

110TH CONGRESS
1ST SESSION

S. 596

To amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of Internet pharmacies.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 14, 2007

Mr. GREGG (for himself and Mr. SMITH) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of Internet pharmacies.

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

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 This Act may be cited as the “Safe Internet Phar-
5 macy Act of 2007”.

6 **SEC. 2. INTERNET PHARMACIES.**

7 (a) INTERNET PHARMACIES.—Chapter V of the Fed-
8 eral Food, Drug, and Cosmetic Act (21 U.S.C. 351 et
9 seq.) is amended by inserting after section 510 the fol-
10 lowing:

1 **“SEC. 511. INTERNET PHARMACIES.**

2 “(a) DEFINITIONS.—In this section:

3 “(1) ADVERTISING SERVICE PROVIDER.—The
4 term ‘advertising service provider’ means an adver-
5 tising company that contracts with a provider of an
6 interactive computer service (as defined in section
7 230(f) of the Communications Act of 1934 (47
8 U.S.C. 230(f)) to provide advertising on the Inter-
9 net.

10 “(2) DESIGNATED PAYMENT SYSTEM.—

11 “(A) IN GENERAL.—The term ‘designated
12 payment system’ means a system used by a per-
13 son described in subparagraph (B) to effect a
14 credit transaction, electronic fund transfer, or
15 money transmitting service that the Board de-
16 termines, by regulation or order, is regularly
17 used in connection with, or to facilitate re-
18 stricted transactions.

19 “(B) PERSONS DESCRIBED.—A person re-
20 ferred to in subparagraph (A) is—

21 “(i) a creditor;

22 “(ii) a credit card issuer;

23 “(iii) a financial institution;

24 “(iv) an operator of a terminal at
25 which an electronic fund transfer may be
26 initiated;

1 “(v) a money transmitting business;

2 or

3 “(vi) a participant in an international,
4 national, regional, or local network con-
5 structed primarily to effect a credit trans-
6 action, electronic fund transfer, or money
7 transmitting service.

8 “(3) FEDERAL FUNCTIONAL REGULATOR.—The
9 term ‘Federal functional regulator’ has the meaning
10 given the term in section 509 of the Gramm-Leach-
11 Bliley Act (15 U.S.C. 6809).

12 “(4) INTERNET PHARMACY.—The term ‘Inter-
13 net pharmacy’ means a person that offers to dis-
14 pense or dispenses in the United States a prescrip-
15 tion drug through an Internet website in interstate
16 commerce, regardless of whether the physical loca-
17 tion of the principal place of business of the Internet
18 pharmacy is in the United States or in another
19 country.

20 “(5) PRESCRIPTION DRUG.—The term ‘pre-
21 scription drug’ means a drug described in section
22 503(b) that is approved by the Secretary under sec-
23 tion 505.

24 “(6) RESTRICTED TRANSACTION.—The term
25 ‘restricted transaction’ means a transaction or trans-

1 mittal, on behalf of a individual who places an un-
2 lawful Internet pharmacy request to any person en-
3 gaged in the operation of an unlicensed Internet
4 pharmacy, of—

5 “(A) credit, or the proceeds of credit, ex-
6 tended to or on behalf of the individual for the
7 purpose of the unlawful Internet request (in-
8 cluding credit extended through the use of a
9 credit card);

10 “(B) an electronic fund transfer or funds
11 transmitted by or through a money transmit-
12 ting business, or the proceeds of an electronic
13 fund transfer or money transmitting service,
14 from or on behalf of the individual for the pur-
15 pose of the unlawful Internet request;

16 “(C) a check, draft, or similar instrument
17 which is drawn by or on behalf of the individual
18 for the purpose of the unlawful Internet request
19 and is drawn on or payable at or through any
20 financial institution; or

21 “(D) the proceeds of any other form of fi-
22 nancial transaction (identified by the Board by
23 regulation) that involves a financial institution
24 as a payor or financial intermediary on behalf

1 of or for the benefit of the individual for the
2 purpose of the unlawful Internet request.

