

110TH CONGRESS
2D SESSION

S. 980

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 may be delivered,
13 distributed, or dispensed by means of the Internet
14 without a valid prescription.

15 “(2) As used in this subsection:

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

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

23 “(ii) a covering practitioner.

24 “(B)(i) The term ‘in-person medical eval-
25 uation’ means a medical evaluation that is con-
26 ducted with the patient in the physical presence

1 of the practitioner, without regard to whether
2 portions of the evaluation are conducted by
3 other health professionals.

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

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

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

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

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

22 “(A) the delivery, distribution, or dis-
23 pensing of a controlled substance by a practi-
24 tioner engaged in the practice of telemedicine;
25 or

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

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

7 **ACT RELATING TO THE DELIVERY OF CON-
8 TROLLED SUBSTANCES BY MEANS OF THE
9 INTERNET.**

10 (a) **IN GENERAL.**—Section 102 of the Controlled
11 Substances Act (21 U.S.C. 802) is amended by adding at
12 the end the following:

13 “(50) The term ‘Internet’ means collectively the
14 myriad of computer and telecommunications facili-
15 ties, including equipment and operating software,
16 which comprise the interconnected worldwide net-
17 work of networks that employ the Transmission
18 Control Protocol/Internet Protocol, or any prede-
19 cessor or successor protocol to such protocol, to com-
20 municate information of all kinds by wire or radio.

21 “(51) The term ‘deliver, distribute, or dispense
22 by means of the Internet’ refers, respectively, to any
23 delivery, distribution, or dispensing of a controlled
24 substance that is caused or facilitated by means of
25 the Internet.

1 “(52) The term ‘online pharmacy’—

2 “(A) means a person, entity, or Internet
3 site, whether in the United States or abroad,
4 that knowingly or intentionally delivers, distrib-
5 utes, or dispenses, or offers or attempts to de-
6 liver, distribute, or dispense, a controlled sub-
7 stance by means of the Internet; and

8 “(B) does not include—

9 “(i) manufacturers or distributors
10 registered under subsection (a), (b), (c), or
11 (d) of section 303 who do not dispense
12 controlled substances to an unregistered
13 individual or entity;

14 “(ii) nonpharmacy practitioners who
15 are registered under section 303(f) and
16 whose activities are authorized by that reg-
17 istration;

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

23 “(iv) a health care facility owned or
24 operated by an Indian tribe or tribal orga-
25 nization, only to the extent such facility is

1 carrying out a contract or compact under
2 the Indian Self-Determination and Edu-
3 cation Assistance Act (25 U.S.C. 450 et
4 seq.);

5 “(v) any agent or employee of any
6 hospital or facility referred to in clause (iii)
7 or (iv), provided such agent or employee is
8 lawfully acting in the usual course of busi-
9 ness or employment, and within the scope
10 of the official duties of such agent or em-
11 ployee, with such hospital or facility, and,
12 with respect to agents or employees of
13 health care facilities specified in clause
14 (iv), only to the extent such individuals are
15 furnishing services pursuant to the con-
16 tracts or compacts described in such
17 clause;

18 “(vi) mere advertisements that do not
19 attempt to facilitate an actual transaction
20 involving a controlled substance;

21 “(vii) a person, entity, or Internet site
22 that is not in the United States and does
23 not facilitate the delivery, distribution, or
24 dispensing of a controlled substance by

1 means of the Internet to any person in the
2 United States;

3 “(viii) a pharmacy registered under
4 section 303(f) whose dispensing of con-
5 trolled substances via the Internet consists
6 solely of—

7 “(I) ‘refilling prescriptions for
8 controlled substances in schedule III,
9 IV, or V’, as defined in paragraph
10 (55); or

11 “(II) ‘filling new prescriptions for
12 controlled substances in schedule III,
13 IV, or V’, as defined in paragraph
14 (56); or

15 “(ix) any other persons for whom the
16 Attorney General and the Secretary have
17 jointly, by regulation, found it to be con-
18 sistent with effective controls against diver-
19 sion and otherwise consistent with the pub-
20 lic health and safety to exempt from the
21 definition of an ‘online pharmacy’.

