

112TH CONGRESS
1ST SESSION

S. 882

To prevent misuse, overutilization, and trafficking of prescription drugs by limiting access to such drugs for Medicare and Medicaid beneficiaries who have been identified as high-risk prescription drug users.

IN THE SENATE OF THE UNITED STATES

MAY 4, 2011

Mr. BROWN of Ohio introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

To prevent misuse, overutilization, and trafficking of prescription drugs by limiting access to such drugs for Medicare and Medicaid beneficiaries who have been identified as high-risk prescription drug users.

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.**

4 This Act may be cited as the “Stop Trafficking of
5 Pills Act” or the “STOP Act”.

6 **SEC. 2. MEDICAID RESTRICTED RECIPIENT PROGRAM.**

7 (a) IN GENERAL.—Title XIX of the Social Security
8 Act (42 U.S.C. 1396 et seq.) is amended—

1 (1) in section 1902(a)—

2 (A) by striking “and” at the end of para-
3 graph (82);

4 (B) by striking the period at the end of
5 paragraph (83) and inserting “; and”; and

6 (C) by inserting after paragraph (83) the
7 following new paragraph:

8 “(84) in accordance with section 1908B, pro-
9 vide for the development and implementation of a
10 restricted recipient program for individuals identified
11 as high-risk prescription drug users.”; and

12 (2) by inserting after section 1908A the fol-
13 lowing new section:

14 “RESTRICTED RECIPIENT PROGRAM FOR HIGH-RISK
15 PRESCRIPTION DRUG USERS

16 “SEC. 1908B (a) IDENTIFICATION OF HIGH-RISK
17 PRESCRIPTION DRUG USERS.—

18 “(1) IN GENERAL.—Subject to paragraph (2),
19 the State shall establish and implement a program,
20 subject to approval by the Secretary, to—

21 “(A) identify any prescription drug that—

22 “(i) may be dispensed on the prescrip-
23 tion of a physician to an individual eligible
24 to receive medical assistance under the
25 State Medicaid program; and

1 “(ii) presents a high risk of misuse or
2 overutilization, as determined by the State;

3 “(B) establish a dosage level for each pre-
4 scription drug identified under subparagraph
5 (A) that would be deemed excessive in the ab-
6 sence of evidence of medical necessity;

7 “(C) using a percentile-based method or
8 other such form of statistical analysis, identify
9 individuals (referred to in this section as ‘indi-
10 viduals identified as high-risk prescription drug
11 users’) who are eligible for medical assistance
12 under the State Medicaid program and—

13 “(i) are receiving a prescription drug
14 that has been identified under subpara-
15 graph (A) at a dosage level that has been
16 determined to be excessive pursuant to
17 subparagraph (B); or

18 “(ii) are determined by the State, pur-
19 suant to the procedure established under
20 paragraph (3), to have been convicted of a
21 drug-related offense; and

22 “(D) ensure that individuals identified as
23 high-risk prescription drug users pursuant to
24 subparagraph (C) are assigned to the restricted
25 recipient program described in subsection (b).

1 “(2) CASE REVIEW.—For purposes of para-
2 graph (1), the State shall establish and implement
3 procedures to ensure that an individual who has
4 been identified as a high-risk prescription drug user
5 and is subject to the requirements under the re-
6 stricted recipient program—

7 “(A) is provided with reasonable notice re-
8 garding their assignment to the program and a
9 description of the requirements under such pro-
10 gram;

11 “(B) is permitted to file an appeal with the
12 State agency and receive a hearing thereon to
13 review whether the individual has been properly
14 identified as a high-risk prescription drug user;

15 “(C) for purposes of subsection (b)(1), is
16 permitted to file a claim with the State agency
17 in order to seek reassignment to a different
18 physician or pharmacist; and

19 “(D) has reasonable access to any pre-
20 scription drug that is medically necessary and
21 required to be dispensed on an emergency basis.

22 “(3) DRUG-RELATED OFFENSES.—For pur-
23 poses of paragraph (1)(C)(ii), the State shall estab-
24 lish and implement procedures to determine whether
25 an individual, at the time of enrollment or re-enroll-

1 ment in the State Medicaid program, has been con-
2 victed (under Federal or State law) of any offense
3 which is classified as a felony by the law of the juris-
4 diction involved and which has as an element the un-
5 lawful possession, manufacture, distribution, or dis-
6 pensing of a prescription drug (including opioids and
7 similar pain-management prescription drugs).