3 “(7) TREATING PROVIDER.—The term ‘treating
4 provider’ means a health care provider licensed in
5 the United States who is authorized to prescribe
6 medications and who—

7 “(A)(i) performs a documented patient
8 evaluation (including a patient history and
9 physical examination) of an individual, portions
10 of which may be conducted by other health pro-
11 fessionals;

12 “(ii) discusses with the individual the
13 treatment options of the individual and the
14 risks and benefits of treatment; and

15 “(iii) maintains contemporaneous medical
16 records concerning the individual; or

17 “(B) provides care to an individual as part
18 of an on-call or cross-coverage arrangement
19 with a health care provider described in sub-
20 paragraph (A).

21 “(8) UNLAWFUL INTERNET PHARMACY RE-
22 QUEST.—The term ‘unlawful Internet pharmacy re-
23 quest’ means the request, or transmittal of a re-
24 quest, made to an unlicensed Internet pharmacy for
25 a prescription drug by mail (including a private car-

rier), facsimile, telephone, or electronic mail, or by
 a means that involves the use, in whole or in part,
 of the Internet.

“(9) UNLICENSED INTERNET PHARMACY.—The
 term ‘unlicensed Internet pharmacy’ means an
 Internet pharmacy that is not licensed under this
 section.

“(10) OTHER DEFINITIONS.—

“(A) BOARD.—The term ‘Board’ means
 the Board of Governors of the Federal Reserve
 System.

“(B) CREDIT; CREDITOR; CREDIT CARD.—
 The terms ‘credit’, ‘creditor’, and ‘credit card’
 have the meanings given the terms in section
 103 of the Truth in Lending Act (15 U.S.C.
 1602).

“(C) ELECTRONIC FUND TRANSFER.—The
 term ‘electronic fund transfer’—

“(i) has the meaning given the term
 in section 903 of the Electronic Fund
 Transfer Act (15 U.S.C. 1693a); and

“(ii) includes any fund transfer cov-
 ered under article 4A of the Uniform Com-
 mercial Code, as in effect in any State.

1 “(D) FINANCIAL INSTITUTION.—The term
2 ‘financial institution’—

3 “(i) has the meaning given the term
4 in section 903 of the Electronic Transfer
5 Fund Act (15 U.S.C. 1693a); and

6 “(ii) includes a financial institution
7 (as defined in section 509 of the Gramm-
8 Leach-Bliley Act (15 U.S.C. 6809)).

9 “(E) MONEY TRANSMITTING BUSINESS;
10 MONEY TRANSMITTING SERVICE.—The terms
11 ‘money transmitting business’ and ‘money
12 transmitting service’ have the meanings given
13 the terms in section 5330(d) of title 31, United
14 States Code.

15 “(b) IN GENERAL.—An Internet pharmacy may only
16 dispense or offer to dispense a prescription drug to a per-
17 son in the United States in accordance with this section.

18 “(c) LICENSING OF INTERNET PHARMACIES.—

19 “(1) IN GENERAL.—An Internet pharmacy shall
20 be licensed by the Secretary in accordance with this
21 section prior to offering to dispense or dispensing a
22 prescription drug to an individual.

23 “(2) CONDITIONS FOR LICENSING.—

1 “(A) APPLICATION REQUIREMENTS.—An
2 Internet pharmacy shall submit to the Sec-
3 retary an application that includes—

4 “(i)(I) in the case of an Internet
5 pharmacy located in the United States,
6 verification that, in each State in which
7 the Internet pharmacy engages in dis-
8 pensing or offering to dispense prescription
9 drugs, the Internet pharmacy, and all em-
10 ployees and agents of the Internet phar-
11 macy, is in compliance with applicable
12 Federal and State laws regarding—

13 “(aa) the practice of pharmacy,
14 including licensing laws and inspec-
15 tion requirements; and

16 “(bb) the manufacturing and dis-
17 tribution of controlled substances, in-
18 cluding with respect to mailing or
19 shipping controlled substances to con-
20 sumers; or

21 “(II) in the case of an Internet phar-
22 macy whose principal place of business is
23 located outside the United States,
24 verification that—

1 “(aa) all employees and agents of
2 the Internet pharmacy are in compli-
3 ance with applicable Federal and
4 State laws regarding the practice of
5 pharmacy, including licensing laws
6 and inspection requirements;

7 “(bb) the Internet pharmacy is in
8 compliance with applicable Federal
9 and State laws regarding the practice
10 of pharmacy, including licensing laws
11 and inspection requirements;