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

1 “(54) The term ‘practice of telemedicine’
2 means, for purposes of this title, the practice of
3 medicine in accordance with applicable Federal and
4 State laws by a practitioner (other than a phar-
5 macist) who is at a location remote from the patient
6 and is communicating with the patient, or health
7 care professional who is treating the patient, using
8 a telecommunications system referred to in section
9 1834(m) of the Social Security Act (42 U.S.C.
10 1395m(m)), and that—

11 “(A) is being conducted—

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

15 “(ii) by a practitioner—

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

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

20 “(III) registered under section
21 303(f) in the State in which the pa-
22 tient is located, unless the practi-
23 tioner—

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

4 “(bb) is—

5 “(AA) an employee or
6 contractor of the Depart-
7 ment of Veterans Affairs
8 who is acting in the scope of
9 such employment or con-
10 tract; and

11 “(BB) registered under
12 section 303(f) in any State
13 or is utilizing the registra-
14 tion of a hospital or clinic
15 operated by the Department
16 of Veterans Affairs reg-
17 istered under section 303(f);

18 “(B) is being conducted while the patient
19 is being treated by, and in the physical presence
20 of, a practitioner—

21 “(i) acting in the usual course of pro-
22 fessional practice;

23 “(ii) acting in accordance with appli-
24 cable State law; and

1 “(iii) registered under section 303(f)
2 in the State in which the patient is located,
3 unless the practitioner—

4 “(I) is exempted from such reg-
5 istration in all States under section
6 302(d); or

7 “(II) is—

8 “(aa) an employee or con-
9 tractor of the Department of Vet-
10 erans Affairs who is acting in the
11 scope of such employment or con-
12 tract; and

13 “(bb) registered under sec-
14 tion 303(f) in any State or is
15 using the registration of a hos-
16 pital or clinic operated by the
17 Department of Veterans Affairs
18 registered under section 303(f);

19 “(C) is being conducted by a practi-
20 tioner—

21 “(i) who is an employee or contractor
22 of the Indian Health Service, or is working
23 for an Indian tribe or tribal organization
24 under its contract or compact with the In-
25 dian Health Service under the Indian Self-

1 Determination and Education Assistance
2 Act (25 U.S.C. 450 et seq.);

3 “(ii) acting within the scope of the
4 employment, contract, or compact de-
5 scribed in clause (i); and

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

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

13 “(ii) involves patients located in such
14 areas, and such controlled substances, as the
15 Secretary, with the concurrence of the Attorney
16 General, designates, provided that such designa-
17 tion shall not be subject to the procedures pre-
18 scribed by subchapter II of chapter 5 of title 5,
19 United States Code;

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

23 “(F) is being conducted—

24 “(i) in a medical emergency situa-
25 tion—

1 “(I) that prevents the patient
2 from being in the physical presence of
3 a practitioner registered under section
4 303(f) who is an employee or con-
5 tractor of the Veterans Health Admin-
6 istration acting in the usual course of
7 business and employment and within
8 the scope of the official duties or con-
9 tract of that employee or contractor;

10 “(II) that prevents the patient
11 from being physically present at a
12 hospital or clinic operated by the De-
13 partment of Veterans Affairs reg-
14 istered under section 303(f);

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

21 “(IV) that requires immediate
22 intervention by a health care practi-
23 tioner using controlled substances to
24 prevent what the practitioner reason-
25 ably believes in good faith will be im-

4 (ii) by a practitioner that—

20 “(G) is being conducted under any other
21 circumstances that the Attorney General and
22 the Secretary have jointly, by regulation, deter-
23 mined to be consistent with effective controls
24 against diversion and otherwise consistent with
25 the public health and safety.

1 “(55) The term ‘refilling prescriptions for con-
2 trolled substances in schedule III, IV, or V’—

3 “(A) means the dispensing of a controlled
4 substance in schedule III, IV, or V in accord-
5 ance with refill instructions issued by a practi-
6 tioner as part of a valid prescription that meets
7 the requirements of subsection (b) or (c) of sec-
8 tion 309, as appropriate; and

9 “(B) does not include the issuance of a
10 new prescription to an individual for a con-
11 trolled substance that individual was previously
12 prescribed.

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

17 “(A) the pharmacy dispensing that pre-
18 scription has previously dispensed to the patient
19 that same controlled substance other than by
20 means of the Internet and pursuant to the valid
21 prescription of a practitioner that meets the ap-
22 plicable requirements of sections 309(b) or (c)
23 (in this paragraph referred to as the ‘original
24 prescription’);

1 “(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

8 “(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.”.

