 2008**

Summary: S.980 amends the Controlled Substances Act (CSA) to address online pharmacies. It requires online pharmacies to register and to report to the Attorney General (AG) regarding controlled substances dispensed via the internet. The legislation requires a valid prescription for controlled substances delivered, distributed, or dispensed by online pharmacies and requires online pharmacies to disclose contact information, and other information, on the website. Online pharmacies are required to notify the AG prior to dispensing, delivering, or distributing medications. S.980 also defines the practice of telemedicine and includes special registration requirements for practitioners who engage in the practice of telemedicine. The legislation establishes criminal penalties for violating the Act.

Registration Requirements: Modifies the CSA to allow for the registration of a pharmacy that dispenses a controlled substance via the internet. The Attorney General will promulgate regulations regarding registration.

Reporting Requirements: A registered pharmacy is required to report to the AG the total quantity of each controlled substance it dispenses in a month. Reporting is not required unless the pharmacy has met one of the following thresholds in the month for which reporting is required:

- 100 or more prescriptions dispensed
- 5,000 or more dosage units of all controlled substances combined

Online Prescription Requirement: Defines a “valid prescription” as one that is issued for a legitimate medical purpose in the usual course of professional practice by a practitioner that has conducted at least one in-person medical evaluation or by a covering practitioner. An in-person medical evaluation must be conducted in the physical presence of the physician and patient. A “covering practitioner” is a practitioner who conducts a medical evaluation at the request of another practitioner who has already conducted at least one in-person medical evaluation and who is temporarily unavailable to conduct an evaluation.

No controlled substance may be dispensed, delivered, or distributed without a valid prescription.

The requirement for a valid prescription does not apply to:

- a. Delivery, distribution, or dispensing of a controlled substance by a practitioner engaged in telemedicine; or
- b. Dispensing or selling of controlled substances pursuant to practices determined by the AG in regulation, which are consistent with effective controls against diversion.

Defines “Practice of Telemedicine” as the practice of medicine in accordance with applicable Federal and State laws by a practitioner, other than a pharmacist, who is at a location remote

from the patient and is communicating with the patient, or health care professional who is treating the patient, using a telecommunications system, and:

- Is conducted while the patient is being treated and physically located in a hospital or clinic registered under 303(f) and by a practitioner acting the usual course of professional practice, acting in accordance with applicable State law, and registered under section 303(f) in the State in which the patient is located (unless exempted from registration by the Secretary) or is:
 - An employee or contractor of the VA or Indian Health Service
 - Conducted during a declared public health emergency
 - Conducted by a practitioner who has obtained a special registration under section 311(h) (related to telemedicine)
 - Conducted in a medical emergency situation

Includes a temporary definition of telemedicine to allow for the phase-in of the definition included in this act.

Online Pharmacy Licensing and Disclosure Requirements:

“Online Pharmacy” means a person, entity, or internet site, whether in the US 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. It does not include:

- Manufacturers;
- Non-pharmacy practitioners registered under section 303(f) (related to research on controlled substances);
- Hospitals or medical facilities operated by the US government, including the Armed Forces, that are registered under section 303(f);
- Health care facilities owned or operated by an Indian tribe or tribal organization;
- Agents or employees of tribal or hospitals/medical facilities registered under 303(f);
- Advertising that does not attempt to facilitate an actual transaction involving a controlled substance;
- A non-US site, person, or entity that does not facilitate delivery, distribution, or dispensing of controlled substances via the internet;
- A pharmacy registered under section 303(f) that dispenses or refills prescriptions for schedule III, IV, or V controlled substances; or
- Any other person identified in regulation by the Attorney General.

An online pharmacy must display in a visible and clear manner on its homepage a statement that it complies with the requirements of the Act.

Each online pharmacy must comply with State law regarding the licensure of pharmacies, including states to which it delivers, distributes or dispenses, or offers to deliver, dispense, or distribute, controlled substances.

Online pharmacies must comply with all applicable State and Federal laws.

