

110TH CONGRESS
2^D SESSION

H. R. 6353

AN ACT

To amend the Controlled Substances Act to address online pharmacies.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Ryan Haight Online
3 Pharmacy Consumer Protection Act of 2008”.

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

7 Section 309 of the Controlled Substances Act (21
8 U.S.C. 829) is amended by adding at the end the fol-
9 lowing:

10 “(e) CONTROLLED SUBSTANCES DISPENSED BY
11 MEANS OF THE INTERNET.—

12 “(1) No controlled substance that is a prescrip-
13 tion drug as determined under the Federal Food,
14 Drug, and Cosmetic Act may be delivered, distrib-
15 uted, or dispensed by means of the Internet without
16 a valid prescription.

17 “(2) As used in this subsection:

18 “(A) The term ‘valid prescription’ means a
19 prescription that is issued for a legitimate med-
20 ical purpose in the usual course of professional
21 practice by—

22 “(i) a practitioner who has conducted
23 at least 1 in-person medical evaluation of
24 the patient; or

25 “(ii) a covering practitioner.

1 “(B)(i) The term ‘in-person medical eval-
2 uation’ means a medical evaluation that is con-
3 ducted with the patient in the physical presence
4 of the practitioner, without regard to whether
5 portions of the evaluation are conducted by
6 other health professionals.

7 “(ii) Nothing in clause (i) shall be con-
8 strued to imply that 1 in-person medical evalua-
9 tion demonstrates that a prescription has been
10 issued for a legitimate medical purpose within
11 the usual course of professional practice.

12 “(C) The term ‘covering practitioner’
13 means, with respect to a patient, a practitioner
14 who conducts a medical evaluation (other than
15 an in-person medical evaluation) at the request
16 of a practitioner who—

17 “(i) has conducted at least 1 in-per-
18 son medical evaluation of the patient or an
19 evaluation of the patient through the prac-
20 tice of telemedicine, within the previous 24
21 months; and

22 “(ii) is temporarily unavailable to con-
23 duct the evaluation of the patient.

24 “(3) Nothing in this subsection shall apply to—

1 “(A) the delivery, distribution, or dis-
2 pensing of a controlled substance by a practi-
3 tioner engaged in the practice of telemedicine;
4 or

5 “(B) the dispensing or selling of a con-
6 trolled substance pursuant to practices as deter-
7 mined by the Attorney General by regulation,
8 which shall be consistent with effective controls
9 against diversion.”.

10 **SEC. 3. AMENDMENTS TO THE CONTROLLED SUBSTANCES**

11 **ACT RELATING TO THE DELIVERY OF CON-**
12 **TROLLED SUBSTANCES BY MEANS OF THE**
13 **INTERNET.**

14 (a) IN GENERAL.—Section 102 of the Controlled
15 Substances Act (21 U.S.C. 802) is amended by adding at
16 the end the following:

17 “(50) The term ‘Internet’ means collectively the myr-
18 riad of computer and telecommunications facilities, includ-
19 ing equipment and operating software, which comprise the
20 interconnected worldwide network of networks that employ
21 the Transmission Control Protocol/Internet Protocol, or
22 any predecessor or successor protocol to such protocol, to
23 communicate information of all kinds by wire or radio.

24 “(51) The term ‘deliver, distribute, or dispense by
25 means of the Internet’ refers, respectively, to any delivery,

1 distribution, or dispensing of a controlled substance that
2 is caused or facilitated by means of the Internet.

3 “(52) The term ‘online pharmacy’—

4 “(A) means a person, entity, or Internet site,
5 whether in the United States or abroad, that know-
6 ingly or intentionally delivers, distributes, or dis-
7 penses, or offers or attempts to deliver, distribute, or
8 dispense, a controlled substance by means of the
9 Internet; and

10 “(B) does not include—

11 “(i) manufacturers or distributors reg-
12 istered under subsection (a), (b), (d), or (e) of
13 section 303 who do not dispense controlled sub-
14 stances to an unregistered individual or entity;

15 “(ii) nonpharmacy practitioners who are
16 registered under section 303(f) and whose ac-
17 tivities are authorized by that registration;

18 “(iii) any hospital or other medical facility
19 that is operated by an agency of the United
20 States (including the Armed Forces), provided
21 such hospital or other facility is registered
22 under section 303(f);

23 “(iv) a health care facility owned or oper-
24 ated by an Indian tribe or tribal organization,
25 only to the extent such facility is carrying out

1 a contract or compact under the Indian Self-
2 Determination and Education Assistance Act;

3 “(v) any agent or employee of any hospital
4 or facility referred to in clause (iii) or (iv), pro-
5 vided such agent or employee is lawfully acting
6 in the usual course of business or employment,
7 and within the scope of the official duties of
8 such agent or employee, with such hospital or
9 facility, and, with respect to agents or employ-
10 ees of health care facilities specified in clause
11 (iv), only to the extent such individuals are fur-
12 nishing services pursuant to the contracts or
13 compacts described in such clause;