12 (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)—

15 (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

20 (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”.

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

4 (1) designating the text as paragraph (1); and
5 (2) inserting after paragraph (1), as so des-
6 ignated by this Act, the following:

7 “(2) Each pharmacy with a modified regis-
8 tration under section 303(f) that authorizes the dis-
9 pensing of controlled substances by means of the
10 Internet shall report to the Attorney General the
11 controlled substances it dispenses, in the amount
12 specified, and in such time and manner as the Attor-
13 ney General by regulation shall require, except that
14 the Attorney General, under this paragraph, may
15 not require any pharmacy to report any information
16 other than the total quantity of each controlled sub-
17 stance that the pharmacy has dispensed each month.
18 For purposes of this subsection, no reporting shall
19 be required unless the pharmacy has met 1 of the
20 following thresholds in the month for which the re-
21 porting is required:

22 “(A) 100 or more prescriptions dispensed.
23 “(B) 5,000 or more dosage units of all
24 controlled substances combined.”.

25 (d) ONLINE PRESCRIPTION REQUIREMENTS.—

4 “ADDITIONAL REQUIREMENTS RELATING TO ONLINE

5 PHARMACIES AND TELEMEDICINE

6 “SEC. 311. (a) IN GENERAL.—An online pharmacy
7 shall display in a visible and clear manner on its homepage
8 a statement that it complies with the requirements of this
9 section with respect to the delivery or sale or offer for sale
10 of controlled substances and shall at all times display on
11 the homepage of its Internet site a declaration of compli-
12 ance in accordance with this section.

13 "(b) LICENSURE.—Each online pharmacy shall com-
14 ply with the requirements of State law concerning the li-
15 censure of pharmacies in each State from which it, and
16 in each State to which it, delivers, distributes, or dispenses
17 or offers to deliver, distribute, or dispense controlled sub-
18 stances by means of the Internet, pursuant to applicable
19 licensure requirements, as determined by each such State.

20 “(c) INTERNET PHARMACY SITE DISCLOSURE IN-
21 FORMATION.—Each online pharmacy shall post in a visible
22 and clear manner on the homepage of each Internet site
23 it operates, or on a page directly linked thereto in which
24 the hyperlink is also visible and clear on the homepage,
25 the following information for each pharmacy that delivers,

1 distributes, or dispenses controlled substances pursuant to
2 orders made on, through, or on behalf of, that website:

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

6 “(2) The pharmacy’s telephone number and
7 email address.

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

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

14 “(5) A certification that the pharmacy is reg-
15 istered under this part to deliver, distribute, or dis-
16 pense by means of the Internet controlled sub-
17 stances.

18 “(6) The name, address, telephone number,
19 professional degree, and States of licensure of any
20 practitioner who has a contractual relationship to
21 provide medical evaluations or issue prescriptions for
22 controlled substances, through referrals from the
23 website or at the request of the owner or operator
24 of the website, or any employee or agent thereof.

1 “(7) The following statement, unless revised by
2 the Attorney General by regulation: ‘This online
3 pharmacy will only dispense a controlled substance
4 to a person who has a valid prescription issued for
5 a legitimate medical purpose based upon a medical
6 relationship with a prescribing practitioner. This in-
7 cludes at least one prior in-person medical evalua-
8 tion or medical evaluation via telemedicine in accord-
9 ance with applicable requirements of section 309 of
10 the Controlled Substances Act (21 U.S.C. 829).’.

11 “(d) NOTIFICATION.—(1) Thirty days prior to offer-
12 ing a controlled substance for sale, delivery, distribution,
13 or dispensing, the online pharmacy shall notify the Attor-
14 ney General, in the form and manner as the Attorney Gen-
15 eral shall determine, and the State boards of pharmacy
16 in any States in which the online pharmacy offers to sell,
17 deliver, distribute, or dispense controlled substances.

