

S.980

Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Referred to House Committee after being Received from Senate)

April 2, 2008

Referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

AN ACT

To amend the Controlled Substances Act to address online pharmacies.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the 'Ryan Haight Online Pharmacy Consumer Protection Act of 2008'.

SEC. 2. REQUIREMENT OF A VALID PRESCRIPTION FOR CONTROLLED SUBSTANCES DISPENSED BY MEANS OF THE INTERNET.

Section 309 of the Controlled Substances Act (21 U.S.C. 829) is amended by adding at the end the following:

- ` (e) Controlled Substances Dispensed by Means of the Internet-
 - ` (1) No controlled substance may be delivered, distributed, or dispensed by means of the Internet without a valid prescription.
 - ` (2) As used in this subsection:
 - ` (A) The term 'valid prescription' means 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 1 in-person medical evaluation of the patient; or
 - ` (ii) a covering practitioner.
 - ` (B)(i) The term 'in-person medical evaluation' means a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to

whether portions of the evaluation are conducted by other health professionals.

` (ii) Nothing in clause (i) shall be construed to imply that 1 in-person medical evaluation demonstrates that a prescription has been issued for a legitimate medical purpose within the usual course of professional practice.

` (C) The term `covering practitioner' means, with respect to a patient, a practitioner who conducts a medical evaluation (other than an in-person medical evaluation) at the request of a practitioner who--

` (i) has conducted at least 1 in-person medical evaluation of the patient or an evaluation of the patient through the practice of telemedicine, within the previous 24 months; and

` (ii) is temporarily unavailable to conduct the evaluation of the patient.

` (3) Nothing in this subsection shall apply to--

` (A) the delivery, distribution, or dispensing of a controlled substance by a practitioner engaged in the practice of telemedicine; or

` (B) the dispensing or selling of a controlled substance pursuant to practices as determined by the Attorney General by regulation, which shall be consistent with effective controls against diversion.'

SEC. 3. AMENDMENTS TO THE CONTROLLED SUBSTANCES ACT RELATING TO THE DELIVERY OF CONTROLLED SUBSTANCES BY MEANS OF THE INTERNET.

(a) In General- Section 102 of the Controlled Substances Act (21 U.S.C. 802) is amended by adding at the end the following:

` (50) The term `Internet' means collectively the myriad of computer and telecommunications facilities, including equipment and operating software, which comprise the interconnected worldwide network of networks that employ the Transmission Control Protocol/Internet Protocol, or any predecessor or successor protocol to such protocol, to communicate information of all kinds by wire or radio.

` (51) The term `deliver, distribute, or dispense by means of the Internet' refers, respectively, to any delivery, distribution, or dispensing of a controlled substance that is caused or facilitated by means of the Internet.

` (52) The term `online pharmacy'--

` (A) 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; and

- ˘ (B) does not include--
 - ˘ (i) manufacturers or distributors registered under subsection (a), (b), (c), or (d) of section 303 who do not dispense controlled substances to an unregistered individual or entity;
 - ˘ (ii) nonpharmacy practitioners who are registered under section 303(f) and whose activities are authorized by that registration;
 - ˘ (iii) any hospital or other medical facility that is operated by an agency of the United States (including the Armed Forces), provided such hospital or other facility is registered under section 303(f);
 - ˘ (iv) a health care facility owned or operated by an Indian tribe or tribal organization, only to the extent such facility is carrying out a contract or compact under the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450 et seq.);
 - ˘ (v) any agent or employee of any hospital or facility referred to in clause (iii) or (iv), provided such agent or employee is lawfully acting in the usual course of business or employment, and within the scope of the official duties of such agent or employee, with such hospital or facility, and, with respect to agents or employees of health care facilities specified in clause (iv), only to the extent such individuals are furnishing services pursuant to the contracts or compacts described in such clause;
 - ˘ (vi) mere advertisements that do not attempt to facilitate an actual transaction involving a controlled substance;
 - ˘ (vii) a person, entity, or Internet site that is not in the United States and does not facilitate the delivery, distribution, or dispensing of a controlled substance by means of the Internet to any person in the United States;
 - ˘ (viii) a pharmacy registered under section 303(f) whose dispensing of controlled substances via the Internet consists solely of--
 - ˘ (I) ˘ refilling prescriptions for controlled substances in schedule III, IV, or V', as defined in paragraph (55); or
 - ˘ (II) ˘ filling new prescriptions for controlled substances in schedule III, IV, or V', as defined in paragraph (56); or
 - ˘ (ix) any other persons for whom the Attorney General and the Secretary have jointly, by regulation, found it to be consistent with effective controls against diversion and otherwise consistent with the public health and

