

106TH CONGRESS
2D SESSION

H. R. 5142

To amend title XVIII of the Social Security Act to provide under contract with a Medicare carrier for an official website through which Medicare beneficiaries and others can obtain Internet access to safe and competitively priced domestic and international prescription drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 7, 2000

Mr. STARK introduced the following bill; which was referred to the Committee on Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend title XVIII of the Social Security Act to provide under contract with a Medicare carrier for an official website through which Medicare beneficiaries and others can obtain Internet access to safe and competitively priced domestic and international prescription drugs, and for other purposes.

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 “Medicare Prescription
3 Drug Internet Access and Safe Importation Act of 2000”.

4 **SEC. 2. PROMOTING ACCESS OF MEDICARE BENEFICIARIES**
5 **TO SAFE AND COMPETITIVELY PRICED PRE-**
6 **SCRIPTION DRUGS THROUGH THE INTERNET.**

7 Section 1842 of the Social Security Act (42 U.S.C.
8 1395u) is amended by adding at the end the following new
9 subsection:

10 “(u) **CONTRACT TO PROVIDE OFFICIAL WEBSITE TO**
11 **PROVIDE ACCESS TO SAFE AND COMPETITIVELY PRICED**
12 **DOMESTIC AND INTERNATIONAL PRESCRIPTION DRUGS**
13 **TO MEDICARE BENEFICIARIES THROUGH THE INTER-**
14 **NET.—**

15 “(1) **CONTRACT.—**

16 “(A) **IN GENERAL.—**The Secretary shall
17 enter into a contract arrangement with a quali-
18 fied carrier under which the carrier will provide
19 for the operation of an Internet site through
20 which medicare beneficiaries, physicians, and
21 pharmacies serving medicare beneficiaries can
22 identify one or more Internet pharmacies
23 (which are qualified under paragraph (2))
24 through which such individuals and pharmacies
25 may directly purchase safe and effective domes-
26 tic and international prescription drugs.

1 “(B) QUALIFICATIONS FOR CARRIER OPER-
2 ATING OFFICIAL WEBSITE.—For purposes of
3 paragraph (1), a qualified carrier is a carrier
4 that demonstrates to the satisfaction of the Sec-
5 retary the ability to operate the Internet site
6 and to provide for appropriate screening and
7 oversight of the qualified Internet pharmacies
8 so as to ensure the delivery of safe products.

9 “(C) CONTRACT WITH ONLY 1 CARRIER.—
10 The Secretary shall enter into such a contract
11 with only 1 carrier.

12 “(D) SEEKING MOST COMPETITIVE
13 PRICE.—In entering into a contract with a car-
14 rier under this subsection, the Secretary shall
15 seek to obtain the greatest accessibility at the
16 most competitive price available for prescription
17 drugs for medicare beneficiaries, physicians,
18 and pharmacies serving medicare beneficiaries.
19 For this purpose, the carrier may limit the
20 number of Internet pharmacies which are linked
21 through the carrier’s website under this sub-
22 section.

23 “(E) POSTING OF PRICES FOR COVERED
24 DRUGS.—The contractor shall agree to post in
25 a clear and visible manner on the homepage for

1 its Internet site, or on a page directly linked to
2 the homepage (by a clear and visible link on the
3 homepage), the five lowest prices for a par-
4 ticular prescription drug, including its thera-
5 peutic brand and generic equivalents, requested
6 by the medicare beneficiary.

7 “(F) RECOVERY OF ADMINISTRATIVE
8 COSTS.—The carrier shall seek to recover the
9 administrative costs of the contract under this
10 subsection by assessing a reasonable fee (which
11 may be based on such criteria as the contractor
12 determines most efficient) on Internet phar-
13 macies which use the carrier’s website to post
14 pharmaceutical products for sale of medicare
15 beneficiaries, physicians, and pharmacies serv-
16 ing medicare beneficiaries. Such fees shall be
17 adjusted from year to year as necessary to re-
18 cover administrative costs over a multi-year pe-
19 riod.

20 “(G) PRIVACY STANDARDS.—The carrier
21 shall not disclose any personal or medical infor-
22 mation regarding a medicare beneficiary if the
23 information is not utilized solely for the proc-
24 essing of claims, delivery of covered drugs, or is

1 not vital to the immediate health or welfare of
2 the medicare beneficiary.