18 “(2) The notification required under paragraph (1)
19 shall include—

20 “(A) the information required to be posted on
21 the online pharmacy’s Internet site under subsection
22 (c) and shall notify the Attorney General and the
23 applicable State boards of pharmacy, under penalty
24 of perjury, that the information disclosed on its

1 Internet site under subsection (c) is true and accu-
2 rate;

3 “(B) the online pharmacy’s Internet site ad-
4 dress and a certification that the online pharmacy
5 shall notify the Attorney General of any change in
6 the address at least 30 days in advance; and

7 “(C) the Drug Enforcement Administration
8 registration numbers of any pharmacies and practi-
9 tioners referred to in subsection (c), as applicable.

10 “(3) An online pharmacy that is already operational
11 as of the effective date of this section, shall notify the At-
12 torney General and applicable State boards of pharmacy
13 in accordance with this subsection not later than 30 days
14 after the effective date of this section.

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

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

24 “(g) NOTICE AND DESIGNATIONS CONCERNING IN-
25 DIAN TRIBES.—

1 “(1) IN GENERAL.—For purposes of sections
2 102(52) and 512(c)(6)(B), the Secretary shall notify
3 the Attorney General, at such times and in such
4 manner as the Secretary and the Attorney General
5 determine appropriate, of the Indian tribes or tribal
6 organizations with which the Secretary has con-
7 tracted or compacted under the Indian Self-Deter-
8 mination and Education Assistance Act (25 U.S.C.
9 450 et seq.) for the tribes or tribal organizations to
10 provide pharmacy services.

11 “(2) DESIGNATIONS.—

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

22 “(B) PRACTITIONERS.—A practitioner de-
23 scribed in this subparagraph is a practitioner
24 who is an employee or contractor of the Indian
25 Health Service, or is working for an Indian

1 tribe or tribal organization under its contract or
2 compact under the Indian Self-Determination
3 and Education Assistance Act (25 U.S.C. 450
4 et seq.) with the Indian Health Service.

5 “(h) SPECIAL REGISTRATION FOR TELEMEDICINE.—

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

11 “(A) demonstrates a legitimate need for
12 the special registration; and

13 “(B) is registered under section 303(f) in
14 the State in which the patient will be located
15 when receiving the telemedicine treatment, un-
16 less the practitioner—

17 “(i) is exempted from such regis-
18 tration in all States under section 302(d); or

19 “(ii) is an employee or contractor of
20 the Department of Veterans Affairs who is
21 acting in the scope of such employment or
22 contract and is registered under section
23 303(f) in any State or is utilizing the reg-
24 istration of a hospital or clinic operated by

1 the Department of Veterans Affairs reg-
2 istered under section 303(f).

3 “(2) REGULATIONS.—The Attorney General
4 shall, with the concurrence of the Secretary, promul-
5 gate regulations specifying the limited circumstances
6 in which a special registration under this subsection
7 may be issued and the procedures for obtaining such
8 a special registration.

9 “(3) DENIALS.—Proceedings to deny an applica-
10 tion for registration under this subsection shall be
11 conducted in accordance with section 304(c).

12 "(i) REPORTING OF TELEMEDICINE BY VHA DUR-
13 ING MEDICAL EMERGENCY SITUATIONS.—

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

22 “(2) TO ATTORNEY GENERAL.—Not later than
23 30 days after the date that a prescription described
24 in subparagraph (A) is issued, the Secretary of Vet-

1 erans Affairs shall report to the Attorney General
2 the authorization of that emergency prescription.

3 “(j) CLARIFICATION CONCERNING PRESCRIPTION
4 TRANSFERS.—Any transfer between pharmacies of infor-
5 mation relating to a prescription for a controlled substance
6 shall meet the applicable requirements under regulations
7 promulgated by the Attorney General under this Act.”.

“Sec. 311. Additional requirements relating to online pharmacies and telemedicine.”.

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

18 (1) in paragraph (1)—

(A) in subparagraph (C), by striking “1 gram of” before “flunitrazepam”;

21 (B) in subparagraph (D), by striking “or
22 in the case of any controlled substance in
23 schedule III (other than gamma hydroxybutyric
24 acid), or 30 milligrams of flunitrazepam”; and

1 (C) by adding at the end the following:

14 “(ii) If any person commits such a viola-
15 tion after a prior conviction for a felony drug
16 offense has become final, such person shall be
17 sentenced to a term of imprisonment of not
18 more than 20 years and if death or serious bod-
19 ily injury results from the use of such substance
20 shall be sentenced to a term of imprisonment of
21 not more than 30 years, a fine not to exceed
22 the greater of twice that authorized in accord-
23 ance with the provisions of title 18, United
24 States Code, or \$1,000,000 if the defendant is

1 an individual or \$5,000,000 if the defendant is
2 other than an individual, or both.