14 “(vi) mere advertisements that do not at-
15 tempt to facilitate an actual transaction involv-
16 ing a controlled substance;

17 “(vii) a person, entity, or Internet site that
18 is not in the United States and does not facili-
19 tate the delivery, distribution, or dispensing of
20 a controlled substance by means of the Internet
21 to any person in the United States;

22 “(viii) a pharmacy registered under section
23 303(f) whose dispensing of controlled sub-
24 stances via the Internet consists solely of—

1 “(I) refilling prescriptions for con-
2 trolled substances in schedule III, IV, or
3 V, as defined in paragraph (55); or

4 “(II) filling new prescriptions for con-
5 trolled substances in schedule III, IV, or
6 V, as defined in paragraph (56); or

7 “(ix) any other persons for whom the At-
8 torney General and the Secretary have jointly,
9 by regulation, found it to be consistent with ef-
10 fective controls against diversion and otherwise
11 consistent with the public health and safety to
12 exempt from the definition of an ‘online phar-
13 macy’.

14 “(53) The term ‘homepage’ means the opening or
15 main page or screen of the website of an online pharmacy
16 that is viewable on the Internet.

17 “(54) The term ‘practice of telemedicine’ means, for
18 purposes of this title, the practice of medicine in accord-
19 ance with applicable Federal and State laws by a practi-
20 tioner (other than a pharmacist) who is at a location re-
21 mote from the patient and is communicating with the pa-
22 tient, or health care professional who is treating the pa-
23 tient, using a telecommunications system referred to in
24 section 1834(m) of the Social Security Act, which prac-
25 tice—

1 “(A) is being conducted—

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

5 “(ii) by a practitioner—

6 “(I) acting in the usual course of pro-
7 fessional practice;

8 “(II) acting in accordance with appli-
9 cable State law; and

10 “(III) registered under section 303(f)
11 in the State in which the patient is located,
12 unless the practitioner—

13 “(aa) is exempted from such reg-
14 istration in all States under section
15 302(d); or

16 “(bb) is—

17 “(AA) an employee or con-
18 tractor of the Department of Vet-
19 erans Affairs who is acting in the
20 scope of such employment or con-
21 tract; and

22 “(BB) registered under sec-
23 tion 303(f) in any State or is uti-
24 lizing the registration of a hos-
25 pital or clinic operated by the

1 Department of Veterans Affairs
2 registered under section 303(f);

3 “(B) is being conducted while the patient is
4 being treated by, and in the physical presence of, a
5 practitioner—

6 “(i) acting in the usual course of profes-
7 sional practice;

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

10 “(iii) registered under section 303(f) in the
11 State in which the patient is located, unless the
12 practitioner—

13 “(I) is exempted from such registra-
14 tion in all States under section 302(d); or

15 “(II) is—

16 “(aa) an employee or contractor
17 of the Department of Veterans Affairs
18 who is acting in the scope of such em-
19 ployment or contract; and

20 “(bb) registered under section
21 303(f) in any State or is using the
22 registration of a hospital or clinic op-
23 erated by the Department of Veterans
24 Affairs registered under section
25 303(f);

1 “(C) is being conducted by a practitioner—

2 “(i) who is an employee or contractor of
3 the Indian Health Service, or is working for an
4 Indian tribe or tribal organization under its
5 contract or compact with the Indian Health
6 Service under the Indian Self-Determination
7 and Education Assistance Act;

8 “(ii) acting within the scope of the employ-
9 ment, contract, or compact described in clause
10 (i); and

11 “(iii) who is designated as an Internet Eli-
12 gible Controlled Substances Provider by the
13 Secretary under section 311(g)(2);

14 “(D)(i) is being conducted during a public
15 health emergency declared by the Secretary under
16 section 319 of the Public Health Service Act; and

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

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

1 “(F) is being conducted—

2 “(i) in a medical emergency situation—

3 “(I) that prevents the patient from
4 being in the physical presence of a practi-
5 tioner registered under section 303(f) who
6 is an employee or contractor of the Vet-
7 erans Health Administration acting in the
8 usual course of business and employment
9 and within the scope of the official duties
10 or contract of that employee or contractor;

11 “(II) that prevents the patient from
12 being physically present at a hospital or
13 clinic operated by the Department of Vet-
14 erans Affairs registered under section
15 303(f);

16 “(III) during which the primary care
17 practitioner of the patient or a practitioner
18 otherwise practicing telemedicine within
19 the meaning of this paragraph is unable to
20 provide care or consultation; and

21 “(IV) that requires immediate inter-
22 vention by a health care practitioner using
23 controlled substances to prevent what the
24 practitioner reasonably believes in good
25 faith will be imminent and serious clinical