safety to exempt from the definition of an 'online pharmacy'.

(53) The term 'homepage' means the opening or main page or screen of the website of an online pharmacy that is viewable on the Internet.

(54) The term 'practice of telemedicine' means, for purposes of this title, 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 referred to in section 1834(m) of the Social Security Act (42 U.S.C. 1395m(m)), and that-

(A) is being conducted--

(i) while the patient is being treated by, and physically located in, a hospital or clinic registered under section 303(f); and

(ii) by a practitioner--

(I) acting in the usual course of professional practice;

(II) acting in accordance with applicable State law; and

(III) registered under section 303(f) in the State in which the patient is located, unless the practitioner--

(aa) is exempted from such registration in all States under section 302(d); or

(bb) is--

(AA) an employee or contractor of the Department of Veterans Affairs who is acting in the scope of such employment or contract; and

(BB) registered under section 303(f) in any State or is utilizing the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(f);

(B) is being conducted while the patient is being treated by, and in the physical presence of, a practitioner--

(i) acting in the usual course of professional practice;

(ii) acting in accordance with applicable State law; and

(iii) registered under section 303(f) in the State in which the patient is located, unless the practitioner--

(I) is exempted from such registration in all States under section 302(d); or

(II) is--

` (aa) an employee or contractor of the Department of Veterans Affairs who is acting in the scope of such employment or contract; and

` (bb) registered under section 303(f) in any State or is using the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(f);

` (C) is being conducted by a practitioner--

` (i) who is an employee or contractor of the Indian Health Service, or is working for an Indian tribe or tribal organization under its contract or compact with the Indian Health Service under the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450 et seq.);

` (ii) acting within the scope of the employment, contract, or compact described in clause (i); and

` (iii) who is designated as an Internet Eligible Controlled Substances Provider by the Secretary under section 311(g)(2);

` (D)(i) is being conducted during a public health emergency declared by the Secretary under section 319 of the Public Health Service Act (42 U.S.C. 247d); and

` (ii) involves patients located in such areas, and such controlled substances, as the Secretary, with the concurrence of the Attorney General, designates, provided that such designation shall not be subject to the procedures prescribed by subchapter II of chapter 5 of title 5, United States Code;

` (E) is being conducted by a practitioner who has obtained from the Attorney General a special registration under section 311(h);

` (F) is being conducted--

` (i) in a medical emergency situation--

` (I) that prevents the patient from being in the physical presence of a practitioner registered under section 303(f) who is an employee or contractor of the Veterans Health Administration acting in the usual course of business and employment and within the scope of the official duties or contract of that employee or contractor;

` (II) that prevents the patient from being physically present at a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(f);

` (III) during which the primary care practitioner of the patient or a practitioner otherwise practicing telemedicine within the meaning of this paragraph is unable to provide care or consultation; and

` (IV) that requires immediate intervention by a health care practitioner using controlled substances to prevent what the practitioner reasonably believes in good faith will be imminent and serious clinical consequences, such as further injury or death; and

` (ii) by a practitioner that--

` (I) is an employee or contractor of the Veterans Health Administration acting within the scope of that employment or contract;

` (II) is registered under section 303(f) in any State or is utilizing the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(f); and

` (III) issues a controlled substance prescription in this emergency context that is limited to a maximum of a 5-day supply which may not be extended or refilled; or

` (G) is being conducted under any other circumstances that the Attorney General and the Secretary have jointly, by regulation, determined to be consistent with effective controls against diversion and otherwise consistent with the public health and safety.