3 “(iii) Any sentence imposing a term of im-
4 prisonment under this subparagraph shall, in
5 the absence of such a prior conviction, impose
6 a term of supervised release of at least 2 years
7 in addition to such term of imprisonment and
8 shall, if there was such a prior conviction, im-
9 pose a term of supervised release of at least 4
10 years in addition to such term of imprison-
11 ment.”;

12 (2) in paragraph (2)—

13 (A) by striking “3 years” and inserting “5
14 years”;

15 (B) by striking “6 years” and inserting
16 “10 years”;

17 (C) by striking “after one or more prior
18 convictions” and all that follows through “have
19 become final,” and inserting “after a prior con-
20 viction for a felony drug offense has become
21 final,”; and

22 (3) in paragraph (3)—

23 (A) by striking “2 years” and inserting “6
24 years”;

1 (B) by striking “after one or more convic-
2 tions” and all that follows through “have be-
3 come final,” and inserting “after a prior convic-
4 tion for a felony drug offense has become
5 final;” and

6 (C) by adding at the end the following
7 “Any sentence imposing a term of imprison-
8 ment under this paragraph may, if there was a
9 prior conviction, impose a term of supervised
10 release of not more than 1 year, in addition to
11 such term of imprisonment.”.

12 (f) OFFENSES INVOLVING DISPENSING OF CON-
13 TROLLED SUBSTANCES BY MEANS OF THE INTERNET.—
14 Section 401 of the Controlled Substances Act (21 U.S.C.
15 841) is amended by adding at the end the following:

16 “(g) OFFENSES INVOLVING DISPENSING OF CON-
17 TROLLED SUBSTANCES BY MEANS OF THE INTERNET.—
18 (1) It shall be unlawful for any person to knowingly or
19 intentionally—

20 “(A) deliver, distribute, or dispense a controlled
21 substance by means of the Internet, except as au-
22 thorized by this title; or
23 “(B) aid or abet (as such terms are used in sec-
24 tion 2 of title 18, United States Code) any activity

1 described in subparagraph (A) that is not authorized
2 by this title.

3 “(2) Examples of activities that violate paragraph (1)
4 include, but are not limited to, knowingly or inten-
5 tionally—

6 “(A) delivering, distributing, or dispensing a
7 controlled substance by means of the Internet by an
8 online pharmacy that is not validly registered with
9 a modification authorizing such activity as required
10 by section 303(f) (unless exempt from such regis-
11 tration);

12 “(B) writing a prescription for a controlled sub-
13 stance for the purpose of delivery, distribution, or
14 dispensation by means of the Internet in violation of
15 section 309(e);

16 “(C) serving as an agent, intermediary, or other
17 entity that causes the Internet to be used to bring
18 together a buyer and seller to engage in the dis-
19 pensing of a controlled substance in a manner not
20 authorized by sections 303(f) or 309(e);

21 “(D) offering to fill a prescription for a con-
22 trolled substance based solely on a consumer’s com-
23 pletion of an online medical questionnaire; and

1 “(E) making a material false, fictitious, or
2 fraudulent statement or representation in the sub-
3 mission to the Attorney General under section 311.

4 “(3)(A) This subsection does not apply to—

5 “(i) the delivery, distribution, or dispensation of
6 controlled substances by nonpractitioners to the ex-
7 tent authorized by their registration under this title;

8 “(ii) the placement on the Internet of material
9 that merely advocates the use of a controlled sub-
10 stance or includes pricing information without at-
11 tempting to propose or facilitate an actual trans-
12 action involving a controlled substance; or

13 “(iii) except as provided in subparagraph (B),
14 any activity that is limited to—

15 “(I) the provision of a telecommunications
16 service, or of an Internet access service or
17 Internet information location tool (as those
18 terms are defined in section 231 of the Commu-
19 nications Act of 1934 (47 U.S.C. 231)); or

20 “(II) the transmission, storage, retrieval,
21 hosting, formatting, or translation (or any com-
22 bination thereof) of a communication, without
23 selection or alteration of the content of the
24 communication, except that deletion of a par-
25 ticular communication or material made by an-

1 other person in a manner consistent with sec-
2 tion 230(c) of the Communications Act of 1934
3 (47 U.S.C. 230(c)) shall not constitute such se-
4 lection or alteration of the content of the com-
5 munication.