12 “(cc) the Internet pharmacy ex-
13 pressly and affirmatively agrees to
14 provide and maintain an agent for
15 service of process in the United
16 States;

17 “(dd) the Internet pharmacy ex-
18 pressly and affirmatively agrees to be
19 subject to the jurisdiction of the
20 United States and any of its States or
21 territories where it engages in com-
22 merce; and

23 “(ee) the Internet pharmacy
24 agrees to affix to each shipping con-
25 tainer of drugs to be shipped in the

1 United States such markings as the
2 Secretary determines to be necessary
3 to identify that the shipment is from
4 a licensed Internet pharmacy, which
5 may include anticounterfeiting or
6 track-and-trace technologies;

7 “(ii) verification that the person that
8 owns the Internet pharmacy has not had a
9 license for an Internet pharmacy termi-
10 nated by the Secretary, and that no other
11 Internet pharmacy owned by the person
12 has had a license under this subsection
13 that has been terminated by the Secretary;

14 “(iii) verification from the person that
15 owns the Internet pharmacy that the per-
16 son will permit inspection of the facilities
17 and business practices of the Internet
18 pharmacy by the Secretary to the extent
19 necessary to determine whether the Inter-
20 net pharmacy is in compliance with this
21 subsection;

22 “(iv) in the case of an agreement be-
23 tween a patient and an Internet pharmacy
24 that releases the Internet pharmacy, and
25 any employee or agent of the Internet

1 pharmacy, from liability for damages arising out of the negligence of the Internet
 2 pharmacy, an assurance that such a limitation of liability shall be null and void;

3 “(v) verification that the Internet
 4 pharmacy expressly and affirmatively
 5 agrees to provide the Secretary with the
 6 identity of any providers of interactive
 7 computer services that provide host services or advertising services for the Internet
 8 pharmacy; and

9 “(vi) assurance that the Internet
 10 pharmacy will comply with the requirements under subparagraphs (B) and (C).

11 “(B) IDENTIFICATION REQUIREMENTS.—

12 An Internet pharmacy shall post in a clear and
 13 visible manner, on each page of the website of
 14 the Internet pharmacy or by a link to a separate page, the following information:

15 “(i) The street address, city, ZIP
 16 Code or comparable mail code, State (or
 17 comparable entity), country, and telephone
 18 number of—

19 “(I) each place of business of the
 20 Internet pharmacy; and

1 “(II) the name of the supervising
2 pharmacist of the Internet pharmacy
3 and each individual who serves as a
4 pharmacist for purposes of the Inter-
5 net pharmacy website.

6 “(ii) The names of all States in which
7 the Internet pharmacy and the phar-
8 macists employed by the Internet phar-
9 macy are licensed or otherwise authorized
10 to dispense prescription drugs.

11 “(iii) If the Internet pharmacy makes
12 referrals to, or solicits on behalf of, a
13 health care practitioner or group of practi-
14 tioners in the United States for prescrip-
15 tion services—

16 “(I) the name, street address,
17 city, ZIP Code or comparable mail
18 code, State, and telephone number of
19 the practitioner or group; and

20 “(II) the name of each State in
21 which each practitioner is licensed or
22 otherwise authorized to prescribe
23 drugs.

24 “(iv) A statement that the Internet
25 pharmacy will dispense prescription drugs

1 only after receipt of a valid prescription
2 from a treating provider.

3 “(v) A distinctive tamper resistant
4 seal to identify that the Internet pharmacy
5 is licensed.

6 “(C) PROFESSIONAL SERVICES REQUIRE-
7 MENTS.—An Internet pharmacy shall carry out
8 the following:

9 “(i) Maintain patient medication pro-
10 files and other related data in a readily ac-
11 cessible format organized to facilitate con-
12 sultation with treating providers, care-
13 givers, and patients.

14 “(ii) Conduct prospective drug use re-
15 views before dispensing medications or
16 medical devices.

17 “(iii) Ensure patient confidentiality
18 and the protection of patient identity and
19 patient-specific information, in accordance
20 with the regulations promulgated under
21 section 264(c) of the Health Insurance
22 Portability and Accountability Act of 1996.

23 “(iv) Offer interactive and meaningful
24 consultation by a licensed pharmacist to
25 the caregiver or patient before and after

1 the time at which the Internet pharmacy
2 dispenses the drug.