` (55) The term `refilling prescriptions for controlled substances in schedule III, IV, or V'--

` (A) means the dispensing of a controlled substance in schedule III, IV, or V in accordance with refill instructions issued by a practitioner as part of a valid prescription that meets the requirements of subsection (b) or (c) of section 309, as appropriate; and

` (B) does not include the issuance of a new prescription to an individual for a controlled substance that individual was previously prescribed.

` (56) The term `filling new prescriptions for controlled substances in schedule III, IV, or V' means a prescription for an individual for a controlled substance in schedule III, IV, or V, if--

` (A) the pharmacy dispensing that prescription has previously dispensed to the patient that same controlled substance other than by means of the Internet and pursuant to the valid prescription of a practitioner that meets the applicable requirements of sections 309(b) or (c) (in this paragraph referred to as the `original prescription');

` (B) the pharmacy contacts the practitioner who issued the original prescription at the request of that individual to determine whether the practitioner will authorize the issuance of a new prescription for that individual for the controlled substance described in subparagraph (A); and

- “(C) the practitioner, acting in the usual course of professional practice, determines there is a legitimate medical purpose for the issuance of the new prescription.”.
- (b) Registration Requirements- Section 303(f) of the Controlled Substances Act (21 U.S.C. 823(f)) is amended in the matter preceding paragraph (1)--
- (1) in the first sentence, by adding after “schedule II, III, IV, or V” the following: “and shall modify the registrations of pharmacies so registered to authorize them to dispense controlled substances by means of the Internet”; and
 - (2) in the second sentence, by striking “if he determines that the issuance of such registration” and inserting “or such modification of registration if the Attorney General determines that the issuance of such registration or modification”.
- (c) Reporting Requirements- Section 307(d) of the Controlled Substances Act (21 U.S.C. 827(d)) is amended by--
- (1) designating the text as paragraph (1); and
 - (2) inserting after paragraph (1), as so designated by this Act, the following:
 - “(2) Each pharmacy with a modified registration under section 303(f) that authorizes the dispensing of controlled substances by means of the Internet shall report to the Attorney General the controlled substances it dispenses, in the amount specified, and in such time and manner as the Attorney General by regulation shall require, except that the Attorney General, under this paragraph, may not require any pharmacy to report any information other than the total quantity of each controlled substance that the pharmacy has dispensed each month. For purposes of this subsection, no reporting shall be required unless the pharmacy has met 1 of the following thresholds in the month for which the reporting is required:
 - “(A) 100 or more prescriptions dispensed.
 - “(B) 5,000 or more dosage units of all controlled substances combined.”.
- (d) Online Prescription Requirements-
- (1) IN GENERAL- The Controlled Substances Act is amended by inserting after section 310 (21 U.S.C. 830) the following:

“(b) ADDITIONAL REQUIREMENTS RELATING TO ONLINE PHARMACIES AND TELEMEDICINE

- “(a) In General- An online pharmacy shall display in a visible and clear manner on its homepage a statement that it complies with the requirements of this section with respect to the delivery or sale or offer for sale of controlled substances and shall at all times display on the homepage of its Internet site a declaration of compliance in accordance with this section.
- “(b) Licensure- Each online pharmacy shall comply with the requirements of State law concerning the licensure of pharmacies in each State from

which it, and in each State to which it, delivers, distributes, or dispenses or offers to deliver, distribute, or dispense controlled substances by means of the Internet, pursuant to applicable licensure requirements, as determined by each such State.

` (c) Internet Pharmacy Site Disclosure Information- Each online pharmacy shall post in a visible and clear manner on the homepage of each Internet site it operates, or on a page directly linked thereto in which the hyperlink is also visible and clear on the homepage, the following information for each pharmacy that delivers, distributes, or dispenses controlled substances pursuant to orders made on, through, or on behalf of, that website:

` (1) The name and address of the pharmacy as it appears on the pharmacy's Drug Enforcement Administration certificate of registration.

` (2) The pharmacy's telephone number and email 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 any practitioner who has a contractual relationship to provide medical evaluations 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 thereof.

` (7) The following statement, unless revised by the Attorney General by 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.