1 consequences, such as further injury or
2 death; and

3 “(ii) by a practitioner that—

4 “(I) is an employee or contractor of
5 the Veterans Health Administration acting
6 within the scope of that employment or
7 contract;

8 “(II) is registered under section
9 303(f) in any State or is utilizing the reg-
10 istration of a hospital or clinic operated by
11 the Department of Veterans Affairs reg-
12 istered under section 303(f); and

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

17 “(G) is being conducted under any other cir-
18 cumstances that the Attorney General and the Sec-
19 retary have jointly, by regulation, determined to be
20 consistent with effective controls against diversion
21 and otherwise consistent with the public health and
22 safety.

23 “(55) The term ‘refilling prescriptions for controlled
24 substances in schedule III, IV, or V’—

1 “(A) means the dispensing of a controlled sub-
2 stance in schedule III, IV, or V in accordance with
3 refill instructions issued by a practitioner as part of
4 a valid prescription that meets the requirements of
5 subsections (b) and (c) of section 309, as appro-
6 priate; and

7 “(B) does not include the issuance of a new
8 prescription to an individual for a controlled sub-
9 stance that individual was previously prescribed.

10 “(56) The term ‘filling new prescriptions for con-
11 trolled substances in schedule III, IV, or V’ means filling
12 a prescription for an individual for a controlled substance
13 in schedule III, IV, or V, if—

14 “(A) the pharmacy dispensing that prescription
15 has previously dispensed to the patient a controlled
16 substance other than by means of the Internet and
17 pursuant to the valid prescription of a practitioner
18 that meets the applicable requirements of sub-
19 sections (b) and (c) of section 309 (in this para-
20 graph referred to as the ‘original prescription’);

21 “(B) the pharmacy contacts the practitioner
22 who issued the original prescription at the request of
23 that individual to determine whether the practitioner
24 will authorize the issuance of a new prescription for

1 that individual for the controlled substance described
2 in subparagraph (A); and

3 “(C) the practitioner, acting in the usual course
4 of professional practice, determines there is a legiti-
5 mate medical purpose for the issuance of the new
6 prescription.”.

7 (b) REGISTRATION REQUIREMENTS.—Section 303(f)
8 of the Controlled Substances Act (21 U.S.C. 823(f)) is
9 amended in the matter preceding paragraph (1)—

10 (1) in the first sentence, by adding after
11 “schedule II, III, IV, or V” the following: “and shall
12 modify the registrations of pharmacies so registered
13 to authorize them to dispense controlled substances
14 by means of the Internet”; and

15 (2) in the second sentence, by striking “if he
16 determines that the issuance of such registration”
17 and inserting “or such modification of registration if
18 the Attorney General determines that the issuance of
19 such registration or modification”.

20 (c) REPORTING REQUIREMENTS.—Section 307(d) of
21 the Controlled Substances Act (21 U.S.C. 827(d)) is
22 amended by—

23 (1) striking “(d) Every” and inserting “(d)(1)
24 Every”; and

25 (2) adding at the end the following:

1 section with respect to the delivery or sale or offer for sale
2 of controlled substances and shall at all times display on
3 the homepage of its Internet site a declaration of compli-
4 ance in accordance with this section.

5 “(b) LICENSURE.—Each online pharmacy shall com-
6 ply with the requirements of State law concerning the li-
7 censure of pharmacies in each State from which it, and
8 in each State to which it, delivers, distributes, or dispenses
9 or offers to deliver, distribute, or dispense controlled sub-
10 stances by means of the Internet, pursuant to applicable
11 licensure requirements, as determined by each such State.

12 “(c) INTERNET PHARMACY SITE DISCLOSURE IN-
13 FORMATION.—Each online pharmacy shall post in a visible
14 and clear manner on the homepage of each Internet site
15 it operates, or on a page directly linked thereto in which
16 the hyperlink is also visible and clear on the homepage,
17 the following information for each pharmacy that delivers,
18 distributes, or dispenses controlled substances pursuant to
19 orders made on, through, or on behalf of, that website:

20 “(1) The name and address of the pharmacy as
21 it appears on the pharmacy’s Drug Enforcement Ad-
22 ministration certificate of registration.

23 “(2) The pharmacy’s telephone number and
24 email address.

1 “(3) The name, professional degree, and States
2 of licensure of the pharmacist-in-charge, and a tele-
3 phone number at which the pharmacist-in-charge
4 can be contacted.

5 “(4) A list of the States in which the pharmacy
6 is licensed to dispense controlled substances.

7 “(5) A certification that the pharmacy is reg-
8 istered under this part to deliver, distribute, or dis-
9 pense by means of the Internet controlled sub-
10 stances.