3 “(2) QUALIFICATIONS FOR INTERNET PHAR-
4 MACIES.—For purposes of this subsection, the Sec-
5 retary shall establish standards for qualification of
6 Internet pharmacies which may participate in the
7 carrier’s website. In establishing such standards, the
8 Secretary shall consider the recommendations of the
9 National Association of Boards of Pharmacy and
10 shall assure that each qualified Internet pharmacy—

11 “(A) is licensed in each State as a phar-
12 macy;

13 “(B) is in compliance with applicable re-
14 quirements of Federal and State law governing
15 the practice of pharmacy;

16 “(C) agrees not to dispense a drug except
17 upon a prescription of a practitioner licensed by
18 law to administer the drug;

19 “(D) agrees to post in a clear and visible
20 manner on the homepage for its Internet site,
21 or on a page directly linked to the homepage
22 (by a clear and visible link on the homepage),
23 such information regarding the identity of the
24 pharmacy and restrictions applicable to its dis-

1 pensing of prescription drugs as the Secretary
2 shall specify; and

3 “(E) meets such other requirements as the
4 Secretary shall establish.”.

5 **SEC. 3. INTERNET PHARMACIES FOR MEDICARE BENE-**
6 **FICIARIES.**

7 (a) IN GENERAL.—Chapter VIII of the Federal
8 Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.)
9 is amended—

10 (1) in section 801(d)(1), by striking “Except as
11 provide in paragraph (2),” and inserting “Except as
12 provided in paragraph (2) or section 801A,”; and

13 (2) by inserting after section 801 the following
14 section:

15 “SEC. 801A. (a) PROMULGATION OF CRITERIA FOR
16 INTERNET PHARMACIES ELIGIBLE TO PARTICIPATE
17 WITH A MEDICARE CARRIER UNDER 1842(u) OF THE SO-
18 CIAL SECURITY ACT.—The Secretary shall by regulation
19 promulgate uniform criteria for the operation of Internet
20 pharmacies pursuant to subsection (d)(1), including re-
21 quirements regarding the manner in which such phar-
22 macies serve medicare beneficiaries and physicians or
23 pharmacies serving medicare beneficiaries. In establishing
24 such criteria, the Secretary shall with respect to Internet
25 pharmacies consider the recommendations of the National

1 Association of Boards of Pharmacy. Such criteria shall
2 provide that a waiver under subsection (c) will be provided
3 to a medicare Internet pharmacy only if the following con-
4 ditions are met:

5 “(1) The Internet pharmacy is licensed under a
6 uniform name as a pharmacy among the States in
7 each State.

8 “(2) The Internet pharmacy is in compliance
9 with applicable requirements of Federal and State
10 law governing the practice of pharmacy.

11 “(3) The Internet pharmacy agrees that it will
12 dispense a drug as written for an individual only
13 upon a prescription of a practitioner licensed by law
14 to administer the drug.

15 “(4) The Internet site of the Internet pharmacy
16 posts in a clear and visible manner on the homepage
17 for the site, or on a page directly linked to the
18 homepage (by a clear and visible link on the home-
19 page), the following information:

20 “(A) A statement that the Internet phar-
21 macy will dispense prescription drugs only upon
22 a valid prescription by a licensed practitioner.

23 “(B) The street address for the principal
24 place of business for the Internet pharmacy.

1 “(C) The name of the chief pharmacist for
2 the Internet pharmacy, the professional degree
3 held by such pharmacist, and an identification
4 of the pharmacy licenses held by the phar-
5 macist.

6 “(D) A telephone number at which phar-
7 macists of the Internet pharmacy may be
8 reached.

9 “(5) The Internet pharmacy contracts that it
10 will make available through the Internet site to phy-
11 sicians or pharmacies serving medicare beneficiaries
12 the same covered drugs as are available to medicare
13 beneficiaries through the site.

14 “(6) The Internet pharmacy shall not disclose
15 any personal or medical information regarding a
16 medicare beneficiary if the information is not uti-
17 lized solely for the processing of claims, delivery of
18 covered drugs, or is not vital to the immediate
19 health or welfare of the medicare beneficiary.

20 “(7) Such other conditions as the Secretary
21 may establish by regulation.

22 “(b) ENFORCEMENT.—

23 “(1) SUSPENSION OR REVOCATION OF WAIV-
24 ER.—After notice and opportunity for a hearing, the
25 Secretary may suspend or revoke the waiver of an

1 Internet pharmacy under subsection (c) on any of
2 the following grounds:

3 “(A) The Internet pharmacy ceases to
4 comply with any condition described in sub-
5 section (a).

6 “(B) The Internet pharmacy has violated
7 any provision of section 301.

8 “(C) The Internet pharmacy has violated a
9 provision of the Controlled Substances Act, or
10 has violated any State law regarding controlled
11 substances.

12 “(D) The Internet pharmacy has violated a
13 State law regarding the unauthorized operation
14 of a pharmacy or the unauthorized practice of
15 medicine.