3 “(v)(I) Establish a mechanism for pa-
4 tients to report errors and suspected ad-
5 verse drug reactions.

6 “(II) Document in the reporting
7 mechanism the response of the Internet
8 pharmacy to those reports.

9 “(III) Submit those reports within 3
10 days of receipt and the response of the
11 Internet pharmacy to the Food and Drug
12 Administration in a manner determined
13 appropriate by the Secretary.

14 “(vi) Develop a system to inform care-
15 givers and patients about drug recalls.

16 “(vii) Educate caregivers and patients
17 about the appropriate means of disposing
18 of expired, damaged, or unusable medica-
19 tions.

20 “(viii) Assure that the sale of a pre-
21 scription drug is in accordance with a valid
22 prescription from the treating provider of
23 the individual.

1 “(ix)(I) Verify the validity of the pre-
2 scription of an individual by using 1 of the
3 following methods:

4 “(aa) If the prescription for any
5 drug other than a controlled sub-
6 stance (as defined in section 102 of
7 the Controlled Substances Act (21
8 U.S.C. 802)) is received from an indi-
9 vidual or the treating provider of the
10 individual by mail (including a private
11 carrier), or from the treating provider
12 of the individual by electronic mail,
13 the validity of the prescription shall be
14 confirmed in accordance with all ap-
15 plicable Federal and State laws.

16 “(bb) If the prescription is for a
17 controlled substance (as defined in
18 section 102 of the Controlled Sub-
19 stances Act), the validity of the pre-
20 scription shall be confirmed with the
21 treating provider as described in sub-
22 clause (II).

23 “(II) When seeking verification of a
24 prescription of an individual under sub-
25 clause (I)(bb), an Internet pharmacy shall

1 provide to the treating provider the fol-
2 lowing information:

3 “(aa) The full name and address
4 of the individual.

5 “(bb) Identification of the pre-
6 scription drug.

7 “(cc) The quantity of the pre-
8 scription drug to be dispensed.

9 “(dd) The date on which the in-
10 dividual presented the prescription to
11 the Internet pharmacy.

12 “(ee) The date and time of the
13 verification request.

14 “(ff) The name of a contact per-
15 son at the Internet pharmacy, includ-
16 ing a voice telephone number, elec-
17 tronic mail address, and facsimile tele-
18 phone number.

19 “(III) A prescription is verified under
20 subclause (I)(bb) only if 1 of the following
21 occurs:

22 “(aa) The treating provider con-
23 firms, by direct communication with
24 the Internet pharmacy, that the pre-
25 scription is accurate.

1 “(bb) The treating provider in-
 2 forms the Internet pharmacy that the
 3 prescription is inaccurate and provides
 4 the accurate prescription.

5 “(IV) An Internet pharmacy shall not
 6 fill a prescription if—

7 “(aa) a treating provider informs
 8 the Internet pharmacy within 72
 9 hours after receipt of a communica-
 10 tion under subclause (I)(bb) that the
 11 prescription is inaccurate or expired;
 12 or

13 “(bb) the treating provider does
 14 not respond within that time.

15 “(x) Maintain, for such period of time
 16 as the Secretary shall prescribe by regula-
 17 tion, a record of all direct communications
 18 with a treating provider regarding the dis-
 19 pensing of a prescription drug, including
 20 verification of the prescription.

21 “(3) LICENSURE PROCEDURE.—

22 “(A) ACTION BY SECRETARY.—On receipt
 23 of a complete licensing application from an
 24 Internet pharmacy under paragraph (2), the
 25 Secretary shall—

1 “(i) assign an identification number
2 to the Internet pharmacy;

3 “(ii) notify the applicant of the receipt
4 of the licensing application; and

5 “(iii) if the Internet pharmacy is in
6 compliance with the conditions under para-
7 graph (2), issue a license not later than 60
8 days after receipt of a licensing application
9 from the Internet pharmacy.

10 “(B) ELECTRONIC FILING.—

11 “(i) IN GENERAL.—For the purpose
12 of reducing paperwork and reporting bur-
13 dens, the Secretary shall require the use of
14 electronic methods of submitting to the
15 Secretary a licensing application required
16 under this section and provide for elec-
17 tronic methods of receiving the applica-
18 tions.