11 “(6) The name, address, telephone number,
12 professional degree, and States of licensure of any
13 practitioner who has a contractual relationship to
14 provide medical evaluations or issue prescriptions for
15 controlled substances, through referrals from the
16 website or at the request of the owner or operator
17 of the website, or any employee or agent thereof.

18 “(7) The following statement, unless revised by
19 the Attorney General by regulation: ‘This online
20 pharmacy will only dispense a controlled substance
21 to a person who has a valid prescription issued for
22 a legitimate medical purpose based upon a medical
23 relationship with a prescribing practitioner. This in-
24 cludes at least one prior in-person medical evalua-

1 tion or medical evaluation via telemedicine in accord-
2 ance with applicable requirements of section 309.’.

3 “(d) NOTIFICATION.—

4 “(1) IN GENERAL.—Thirty days prior to offer-
5 ing a controlled substance for sale, delivery, distribu-
6 tion, or dispensing, the online pharmacy shall notify
7 the Attorney General, in such form and manner as
8 the Attorney General shall determine, and the State
9 boards of pharmacy in any States in which the on-
10 line pharmacy offers to sell, deliver, distribute, or
11 dispense controlled substances.

12 “(2) CONTENTS.—The notification required
13 under paragraph (1) shall include—

14 “(A) the information required to be posted
15 on the online pharmacy’s Internet site under
16 subsection (c) and shall notify the Attorney
17 General and the applicable State boards of
18 pharmacy, under penalty of perjury, that the
19 information disclosed on its Internet site under
20 subsection (c) is true and accurate;

21 “(B) the online pharmacy’s Internet site
22 address and a certification that the online phar-
23 macy shall notify the Attorney General of any
24 change in the address at least 30 days in ad-
25 vance; and

1 “(C) the Drug Enforcement Administra-
2 tion registration numbers of any pharmacies
3 and practitioners referred to in subsection (c),
4 as applicable.

5 “(3) EXISTING ONLINE PHARMACIES.—An on-
6 line pharmacy that is already operational as of the
7 effective date of this section, shall notify the Attor-
8 ney General and applicable State boards of phar-
9 macy in accordance with this subsection not later
10 than 30 days after such date.

11 “(e) DECLARATION OF COMPLIANCE.—On and after
12 the date on which it makes the notification under sub-
13 section (d), each online pharmacy shall display on the
14 homepage of its Internet site, in such form as the Attorney
15 General shall by regulation require, a declaration that it
16 has made such notification to the Attorney General.

17 “(f) REPORTS.—Any statement, declaration, notifica-
18 tion, or disclosure required under this section shall be con-
19 sidered a report required to be kept under this part.

20 “(g) NOTICE AND DESIGNATIONS CONCERNING IN-
21 DIAN TRIBES.—

22 “(1) IN GENERAL.—For purposes of sections
23 102(52) and 512(c)(6)(B), the Secretary shall notify
24 the Attorney General, at such times and in such
25 manner as the Secretary and the Attorney General

1 determine appropriate, of the Indian tribes or tribal
2 organizations with which the Secretary has con-
3 tracted or compacted under the Indian Self-Deter-
4 mination and Education Assistance Act for the
5 tribes or tribal organizations to provide pharmacy
6 services.

7 “(2) DESIGNATIONS.—

8 “(A) IN GENERAL.—The Secretary may
9 designate a practitioner described in subpara-
10 graph (B) as an Internet Eligible Controlled
11 Substances Provider. Such designations shall be
12 made only in cases where the Secretary has
13 found that there is a legitimate need for the
14 practitioner to be so designated because the
15 population served by the practitioner is in a
16 sufficiently remote location that access to med-
17 ical services is limited.

18 “(B) PRACTITIONERS.—A practitioner de-
19 scribed in this subparagraph is a practitioner
20 who is an employee or contractor of the Indian
21 Health Service, or is working for an Indian
22 tribe or tribal organization under its contract or
23 compact under the Indian Self-Determination
24 and Education Assistance Act with the Indian
25 Health Service.

1 “(h) SPECIAL REGISTRATION FOR TELEMEDICINE.—

2 “(1) IN GENERAL.—The Attorney General may
3 issue to a practitioner a special registration to en-
4 gage in the practice of telemedicine for purposes of
5 section 102(54)(E) if the practitioner, upon applica-
6 tion for such special registration—

7 “(A) demonstrates a legitimate need for
8 the special registration; and

9 “(B) is registered under section 303(f) in
10 the State in which the patient will be located
11 when receiving the telemedicine treatment, un-
12 less the practitioner—

13 “(i) is exempted from such registra-
14 tion in all States under section 302(d); or

15 “(ii) is an employee or contractor of
16 the Department of Veterans Affairs who is
17 acting in the scope of such employment or
18 contract and is registered under section
19 303(f) in any State or is utilizing the reg-
20 istration of a hospital or clinic operated by
21 the Department of Veterans Affairs reg-
22 istered under section 303(f).