6 “(B) The exceptions under subclauses (I) and (II) of
7 subparagraph (A)(iii) shall not apply to a person acting
8 in concert with a person who violates paragraph (1).

9 “(4) Any person who knowingly or intentionally vio-
10 lates this subsection shall be sentenced in accordance with
11 subsection (b) of this section.”.

12 (g) PUBLICATION.—Section 403(c) of the Controlled
13 Substances Act (21 U.S.C. 843(c)) is amended by—
14 (1) designating the text as paragraph (1); and
15 (2) adding at the end the following:

16 “(2)(A) Except as authorized by this title, it shall be
17 unlawful for any person by means of the Internet to know-
18 ingly advertise the sale or distribution of, or to offer to
19 sell, distribute, or dispense, a controlled substance.

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

22 “(A) to enjoin the conduct which violates this
23 section;

24 “(B) to enforce compliance with this section;

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

4 “(D) to obtain such other legal or equitable re-
5 lief as the court may find appropriate.

6 “(2)(A) Prior to filing a complaint under paragraph
7 (1), the State shall serve a copy of the complaint upon
8 the Attorney General and upon the United States Attor-
9 ney for the judicial district in which the complaint is to
10 be filed. In any case where such prior service is not fea-
11 sible, the State shall serve the complaint on the Attorney
12 General and the appropriate United States Attorney on
13 the same day that the State’s complaint is filed in Federal
14 district court of the United States. Such proceedings shall
15 be independent of, and not in lieu of, criminal prosecutions
16 or any other proceedings under this title or any other laws
17 of the United States.

18 “(B) Upon receiving notice respecting a civil action
19 pursuant to this section, the United States shall have the
20 right to intervene in such action, upon so intervening, to
21 be heard on all matters arising therein, and to file peti-
22 tions for appeal.

23 “(C) Service of a State’s complaint on the United
24 States as required in this paragraph shall be made in ac-

1 cord with the requirements of rule 4(i)(1) of the Federal
2 Rule of Civil Procedure.

3 “(3) For purposes of bringing any civil action under
4 paragraph (1), nothing in this Act shall prevent an attorney
5 general of a State from exercising the powers con-
6 fered on the attorney general of a State by the laws of
7 such State to conduct investigations or to administer oaths
8 or affirmations or to compel the attendance of witnesses
9 or the production of documentary or other evidence.

10 “(4) Any civil action brought under paragraph (1) in
11 a district court of the United States may be brought in
12 the district in which the defendant is found, is an inhab-
13 itant, or transacts business or wherever venue is proper
14 under section 1391 of title 28, United States Code. Pro-
15 cess in such action may be served in any district in which
16 the defendant is an inhabitant or in which the defendant
17 may be found.

18 “(5) No private right of action is created under this
19 subsection.

20 “(6) No civil action may be brought under paragraph
21 (1) against—

22 “(A) the United States;

23 “(B) an Indian Tribe or tribal organization, to
24 the extent such tribe or tribal organization is law-
25 fully carrying out a contract or compact under the

1 Indian Self-Determination and Education Assistance
2 Act; or

3 “(C) any employee of the United States or such
4 Indian tribe or tribal organization, provided such
5 agent or employee is acting in the usual course of
6 business or employment, and within the scope of the
7 official duties of such agent or employee therewith.”.

8 (i) FORFEITURE OF FACILITATING PROPERTY IN
9 DRUG CASES.—Section 511(a)(4) of the Controlled Sub-
10 stances Act (21 U.S.C. 881(a)(4)) is amended to read as
11 follows:

12 “(4) Any property, real or personal, tangible or
13 intangible, used or intended to be used to commit,
14 or to facilitate the commission, of a violation of this
15 title or title III, and any property traceable there-
16 to.”.