19 “(ii) AUTHENTICATION.—In providing
20 for the electronic submission of such li-
21 censing applications under this section, the
22 Secretary shall ensure that adequate au-
23 thentication protocols are used to allow
24 identification of the Internet pharmacy and
25 validation of the data as appropriate.

1 “(4) DATABASE.—

2 “(A) IN GENERAL.—The Secretary shall
3 compile, maintain, and periodically update a
4 database of the Internet pharmacies licensed
5 under this section.

6 “(B) AVAILABILITY.—The Secretary shall
7 make the database described under subpara-
8 graph (A) and information submitted by the li-
9 censee under paragraph (2)(B) available to the
10 public on an Internet website and through a
11 toll-free telephone number.

12 “(5) FEES.—

13 “(A) IN GENERAL.—

14 “(i) LICENSING APPLICATION FEE.—
15 The Secretary shall establish a licensing
16 application fee to be paid by all applicants.

17 “(ii) RENEWAL FEE.—The Secretary
18 shall establish a yearly renewal fee to be
19 paid by all Internet pharmacies licensed
20 under this section.

21 “(B) COLLECTION.—

22 “(i) COLLECTION OF LICENSING AP-
23 PPLICATION FEE.—A licensing application
24 fee payable for the fiscal year in which the
25 Internet pharmacy submits a licensing ap-

1 plication, as established under subpara-
2 graph (C), shall be payable upon the sub-
3 mission to the Secretary of such licensing
4 application.

5 “(ii) COLLECTION OF RENEWAL
6 FEES.—After the licensing application fee
7 is paid for the first fiscal year of licensure,
8 the yearly renewal fee, as established
9 under subparagraph (C), shall be payable
10 on or before October 1 of each subsequent
11 fiscal year.

12 “(iii) ONE FEE PER INTERNET PHAR-
13 MACY.—The licensing application fee and
14 yearly renewal fee shall be paid only once
15 for each Internet pharmacy for a fiscal
16 year in which the fee is payable.

17 “(C) FEE AMOUNT.—The amount of the li-
18 censing application fee and the yearly renewal
19 fee for an Internet pharmacy shall be deter-
20 mined each year by the Secretary based on the
21 anticipated costs to the Secretary of enforcing
22 the requirements of this section in the subse-
23 quent fiscal year.

24 “(D) ANNUAL FEE DETERMINATION.—

1 “(i) IN GENERAL.—Not later than 60
2 days before the beginning of each fiscal
3 year beginning after September 30, 2007,
4 the Secretary shall determine the amount
5 of the licensing application fee and the
6 yearly renewal fee for that fiscal year.

7 “(ii) PUBLICATION OF FEE
8 AMOUNT.—Not later than 60 days before
9 each fiscal year, the Secretary shall publish
10 the amount of the licensing application fee
11 and the yearly renewal fee under this sec-
12 tion for that fiscal year and provide for a
13 period of 30 days for the public to provide
14 written comments on the fees.

15 “(E) USE OF FEES.—The fees collected
16 under this section shall be used, without further
17 appropriation, to carry out this section.

18 “(F) FAILURE TO PAY FEE.—

19 “(i) DUE DATE.—A fee payable under
20 this section shall be paid by the date that
21 is 30 days after the date on which the fee
22 is due.

23 “(ii) FAILURE TO PAY.—If an Inter-
24 net pharmacy subject to a fee under this
25 section fails to pay the fee by the date

1 specified under clause (i), the Secretary
2 shall not permit the Internet pharmacy to
3 engage in the dispensing of drugs as de-
4 scribed under this section until all such
5 fees owed by the Internet pharmacy are
6 paid.

7 “(G) REPORTS.—Beginning with fiscal
8 year 2008, not later than 60 days after the end
9 of each fiscal year during which licensing appli-
10 cation fees are collected under this section, the
11 Secretary shall submit to the Committee on
12 Health, Education, Labor, and Pensions of the
13 Senate and the Committee on Energy and Com-
14 merce of the House of Representatives a report
15 that describes—

16 “(i) implementation of the licensing
17 fee authority during the fiscal year; and

18 “(ii) the use by the Secretary of the
19 licensing fees collected during the fiscal
20 year for which the report is made.