23 “(2) REGULATIONS.—The Attorney General
24 shall, with the concurrence of the Secretary, promul-
25 gate regulations specifying the limited circumstances

1 in which a special registration under this subsection
2 may be issued and the procedures for obtaining such
3 a special registration.

4 “(3) DENIALS.—Proceedings to deny an appli-
5 cation for registration under this subsection shall be
6 conducted in accordance with section 304(c).

7 “(i) REPORTING OF TELEMEDICINE BY VHA DUR-
8 ING MEDICAL EMERGENCY SITUATIONS.—

9 “(1) IN GENERAL.—Any practitioner issuing a
10 prescription for a controlled substance under the au-
11 thorization to conduct telemedicine during a medical
12 emergency situation described in section 102(54)(F)
13 shall report to the Secretary of Veterans Affairs the
14 authorization of that emergency prescription, in ac-
15 cordance with such requirements as the Secretary of
16 Veterans Affairs shall, by regulation, establish.

17 “(2) TO ATTORNEY GENERAL.—Not later than
18 30 days after the date that a prescription described
19 in subparagraph (A) is issued, the Secretary of Vet-
20 erans Affairs shall report to the Attorney General
21 the authorization of that emergency prescription.

22 “(j) CLARIFICATION CONCERNING PRESCRIPTION
23 TRANSFERS.—Any transfer between pharmacies of infor-
24 mation relating to a prescription for a controlled substance

1 shall meet the applicable requirements under regulations
2 promulgated by the Attorney General under this Act.”.

3 (2) TECHNICAL AND CONFORMING AMEND-
4 MENTS.—The table of contents for the Comprehen-
5 sive Drug Abuse Prevention and Control Act of
6 1970 (Public Law 91–513; 84 Stat. 1236) is amend-
7 ed by inserting after the item relating to section 310
8 the following:

“Sec. 311. Additional requirements relating to online pharmacies and telemedi-
cine.”.

9 (e) OFFENSES INVOLVING CONTROLLED SUB-
10 STANCES IN SCHEDULES III, IV, AND V.—Section 401(b)
11 of the Controlled Substances Act (21 U.S.C. 841(b)) is
12 amended—

13 (1) in paragraph (1)—

14 (A) in subparagraph (D), by striking “or
15 in the case of any controlled substance in
16 schedule III (other than gamma hydroxybutyric
17 acid), or 30 milligrams of flunitrazepam”; and

18 (B) by adding at the end the following:

19 “(E)(i) Except as provided in subparagraphs (C) and
20 (D), in the case of any controlled substance in schedule
21 III, such person shall be sentenced to a term of imprison-
22 ment of not more than 10 years and if death or serious
23 bodily injury results from the use of such substance shall
24 be sentenced to a term of imprisonment of not more than

1 15 years, a fine not to exceed the greater of that author-
2 ized in accordance with the provisions of title 18, United
3 States Code, or \$500,000 if the defendant is an individual
4 or \$2,500,000 if the defendant is other than an individual,
5 or both.

6 “(ii) If any person commits such a violation after a
7 prior conviction for a felony drug offense has become final,
8 such person shall be sentenced to a term of imprisonment
9 of not more than 20 years and if death or serious bodily
10 injury results from the use of such substance shall be sen-
11 tenced to a term of imprisonment of not more than 30
12 years, a fine not to exceed the greater of twice that author-
13 ized in accordance with the provisions of title 18, United
14 States Code, or \$1,000,000 if the defendant is an indi-
15 vidual or \$5,000,000 if the defendant is other than an in-
16 dividual, or both.

17 “(iii) Any sentence imposing a term of imprisonment
18 under this subparagraph shall, in the absence of such a
19 prior conviction, impose a term of supervised release of
20 at least 2 years in addition to such term of imprisonment
21 and shall, if there was such a prior conviction, impose a
22 term of supervised release of at least 4 years in addition
23 to such term of imprisonment.”;

24 (2) in paragraph (2)—

1 (A) by striking “3 years” and inserting “5
2 years”;

3 (B) by striking “6 years” and inserting
4 “10 years”;

5 (C) by striking “after one or more prior
6 convictions” and all that follows through “have
7 become final,” and inserting “after a prior con-
8 viction for a felony drug offense has become
9 final,”; and

10 (3) in paragraph (3)—

11 (A) by striking “2 years” and inserting “4
12 years”;

13 (B) by striking “after one or more convic-
14 tions” and all that follows through “have be-
15 come final,” and inserting “after a prior convic-
16 tion for a felony drug offense has become
17 final,”; and

18 (C) by adding at the end the following
19 “Any sentence imposing a term of imprison-
20 ment under this paragraph may, if there was a
21 prior conviction, impose a term of supervised
22 release of not more than 1 year, in addition to
23 such term of imprisonment.”.