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

20 (1) in paragraph (4)—

21 (A) by striking “or any quantity of a con-
22 trolled substance in schedule III, IV, or V, (ex-
23 cept a violation involving flunitrazepam and ex-
24 cept a violation involving gamma hydroxy-
25 butyric acid)”;

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

3 (C) striking “imprisoned” and all that fol-
4 lows through the end of the paragraph and in-
5 serting “sentenced in accordance with section
6 401(b)(1)(D) of this title (21 U.S.C.
7 841(b)(1)(E)).”;

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

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

13 “(6) In the case of a violation of subsection (a)
14 of this section involving a controlled substance in
15 schedule IV (except a violation involving
16 flunitrazepam), such person shall be sentenced in ac-
17 cordance with section 401(b)(2).

18 “(7) In the case of a violation of subsection (a)
19 of this section involving a controlled substance in
20 schedule V, such person shall be sentenced in ac-
21 cordance with section 401(b)(3).”; and

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

25 (k) EFFECTIVE DATE.—

5 (2) DEFINITION OF PRACTICE OF TELEMEDI-
6 CINE.—

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

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

21 (B) TEMPORARY PHASE-IN OF TELEMEDE-
22 CINE REGULATION.—During the period speci-
23 fied in subparagraph (A), the term “practice of
24 telemedicine” means the practice of medicine in
25 accordance with applicable Federal and State

1 laws by a practitioner (as that term is defined
2 in section 102 of the Controlled Substances Act
3 (21 U.S.C. 802)) (other than a pharmacist)
4 who is at a location remote from the patient
5 and is communicating with the patient, or
6 health care professional who is treating the pa-
7 tient, using a telecommunications system re-
8 ferred to in section 1834(m) of the Social Secu-
9 rity Act (42 U.S.C. 1395m(m)), if the practi-
10 tioner is using an interactive telecommuni-
11 cations system that satisfies the requirements
12 of section 410.78(a)(3) of title 42, Code of Fed-
13 eral Regulations.

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

22 (l) GUIDELINES AND REGULATIONS.—

23 (1) IN GENERAL.—The Attorney General may
24 promulgate and enforce any rules, regulations, and
25 procedures which may be necessary and appropriate

1 for the efficient execution of functions under this
2 Act or the amendments made by this Act, and, with
3 the concurrence of the Secretary of Health and
4 Human Services where this Act or the amendments
5 made by this Act so provides, promulgate any in-
6 terim rules necessary for the implementation of this
7 Act or the amendments made by this Act, prior to
8 its effective date.

9 (2) SENTENCING GUIDELINES.—The United
10 States Sentencing Commission, in determining
11 whether to amend, or establish new, guidelines or
12 policy statements, to conform the Federal sentencing
13 guidelines and policy statements to this Act and the
14 amendments made by this Act—

15 (A) shall consult with the Department of
16 Justice, experts and other affected parties con-
17 cerning which penalties for scheduled sub-
18 stances amended by this Act should be reflected
19 in the Federal sentencing guidelines; and

20 (B) should not construe any change in the
21 maximum penalty for a violation involving a
22 controlled substance in a particular schedule as
23 being the sole reason to amend a, or establish
24 a new, guideline or policy statement.

1 (m) ANNUAL REPORT.—Not later than 180 days
2 after the date of enactment of this Act, and annually for
3 2 years after the initial report, the Drug Enforcement Ad-
4 ministration, in consultation with the Department of
5 State, shall submit to Congress a report describing—

6 (1) the foreign supply chains and sources of
7 controlled substances offered for sale without a valid
8 prescription on the Internet;

9 (2) the efforts and strategy of the Drug En-
10 forcement Administration to decrease the foreign
11 supply chain and sources of controlled substances of-
12 fered for sale without a valid prescription on the
13 Internet; and

14 (3) the efforts of the Drug Enforcement Ad-
15 ministration to work with domestic and multi-
16 national pharmaceutical companies and others to
17 build international cooperation and a commitment to
18 fight on a global scale the problem of distribution of
19 controlled substances over the Internet without a
20 valid prescription.

21 **SEC. 4. RULE OF CONSTRUCTION.**

22 Nothing in this Act or the amendments made by this
23 Act shall be construed as authorizing, prohibiting, or lim-

1 iting the use of electronic prescriptions for controlled sub-
2 stances.

Passed the Senate April 1 (legislative day, March
13), 2008.

Attest:

Secretary.

110TH CONGRESS
2D SESSION
S. 980

AN ACT

To amend the Controlled Substances Act to address
online pharmacies.