21 “(6) SUSPENSION.—

22 “(A) IN GENERAL.—If the Secretary deter-
23 mines that an Internet pharmacy is engaged in
24 a pattern of violations of any of the require-
25 ments of this Act, the Secretary may imme-

diately order the suspension of the license of the Internet pharmacy.

“(B) APPEAL OF SUSPENSION ORDER.—

An Internet pharmacy subject to a suspension order under subparagraph (A) may appeal the suspension order to the Secretary. Not later than 30 days after an appeal is filed, the Secretary, after providing opportunity for an informal hearing, shall affirm or terminate the order.

“(C) FAILURE TO ACT.—If, during the 30-

day period specified in subparagraph (B), the Secretary fails to provide an opportunity for a hearing or to affirm or terminate the order, the order shall be deemed to be terminated.

“(D) NO JUDICIAL REVIEW.—An order

under this paragraph shall not be subject to judicial review.

“(7) TERMINATION OF LICENSE.—The Sec-

retary may terminate a license issued under this subsection, after notice to the Internet pharmacy and an opportunity for a hearing, and if the Secretary determines that the Internet pharmacy—

“(A) has demonstrated a pattern of non-compliance with this section;

1 “(B) has made an untrue statement of ma-
2 terial fact in its licensing application; or

3 “(C) is in violation of any applicable Fed-
4 eral or State law relating to the dispensing of
5 a prescription drug.

6 “(8) RENEWAL EVALUATION.—

7 “(A) IN GENERAL.—Before renewing a li-
8 cense of an Internet pharmacy under this sub-
9 section, the Secretary shall conduct an evalua-
10 tion to determine whether the Internet phar-
11 macy is in compliance with this section.

12 “(B) EVALUATION OF INTERNET PHAR-
13 MACIES.—At the discretion of the Secretary and
14 as applicable, an evaluation under subpara-
15 graph (A) may include testing of the Internet
16 pharmacy website or other systems through
17 which the Internet pharmacy communicates
18 with consumers, and a physical inspection of
19 the records and premises of the pharmacy.

20 “(9) CONTRACT FOR OPERATION OF PRO-
21 GRAM.—

22 “(A) IN GENERAL.—The Secretary may
23 award a contract under this subsection for the
24 operation of the licensing program.

1 “(B) TERM.—The duration of a contract
2 under subparagraph (A) shall not exceed 5
3 years and may be renewable.

4 “(C) PERFORMANCE REVIEW.—The Sec-
5 retary shall annually review performance under
6 a contract under subparagraph (A).

7 “(d) PROVIDERS OF INTERACTIVE COMPUTER SERV-
8 ICES OR ADVERTISING SERVICES.—No provider of inter-
9 active computer services (as defined in section 230(f) of
10 the Communications Act of 1934 (47 U.S.C. 230(f)) or
11 an advertising service provider shall be liable under this
12 section on account of another person’s selling or dis-
13 pensing of a prescription drug, so long as the provider of
14 the interactive computer service or the advertising service
15 provider does not own or exercise corporate control over
16 such person.

17 “(e) POLICIES AND PROCEDURES REQUIRED TO
18 PREVENT PAYMENTS FOR UNLAWFUL INTERNET PHAR-
19 MACY REQUESTS.—

20 “(1) REGULATIONS.—Not later than 180 days
21 after designating a system under subsection (a)(2),
22 the Board shall promulgate regulations that re-
23 quire—

24 “(A) an operator of a credit card system
25 that is a designated payment system, an oper-

ator of an international, national, or local network used to effect a credit transaction, electronic fund transfer, or money transmitting service that is a designated payment system, and an operator of any other designated payment system specified by the Board that is centrally managed and is primarily engaged in the transmission and settlement of credit transactions, electronic transfers, or money transmitting services where at least 1 party to the transaction or transfer is an individual; and

“(B) in the case of a designated payment system, other than a designated payment system described in subparagraph (A), a person described in subsection (a)(2)(B);

to establish policies and procedures that are reasonably designed to prevent the introduction of restricted transactions into a designated payment system or the completion of restricted transactions using a designated payment system.