24 (f) OFFENSES INVOLVING DISPENSING OF CON-
25 TROLLED SUBSTANCES BY MEANS OF THE INTERNET.—

1 Section 401 of the Controlled Substances Act (21 U.S.C.
2 841) is amended by adding at the end the following:

3 “(h) OFFENSES INVOLVING DISPENSING OF CON-
4 TROLLED SUBSTANCES BY MEANS OF THE INTERNET.—

5 “(1) IN GENERAL.—It shall be unlawful for any
6 person to knowingly or intentionally—

7 “(A) deliver, distribute, or dispense a con-
8 trolled substance by means of the Internet, ex-
9 cept as authorized by this title; or

10 “(B) aid or abet (as such terms are used
11 in section 2 of title 18, United States Code)
12 any activity described in subparagraph (A) that
13 is not authorized by this title.

14 “(2) EXAMPLES.—Examples of activities that
15 violate paragraph (1) include, but are not limited to,
16 knowingly or intentionally—

17 “(A) delivering, distributing, or dispensing
18 a controlled substance by means of the Internet
19 by an online pharmacy that is not validly reg-
20 istered with a modification authorizing such ac-
21 tivity as required by section 303(f) (unless ex-
22 empt from such registration);

23 “(B) writing a prescription for a controlled
24 substance for the purpose of delivery, distribu-

1 tion, or dispensation by means of the Internet
2 in violation of section 309(e);

3 “(C) serving as an agent, intermediary, or
4 other entity that causes the Internet to be used
5 to bring together a buyer and seller to engage
6 in the dispensing of a controlled substance in a
7 manner not authorized by sections 303(f) or
8 309(e);

9 “(D) offering to fill a prescription for a
10 controlled substance based solely on a con-
11 sumer’s completion of an online medical ques-
12 tionnaire; and

13 “(E) making a material false, fictitious, or
14 fraudulent statement or representation in a no-
15 tification or declaration under subsection (d) or
16 (e), respectively, of section 311.

17 “(3) INAPPLICABILITY.—

18 “(A) This subsection does not apply to—

19 “(i) the delivery, distribution, or dis-
20 pensation of controlled substances by non-
21 practitioners to the extent authorized by
22 their registration under this title;

23 “(ii) the placement on the Internet of
24 material that merely advocates the use of
25 a controlled substance or includes pricing

1 information without attempting to propose
2 or facilitate an actual transaction involving
3 a controlled substance; or

4 “(iii) except as provided in subpara-
5 graph (B), any activity that is limited to—

6 “(I) the provision of a tele-
7 communications service, or of an
8 Internet access service or Internet in-
9 formation location tool (as those
10 terms are defined in section 231 of
11 the Communications Act of 1934); or

12 “(II) the transmission, storage,
13 retrieval, hosting, formatting, or
14 translation (or any combination there-
15 of) of a communication, without selec-
16 tion or alteration of the content of the
17 communication, except that deletion of
18 a particular communication or mate-
19 rial made by another person in a man-
20 ner consistent with section 230(c) of
21 the Communications Act of 1934 shall
22 not constitute such selection or alter-
23 ation of the content of the commu-
24 nication.

1 “(B) The exceptions under subclauses (I)
2 and (II) of subparagraph (A)(iii) shall not
3 apply to a person acting in concert with a per-
4 son who violates paragraph (1).

5 “(4) KNOWING OR INTENTIONAL VIOLATION.—
6 Any person who knowingly or intentionally violates
7 this subsection shall be sentenced in accordance with
8 subsection (b).”.

9 (g) PUBLICATION.—Section 403(c) of the Controlled
10 Substances Act (21 U.S.C. 843(c)) is amended by—

- 11 (1) striking “(c)” and inserting “(c)(1)”; and
12 (2) adding at the end the following:

13 “(2)(A) It shall be unlawful for any person to know-
14 ingly or intentionally use the Internet, or cause the Inter-
15 net to be used, to advertise the sale of, or to offer to sell,
16 distribute, or dispense, a controlled substance where such
17 sale, distribution, or dispensing is not authorized by this
18 title or by the Controlled Substances Import and Export
19 Act.

20 “(B) Examples of activities that violate subparagraph
21 (A) include, but are not limited to, knowingly or inten-
22 tionally causing the placement on the Internet of an adver-
23 tisement that refers to or directs prospective buyers to
24 Internet sellers of controlled substances who are not reg-
25 istered with a modification under section 303(f).

1 “(C) Subparagraph (A) does not apply to material
2 that either—

3 “(i) merely advertises the distribution of con-
4 trolled substances by nonpractitioners to the extent
5 authorized by their registration under this title; or

6 “(ii) merely advocates the use of a controlled
7 substance or includes pricing information without at-
8 tempting to facilitate an actual transaction involving
9 a controlled substance.”.