8 “(b) RESTRICTED RECIPIENT PROGRAM.—

9 “(1) MEDICAID LOCK-IN PROGRAM.—

10 “(A) IN GENERAL.—Subject to subpara-
11 graph (B), the State shall establish and imple-
12 ment a program (referred to in this section as
13 the ‘Medicaid Lock-in Program’) to ensure that
14 any individual identified as a high-risk prescrip-
15 tion drug user is—

16 “(i) assigned to a single and exclusive
17 physician (as defined in section 1861(r))
18 for purposes of receiving any medical as-
19 sistance that is related to a prescription
20 drug; and

21 “(ii) assigned to a single and exclusive
22 pharmacy for purposes of receiving any
23 prescription drug that has been prescribed
24 by a physician described in clause (i).

1 “(2) MEDICAID PRESCRIPTION DRUG RESTRIC-
2 TION PROGRAM.—

3 “(A) IN GENERAL.—Subject to subpara-
4 graph (B), the State, in conjunction with the
5 Secretary, shall establish and implement a pro-
6 gram to ensure that the claims processing sys-
7 tem for the State does not permit a prescription
8 drug to be dispensed by a provider to an indi-
9 vidual identified as a high-risk prescription
10 drug user if the same prescription drug has
11 been dispensed to such individual within the
12 previous 20 days.

13 “(B) EXCEPTIONS.—

14 “(i) INCREASED DOSAGE.—For pur-
15 poses of subparagraph (A), the restrictions
16 described in such subparagraph shall not
17 apply to an individual identified as a high-
18 risk prescription drug user—

19 “(I) if the current prescription is
20 for an increased dosage of the pre-
21 scription drug and has been issued by
22 the same physician that issued the
23 previous prescription; or

24 “(II) in such other circumstances
25 as determined by the Secretary.

1 “(ii) PROCEDURAL DEVELOPMENT.—

2 The State, in conjunction with the Sec-
3 retary, shall develop adequate procedures
4 to ensure that prescriptions described in
5 clause (i) are not affected by the restric-
6 tions described in subparagraph (A) and
7 are permitted to be dispensed by a pro-
8 vider to an individual identified as a high-
9 risk prescription drug user.

10 “(c) EXISTING STATE PROGRAMS.—

11 “(1) IN GENERAL.—Subject to paragraphs (2)
12 and (3), as well as any procedures as are determined
13 appropriate by the Secretary, a restricted recipient
14 program that has been established by a State prior
15 to the date of enactment of the Stop Trafficking of
16 Pills Act may be reviewed and certified by the Sec-
17 retary as being in accordance with the requirements
18 under this section for purposes of section
19 1902(a)(84).

20 “(2) PROGRAM IMPROVEMENT.—For purposes
21 of paragraph (1), if the Secretary does not certify an
22 existing State restricted recipient program as being
23 in accordance with the requirements under this sec-
24 tion, the Secretary shall identify any necessary en-
25 hancements or additional developments that are re-

1 quired in order for such program to be deemed in
2 accordance with such requirements.

3 “(3) DRUG-RELATED OFFENSES.—For pur-
4 poses of paragraph (1), an existing State restricted
5 recipient program shall be required to include proce-
6 dures described in subsection (a)(3) for the identi-
7 fication and inclusion of individuals convicted of a
8 drug-related offense.

9 “(d) ADMINISTRATIVE EXPENSES.—Subject to such
10 requirements as are determined appropriate by the Sec-
11 retary, for purposes of section 1903(a)(7), any amounts
12 expended by the State to develop and implement a re-
13 stricted recipient program for individuals identified as
14 high-risk prescription drug users under this section, in-
15 cluding any necessary enhancements or additional develop-
16 ments identified under subsection (c)(2), shall be consid-
17 ered amounts expended as necessary for the proper and
18 efficient administration of the State Medicaid plan.

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

20 “(1) STATE MEDICAID PROGRAM.—The term
21 ‘State Medicaid program’ means the State program
22 for medical assistance provided under a State plan
23 under this title, including any waiver approved with
24 respect to such State plan.

1 “(2) PRESCRIPTION DRUG.—The term ‘pre-
2 scription drug’ means a drug subject to section
3 503(b)(1) of the Federal Food, Drug, and Cosmetic
4 Act (21 U.S.C. 353(b)(1)).”.

5 (b) WITHHOLDING OF PAYMENT.—Section 1903(i) of
6 the Social Security Act (42 U.S.C. 1396b(i)), as amended
7 by section 2001(a)(2)(B) of the Patient Protection and
8 Affordable Care Act (Public Law 111–148), is amended—

9 (1) in paragraph (25), by striking “or” at the
10 end;

11 (2) in paragraph (26), by striking the period
12 and inserting “; or”; and

13 (3) by adding at the end the following new
14 paragraph:

15 “(27) with respect to amounts expended for
16 medical assistance for any prescription drug dis-
17 pensed to an individual identified as a high-risk pre-
18 scription drug user (as described in section
19 1908B(a)(1)(C)), unless the requirements under sec-
20 tion 1908B are met.”.