“(2) REQUIREMENTS FOR POLICIES AND PROCEDURES.—In promulgating regulations under paragraph (1), the Board shall—

“(A) identify types of policies and procedures, including nonexclusive examples, that

1 shall be considered to be reasonably designed to
 2 identify and reasonably designed to prevent the
 3 introduction of a restricted transaction in a des-
 4 ignated payment or the completion of restricted
 5 transactions using a designated payment sys-
 6 tem; and

7 “(B) to the extent practicable, permit any
 8 designated payment system, or person described
 9 in subsection (a)(2)(B), as applicable, to choose
 10 among alternative means of preventing the in-
 11 troduction or completion of restricted trans-
 12 actions.

13 “(3) NO LIABILITY FOR BLOCKING OR REFUS-
 14 ING TO HONOR RESTRICTED TRANSACTION.—

15 “(A) IN GENERAL.—A designated payment
 16 system, or a person described in subsection
 17 (a)(2)(B), that is subject to a regulation or an
 18 order issued under this subsection, and any
 19 participant in such payment system, that—

20 “(i) prevents or otherwise refuses to
 21 honor restricted transactions, in an effort
 22 to implement the policies and procedures
 23 required under this subsection or to other-
 24 wise comply with this section, shall not be
 25 liable to any party for such action; and

1 “(ii) prevents or otherwise refuses to
2 honor a nonrestricted transaction in an ef-
3 fort to implement the policies and proce-
4 dures under this subsection or to otherwise
5 comply with this section, shall not be liable
6 to any party for such action.

7 “(B) COMPLIANCE WITH THIS SUB-
8 SECTION.—A person described in subsection
9 (a)(2)(B) meets the requirements of this sub-
10 section, if any, if the person relies on and com-
11 plies with the policies and procedures of a des-
12 ignated payment system of which the person is
13 a member or in which the person is a partici-
14 pant, and such policies and procedures of the
15 designated payment system comply with the re-
16 quirements of the regulations under paragraph
17 (1)(B).

18 “(4) ENFORCEMENT.—

19 “(A) IN GENERAL.—This subsection shall
20 be enforced by the Federal functional regulators
21 and the Federal Trade Commission under appli-
22 cable law in the manner provided in section
23 505(a) of the Gramm-Leach-Bliley Act (21
24 U.S.C. 6805(a)).

1 “(B) FACTORS TO BE CONSIDERED.—In
2 considering any enforcement action under this
3 subsection against a payment system or person
4 described in subsection (a)(2)(B), the Federal
5 functional regulators and the Federal Trade
6 Commission shall consider the following factors:

7 “(i) The extent to which the payment
8 system or person knowingly permits re-
9 stricted transactions.

10 “(ii) The history of the payment sys-
11 tem or person in connection with permit-
12 ting restricted transactions.

13 “(iii) The extent to which the pay-
14 ment system or person has established and
15 is maintaining policies and procedures in
16 compliance with regulations prescribed
17 under this subsection.

18 “(iv) The feasibility that any specific
19 remedy prescribed can be implemented by
20 the payment system or person without sub-
21 stantial deviation from normal business
22 practice.

23 “(v) The costs and burdens the spe-
24 cific remedy will have on the payment sys-
25 tem or person.

1 “(f) REPORTS REGARDING INTERNET-RELATED VIO-
 2 LATIONS OF FEDERAL AND STATE LAWS ON DISPENSING
 3 OF DRUGS.—The Secretary shall, pursuant to the submis-
 4 sion of an application meeting criteria prescribed by the
 5 Secretary, make an award of a grant or contract to an
 6 entity with experience in developing and maintaining sys-
 7 tems for the purpose of—

8 “(1) identifying Internet pharmacy websites
 9 that are not licensed or that appear to be operating
 10 in violation of Federal or State laws concerning the
 11 dispensing of drugs;

12 “(2) reporting such Internet pharmacy websites
 13 to State medical licensing boards and State phar-
 14 macy licensing boards, and to the Attorney General
 15 and the Secretary, for further investigation; and

16 “(3) submitting, for each fiscal year for which
 17 the award under this subsection is made, a report to
 18 the Secretary describing investigations undertaken
 19 with respect to violations described in paragraph (1).