10 (h) INJUNCTIVE RELIEF.—Section 512 of the Con-
11 trolled Substances Act (21 U.S.C. 882) is amended by
12 adding at the end the following:

13 “(c) STATE CAUSE OF ACTION PERTAINING TO ON-
14 LINE PHARMACIES.—

15 “(1) IN GENERAL.—In any case in which the
16 State has reason to believe that an interest of the
17 residents of that State has been or is being threat-
18 ened or adversely affected by the action of a person,
19 entity, or Internet site that violates the provisions of
20 section 303(f), 309(e), or 311, the State may bring
21 a civil action on behalf of such residents in a district
22 court of the United States with appropriate jurisdic-
23 tion—

24 “(A) to enjoin the conduct which violates
25 this section;

1 “(B) to enforce compliance with this sec-
2 tion;

3 “(C) to obtain damages, restitution, or
4 other compensation, including civil penalties
5 under section 402(b); and

6 “(D) to obtain such other legal or equi-
7 table relief as the court may find appropriate.

8 “(2) SERVICE; INTERVENTION.—

9 “(A) Prior to filing a complaint under
10 paragraph (1), the State shall serve a copy of
11 the complaint upon the Attorney General and
12 upon the United States Attorney for the judi-
13 cial district in which the complaint is to be
14 filed. In any case where such prior service is
15 not feasible, the State shall serve the complaint
16 on the Attorney General and the appropriate
17 United States Attorney on the same day that
18 the State’s complaint is filed in Federal district
19 court of the United States. Such proceedings
20 shall be independent of, and not in lieu of,
21 criminal prosecutions or any other proceedings
22 under this title or any other laws of the United
23 States.

24 “(B) Upon receiving notice respecting a
25 civil action pursuant to this section, the United

1 States shall have the right to intervene in such
2 action and, upon so intervening, to be heard on
3 all matters arising therein, and to file petitions
4 for appeal.

5 “(C) Service of a State’s complaint on the
6 United States as required in this paragraph
7 shall be made in accord with the requirements
8 of rule 4(i)(1) of the Federal Rule of Civil Pro-
9 cedure.

10 “(3) POWERS CONFERRED BY STATE LAW.—
11 For purposes of bringing any civil action under
12 paragraph (1), nothing in this Act shall prevent an
13 attorney general of a State from exercising the pow-
14 ers conferred on the attorney general of a State by
15 the laws of such State to conduct investigations or
16 to administer oaths or affirmations or to compel the
17 attendance of witnesses or the production of docu-
18 mentary or other evidence.

19 “(4) VENUE.—Any civil action brought under
20 paragraph (1) in a district court of the United
21 States may be brought in the district in which the
22 defendant is found, is an inhabitant, or transacts
23 business or wherever venue is proper under section
24 1391 of title 28, United States Code. Process in
25 such action may be served in any district in which

1 the defendant is an inhabitant or in which the de-
2 fendant may be found.

3 “(5) NO PRIVATE RIGHT OF ACTION.—No pri-
4 vate right of action is created under this subsection.

5 “(6) LIMITATION.—No civil action may be
6 brought under paragraph (1) against—

7 “(A) the United States;

8 “(B) an Indian Tribe or tribal organiza-
9 tion, to the extent such tribe or tribal organiza-
10 tion is lawfully carrying out a contract or com-
11 pact under the Indian Self-Determination and
12 Education Assistance Act; or

13 “(C) any employee of the United States or
14 such Indian tribe or tribal organization, pro-
15 vided such agent or employee is acting in the
16 usual course of business or employment, and
17 within the scope of the official duties of such
18 agent or employee therewith.”.

19 (i) IMPORT AND EXPORT ACT.—Section 1010(b) of
20 the Controlled Substances Import and Export Act (21
21 U.S.C. 960(b)) is amended—

22 (1) in paragraph (4)—

23 (A) by striking “or any quantity of a con-
24 trolled substance in schedule III, IV, or V, (ex-
25 cept a violation involving flunitrazepam and ex-

1 cept a violation involving gamma hydroxy-
2 butyric acid)”;

3 (B) by inserting “or” before “less than one
4 kilogram of hashish oil”; and

5 (C) by striking “imprisoned” and all that
6 follows through the end of the paragraph and
7 inserting “sentenced in accordance with section
8 401(b)(1)(D).”;

9 (2) by adding at the end the following:

10 “(5) In the case of a violation of subsection (a) in-
11 volving a controlled substance in schedule III, such person
12 shall be sentenced in accordance with section 401(b)(1).

13 “(6) In the case of a violation of subsection (a) in-
14 volving a controlled substance in schedule IV, such person
15 shall be sentenced in accordance with section 401(b)(2).