21 **SEC. 3. MEDICARE RESTRICTED RECIPIENT PROGRAM.**

22 Part D of title XVIII of the Social Security Act
23 (U.S.C. 1395w–101 et seq.) is amended by adding at the
24 end the following new section:

1 “RESTRICTED RECIPIENT PROGRAM FOR HIGH-RISK
2 PRESCRIPTION DRUG USERS

3 “SEC. 1860D–44 (a) IDENTIFICATION OF HIGH-RISK
4 PRESCRIPTION DRUG USERS.—

5 “(1) IN GENERAL.—Subject to paragraph (2),
6 the Secretary shall establish and implement a pro-
7 gram to—

8 “(A) identify any prescription drug that—

9 “(i) may be dispensed on the prescrip-
10 tion of a physician to an individual en-
11 rolled in a prescription drug plan under
12 this part; and

13 “(ii) presents a high risk of misuse or
14 overutilization, as determined by the Sec-
15 retary;

16 “(B) establish a dosage level for each pre-
17 scription drug identified under subparagraph
18 (A) that would be deemed excessive in the ab-
19 sence of evidence of medical necessity;

20 “(C) using a percentile-based method or
21 other such form of statistical analysis, identify
22 individuals (referred to in this section as ‘indi-
23 viduals identified as high-risk prescription drug
24 users’) who are enrolled in a prescription drug
25 plan under this part; and

1 “(i) are receiving a prescription drug
2 that has been identified under subpara-
3 graph (A) at a dosage level that has been
4 determined to be excessive pursuant to
5 subparagraph (B); or

6 “(ii) are determined by the Secretary,
7 pursuant to the procedure established
8 under paragraph (3), to have been con-
9 victed of a drug-related offense; and

10 “(D) ensure that individuals identified as
11 high-risk prescription drug users pursuant to
12 subparagraph (C) are assigned to the restricted
13 recipient program described in subsection (b).

14 “(2) CASE REVIEW.—For purposes of para-
15 graph (1), the Secretary shall establish and imple-
16 ment procedures to ensure that an individual who
17 has been identified as a high-risk prescription drug
18 user and is subject to the requirements under the re-
19 stricted recipient program—

20 “(A) is provided with reasonable notice re-
21 garding their assignment to the program and a
22 description of the requirements under such pro-
23 gram;

24 “(B) is permitted to file an appeal and re-
25 ceive a hearing thereon to review whether the

1 individual has been properly identified as a
2 high-risk prescription drug user; and

3 “(C) has reasonable access to any prescrip-
4 tion drug that is medically necessary and re-
5 quired to be dispensed on an emergency basis.

6 “(3) DRUG-RELATED OFFENSE.—For purposes
7 of paragraph (1)(C)(ii), the Secretary shall establish
8 and implement procedures to determine whether an
9 individual, at the time of enrollment or re-enrollment
10 in a prescription drug plan under this part, has been
11 convicted (under Federal or State law) of any of-
12 fense which is classified as a felony by the law of the
13 jurisdiction involved and which has as an element
14 the unlawful possession, manufacture, distribution,
15 or dispensing of a prescription drug (including
16 opioids and similar prescription pain-management
17 drugs).

18 “(b) PRESCRIPTION DRUG RESTRICTION PRO-
19 GRAM.—The Secretary shall establish policies and proce-
20 dures to ensure that the provisions described in section
21 1908B(b)(3) are applied to any individual identified, pur-
22 suant to subsection (a)(1), as a high-risk prescription drug
23 user in a similar manner as such provisions are applied
24 to such individuals for purposes of title XIX.”.

1 **SEC. 4. EFFECTIVE DATE.**

2 (a) IN GENERAL.—Except as provided in subsection
3 (b), the amendments made by this section shall take effect
4 120 days after the date of enactment of this Act.

5 (b) EXTENSION OF EFFECTIVE DATE FOR STATE
6 LAW AMENDMENT.—In the case of a State plan under
7 title XIX of the Social Security Act (42 U.S.C. 1396 et
8 seq.) which the Secretary determines requires State legis-
9 lation in order for the plan to meet the additional require-
10 ments imposed by the amendments made by this section,
11 the State plan shall not be regarded as failing to comply
12 with the requirements of the amendments made by this
13 section solely on the basis of its failure to meet such addi-
14 tional requirements before the first day of the first cal-
15 endar quarter beginning after the close of the first regular
16 session of the State legislature that begins after the date
17 of the enactment of this Act. For purposes of the previous
18 sentence, in the case of a State that has a 2-year legisla-
19 tive session, each year of the session is considered to be
20 a separate regular session of the State legislature.

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