20 “(g) TRANSACTIONS PERMITTED.—A designated
 21 payment system or person subject to a regulation or an
 22 order issued under subsection (e) may engage in trans-
 23 actions with licensed and unlicensed Internet pharmacies
 24 in connection with investigating violations or potential vio-
 25 lations of any rule or requirement adopted by the payment

1 system or person in connection with complying with sub-
2 section (e). A person subject to a regulation or an order
3 issued under subsection (e) and the agents and employees
4 of that person shall not be found to be in violation of,
5 or liable under, any Federal, State, or other law for engag-
6 ing in any such transaction.

7 “(h) RELATION TO STATE LAWS.—No requirement,
8 prohibition, or liability may be imposed on a designated
9 payment system or person subject to a regulation or an
10 order issued under subsection (e) under the laws of any
11 State with respect to any payment transaction by an indi-
12 vidual because the payment transaction involves a pay-
13 ment to an Internet pharmacy.

14 “(i) TIMING OF REQUIREMENTS.—A designated pay-
15 ment system or a person subject to a regulation under
16 subsection (e) shall adopt policies and procedures reason-
17 ably designed to comply with any regulations required
18 under subsection (e) not later than 180 days after the date
19 on which such final regulations are issued.”.

20 (b) PROHIBITED ACTS.—Section 301 of the Federal
21 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-
22 ed by adding at the end the following:

23 “(hh)(1) The sale, under section 511, of a drug that
24 is not a prescription drug, the sale of such a prescription
25 drug without a valid prescription from a treating provider,

1 or the ownership or operation of an Internet pharmacy,
 2 in violation of section 511.

3 “(2) The representation by advertisement, sales pres-
 4 entation, direct communication (including telephone, fac-
 5 simile, or electronic mail), or otherwise by an Internet
 6 pharmacy, that a prescription drug may be obtained from
 7 the Internet pharmacy without a prescription, in violation
 8 of section 511.

9 “(3) The advertisement related to a prescription drug
 10 through any media including sales presentation, direct
 11 communication (including telephone, facsimile, or elec-
 12 tronic mail), by an unlicensed Internet pharmacy.

13 “(4) The provision of an untrue statement of material
 14 fact in the licensing application of an Internet pharmacy.

15 “(5) For purposes of this subsection, any term used
 16 in this subsection that is also used in section 511 shall
 17 have the meaning given that term in section 511.”.

18 (c) LINKS TO UNLICENSED INTERNET PHAR-
 19 MACIES.—Section 302 of the Federal Food, Drug, and
 20 Cosmetic Act (21 U.S.C. 332) is amended by adding at
 21 the end the following:

22 “(c)(1) In the case of a violation of section 511 relat-
 23 ing to an unlicensed Internet pharmacy (as defined in such
 24 section 511), the district courts of the United States and
 25 the United States courts of the territories shall have juris-

1 diction to order a provider of an interactive computer serv-
 2 ice to remove, or disable access to, links to a website vio-
 3 lating that section that resides on a computer server that
 4 the provider controls or operates.

5 “(2) Relief under paragraph (1)—

6 “(A) shall be available only after provision to
 7 the provider of notice and an opportunity to appear;

8 “(B) shall not impose any obligation on the
 9 provider to monitor its service or to affirmatively
 10 seek facts indicating activity violating section 511;

11 “(C) shall specify the provider to which the re-
 12 lief applies; and

13 “(D) shall specifically identify the location of
 14 the website to be removed or to which access is to
 15 be disabled.”.

16 (d) REGULATIONS.—

17 (1) IN GENERAL.—Not later than 1 year after
 18 the date of enactment of this Act, the Secretary of
 19 Health and Human Services shall promulgate in-
 20 terim final regulations to carry out the amendments
 21 made by this section.

22 (2) EFFECTIVE DATE.—The requirement of li-
 23 censure under section 511 of the Federal Food,
 24 Drug, and Cosmetic Act (as added by this section)
 25 shall take effect on the date determined by the Sec-

1 retary of Health and Human Services but in no
2 event later than 90 days after the effective date of
3 the interim final regulations under paragraph (1).

4 (e) PENALTIES.—Section 303 of the Federal Food,
5 Drug, and Cosmetic Act (21 U.S.C. 333) is amended by
6 adding at the end the following:

7 “(g) Notwithstanding subsection (a), any person who
8 knowingly violates paragraph (1), (2), (3), or (4) of sec-
9 tion 301(hh) shall be imprisoned for not more than 10
10 years or fined in accordance with title 18, United States
11 Code, or both.”.

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