16 “(7) In the case of a violation of subsection (a) in-
17 volving a controlled substance in schedule V, such person
18 shall be sentenced in accordance with section 401(b)(3).”;

19 and

20 (3) in paragraph (3), by striking “, nor shall a
21 person so sentenced be eligible for parole during the
22 term of such a sentence” in the final sentence.

23 (j) EFFECTIVE DATE.—

24 (1) IN GENERAL.—Except as provided in para-
25 graph (2), the amendments made by this Act shall

1 take effect 180 days after the date of enactment of
2 this Act.

3 (2) DEFINITION OF PRACTICE OF TELEMEDI-
4 CINE.—

5 (A) IN GENERAL.—Until the earlier of 3
6 months after the date on which regulations are
7 promulgated to carry out section 311(h) of the
8 Controlled Substances Act, as amended by this
9 Act, or 15 months after the date of enactment
10 of this Act—

11 (i) the definition of the term “practice
12 of telemedicine” in subparagraph (B) of
13 this paragraph shall apply for purposes of
14 the Controlled Substances Act; and

15 (ii) the definition of the term “prac-
16 tice of telemedicine” in section 102(54) of
17 the Controlled Substances Act, as amended
18 by this Act, shall not apply.

19 (B) TEMPORARY PHASE-IN OF TELEMEDI-
20 CINE REGULATION.—During the period speci-
21 fied in subparagraph (A), the term “practice of
22 telemedicine” means the practice of medicine in
23 accordance with applicable Federal and State
24 laws by a practitioner (as that term is defined
25 in section 102 of the Controlled Substances Act

1 (21 U.S.C. 802)) (other than a pharmacist)
2 who is at a location remote from the patient
3 and is communicating with the patient, or
4 health care professional who is treating the pa-
5 tient, using a telecommunications system re-
6 ferred to in section 1834(m) of the Social Secu-
7 rity Act (42 U.S.C. 1395m(m)), if the practi-
8 tioner is using an interactive telecommuni-
9 cations system that satisfies the requirements
10 of section 410.78(a)(3) of title 42, Code of Fed-
11 eral Regulations.

12 (C) RULE OF CONSTRUCTION.—Nothing in
13 this subsection may be construed to create a
14 precedent that any specific course of conduct
15 constitutes the “practice of telemedicine” (as
16 that term is defined in section 102(54) of the
17 Controlled Substances Act, as amended by this
18 Act) after the end of the period specified in
19 subparagraph (A).

20 (k) GUIDELINES AND REGULATIONS.—

21 (1) IN GENERAL.—The Attorney General may
22 promulgate and enforce any rules, regulations, and
23 procedures which may be necessary and appropriate
24 for the efficient execution of functions under this
25 Act or the amendments made by this Act, and, with

1 the concurrence of the Secretary of Health and
2 Human Services where this Act or the amendments
3 made by this Act so provide, promulgate any interim
4 rules necessary for the implementation of this Act or
5 the amendments made by this Act, prior to its effective
6 date.

7 (2) SENTENCING GUIDELINES.—The United
8 States Sentencing Commission, in determining
9 whether to amend, or establish new, guidelines or
10 policy statements, to conform the Federal sentencing
11 guidelines and policy statements to this Act and the
12 amendments made by this Act, should not construe
13 any change in the maximum penalty for a violation
14 involving a controlled substance in a particular
15 schedule as being the sole reason to amend, or establish
16 a new, guideline or policy statement.

17 (1) ANNUAL REPORT.—Not later than 180 days after
18 the date of enactment of this Act, and annually for 2 years
19 after the initial report, the Drug Enforcement Administration,
20 in consultation with the Department of State, shall
21 submit to Congress a report describing—

22 (1) the foreign supply chains and sources of
23 controlled substances offered for sale without a valid
24 prescription on the Internet;

1 (2) the efforts and strategy of the Drug En-
2 forcement Administration to decrease the foreign
3 supply chain and sources of controlled substances of-
4 fered for sale without a valid prescription on the
5 Internet; and

6 (3) the efforts of the Drug Enforcement Ad-
7 ministration to work with domestic and multi-
8 national pharmaceutical companies and others to
9 build international cooperation and a commitment to
10 fight on a global scale the problem of distribution of
11 controlled substances over the Internet without a
12 valid prescription.

13 **SEC. 4. RULE OF CONSTRUCTION.**

14 Nothing in this Act or the amendments made by this
15 Act shall be construed as authorizing, prohibiting, or lim-
16 iting the use of electronic prescriptions for controlled sub-
17 stances.

 Passed the House of Representatives September 23,
2008.

Attest:

Clerk.

110TH CONGRESS
2^D SESSION

H. R. 6353

AN ACT

To amend the Controlled Substances Act to address
online pharmacies.