Each online pharmacy must disclose in a visible and clear manner on its homepage the following information:

1. The name and address of the pharmacy as it appears on the pharmacy's DEA registration.
2. The pharmacy's telephone number and e-mail address.
3. The name, professional degree, and States of licensure of the pharmacist-in-charge, and a telephone number at which the pharmacist-in-charge can be contacted.
4. A list of the states in which the pharmacy is licensed to dispense controlled substances.
5. A certification that the pharmacy is registered under this part to deliver, distribute, or dispense by means of the Internet controlled substances.
6. The name, address, telephone number, professional degree, and states of licensure of practitioners who provide medical consultations or issue prescriptions for controlled substances through referrals from the website or at the request of the owner or operator of the website, or any employee or agent.
7. The following statement (unless revised by the AG in regulation): "This online pharmacy will only dispense a controlled substance to a person who has a valid prescription issued for a legitimate medical purpose based upon a medical relationship with a prescribing practitioner. This includes at least one prior in-person medical evaluation or medical evaluation via telemedicine in accordance with applicable requirements of section 309 of the Controlled Substances Act (21 U.S.C., 829)."

Defines "refilling prescriptions" for schedule III, IV, or V controlled substances as:

- Dispensing in accordance with refill instructions issued by a practitioner as part of a valid prescription, and
- Does not include issuance of a new prescription to an individual for a controlled substance that was previously prescribed for that individual

Defines "filling new prescriptions" for schedule III, IV, or V controlled substances as a prescription for an individual if:

- The dispensing pharmacy previously dispensed the same controlled substance to the individual other than by means of the internet, and pursuant to a valid prescription;
- The pharmacy contacts the practitioner who issued the original prescription to determine whether the practitioner will authorize the issuance of a new prescription; and
- The practitioner, acting the usual course of professional practice, determines there is a legitimate medical purpose for the issuance of a new prescription.

Notification: 30 days prior to offering to deliver, distribute, or dispense, the online pharmacy shall notify the AG and the State board of pharmacy:

1. The information required to be posted on the online pharmacy's website and attest, under penalty of perjury, that the information disclosed is true and accurate;
2. The online pharmacy's Internet site address and a certification that the online pharmacy shall notify the AG of any change in the address at least 30 days in advance; and
3. The DEA registration numbers of any pharmacies and practitioners

An online pharmacy that is already operational as of the effective date of this act shall notify the AG and applicable state boards within 30 days of the effective date.

The online pharmacy must post a “declaration of compliance”, that it has made such notification to the AG.

Any statement, declaration, notification, or disclosure required shall be considered a report required to be kept by the online pharmacy.

Authorizes the Secretary to designate a practitioner within the Indian Health Service as an Internet Eligible Controlled Substances Provider, but only in cases where it is found that there is a legitimate need for the designation because the population served is in a sufficiently remote location that access to medical services is limited.

Special Registration for Telemedicine:

Allows for a special registration for a practitioner who engages in the practice of telemedicine, if the practitioner:

- Demonstrates a legitimate need for the special registration; and
- Is registered under section 303(f) in the state in which the patient will be located when receiving the telemedicine treatment, unless the practitioner is exempted from registration or is an employee or contractor of the VA

Requires regulations which limit the circumstances in which special registrations may be issued, and procedures for obtaining a special registration, including denials.

Requires practitioners who issue a prescription for a controlled substance under the authorization to conduct telemedicine during a medical emergency to report to the VA in accordance with regulations established by the Secretary.

Prescription Transfers:

Requires the AG to develop regulations related to the transfer of information between pharmacies relating to a prescription for a controlled substance.

Offenses Involving the CSA: Establishes criminal penalties for violations of the Controlled Substances Act, including failure to register, or making false, fictitious or fraudulent statements to the AG. Allows for State actions related to online pharmacies if the State has reason to believe residents are being threatened or adversely affected by the action of person, entity, or internet site that violates the Act.

Requires the US Sentencing Commission to consult with the Department of Justice, experts and other affected parties concerning which penalties should be reflected in Federal sentencing guidelines and should not construe any change in the maximum penalty for a violation as the sole reason to amend, or establish, a new guideline or policy statement.

Annual Report:

Requires DEA to report to Congress describing:

- The foreign supply chains and sources of controlled substances offered without a valid prescription on the internet;
- The efforts and strategy of the DEA to decrease the foreign supply and sources; and
- The efforts of the DEA to work with domestic and multinational pharmaceutical companies and others to build international cooperation to fight the problem of distribution of controlled substances over the internet without a valid prescription.