16 “(E) The Internet pharmacy has engaged
17 in such other conduct as, with respect to finan-
18 cial misconduct as well as the safety or effec-
19 tiveness of drugs, justifies the suspension or
20 revocation in the interest of protecting medicare
21 beneficiaries from the Internet pharmacy.

22 “(2) CRIMINAL PENALTY FOR SUBSEQUENT IM-
23 PORTATIONS.—If the waiver of an Internet phar-
24 macy under subsection (c) is suspended or revoked
25 by the Secretary under paragraph (1), any importa-

1 tion by the Internet pharmacy of a covered drug into
2 the United States after the suspension or revocation
3 takes effect shall be considered to be a violation of
4 the provisions of section 301(t) that relate to section
5 801(d).

6 “(3) FEE TO FUND THE SECRETARY’S EN-
7 FORCEMENT OF THIS ACT.—The Secretary shall col-
8 lect a reasonable fee necessary to carry out the en-
9 forcement of this act.

10 “(c) WAIVER OF RESTRICTION ON REENTRY OF EX-
11 PORTED DRUGS.—

12 “(1) IN GENERAL.—If the Secretary determines
13 that an Internet pharmacy meets the requirements
14 described in paragraphs (1) and (2) of subsection
15 (d), the Secretary shall establish a waiver providing
16 that, notwithstanding section 801(b)(1), the Internet
17 pharmacy may import into the United States any
18 covered drug.

19 “(2) COVERED DRUGS.—For purposes of this
20 section, the term ‘covered drug’ means a drug
21 that—

22 “(A) is a drug for which an application has
23 been approved pursuant to section 505 or pur-
24 suant to section 351 of the Public Health Serv-
25 ice Act; and

1 “(B)(i) is a prescription drug; or

2 “(ii) is a drug composed wholly or partly
3 of insulin.

4 “(3) RULE OF CONSTRUCTION REGARDING
5 SAFETY AND EFFECTIVENESS, ADULTERATION AND
6 MISBRANDING, AND OTHER REQUIREMENTS.—A
7 waiver of section 801(d)(1) under paragraph (1)
8 may not be construed as waiving any other provision
9 of Federal law regarding the drugs involved.

10 “(d) REQUIREMENTS FOR WAIVER.—

11 “(1) INTERNET PHARMACY QUALIFIED UNDER
12 1842(u) OF THE SOCIAL SECURITY ACT.—For pur-
13 poses of subsection (c)(1), the requirement described
14 in this paragraph is that the Internet pharmacy in-
15 volved operate, in accordance with criteria under
16 subsection (a), an Internet site through which medi-
17 care beneficiaries, physicians, and pharmacies serv-
18 ing medicare beneficiaries can purchase covered
19 drugs.

20 “(2) INFORMATION REGARDING IMPORTATION—
21 For purposes of subsection (c)(1), the requirement
22 described in this paragraph is that the Internet
23 pharmacy involved provide to the Secretary such in-
24 formation as the Secretary may require for purposes
25 of determining whether the requirements of this Act

1 have been met with respect to the covered drug
2 being imported.

3 “(e) DEFINITIONS.—For purposes of this section:

4 “(1) The term ‘covered drug’ has the meaning
5 given such term in subsection (c)(2).

6 “(2) The term ‘generic drug’ means a drug ap-
7 proved under section 505(j) of the Federal Food,
8 Drug, and Cosmetic Act.

9 “(3) The term ‘Internet’ means collectively the
10 myriad of computer and telecommunications facili-
11 ties, including equipment and operating software,
12 which comprise the interconnected world-wide net-
13 work of networks that employ the Transmission
14 Control Protocol/Internet Protocol, or any prede-
15 cessor or successor protocols to such protocol, to
16 communicate information of all kinds by wire or
17 radio.

18 “(4) The term ‘Internet pharmacy’ means an
19 Internet site through which a medicare beneficiary
20 or a physician or pharmacy serving medicare bene-
21 ficiaries can purchase a drug, whether the purchase
22 is a sale for resale or sale at retail.

23 “(5) The term ‘Internet site’ means a site on
24 the telecommunications medium known as the World
25 Wide Web of the Internet.

1 “(6) The term ‘Medicare beneficiary’ means an
2 individual entitled to benefits under part A of title
3 XVIII of the Social Security Act, or enrolled under
4 part B of such title, or both.

5 “(7) The term ‘prescription drug’ means a drug
6 that is subject to section 503(b).”.

7 (b) EFFECTIVE DATE.—This act shall take effect six
8 months after the date of enactment.

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