

113TH CONGRESS
1ST SESSION

H. R. 3392

To amend title XVIII of the Social Security Act to provide for a PDP safety program to prevent fraud and abuse in the dispensing of controlled substances under part D of the Medicare program, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 30, 2013

Mr. BILIRAKIS (for himself and Mr. BEN RAY LUJÁN of New Mexico) introduced the following bill; which was referred to the Committee on Energy and 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 for a PDP safety program to prevent fraud and abuse in the dispensing of controlled substances under part D of the Medicare program, 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,*

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

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Medicare Part D Patient Safety and Drug Abuse Preven-
6 tion Act of 2013”.

1 (b) TABLE OF CONTENTS.—The table of contents of
 2 this Act is as follows:

- Sec. 1. Short title; table of contents.
- Sec. 2. Establishing PDP safety program to prevent fraud and abuse in Medicare prescription drug plans.
- Sec. 3. Part D suspension of claims payment.
- Sec. 4. Improving activities of Medicare Drug Integrity Contractors (MEDICs).
- Sec. 5. Requiring e-prescribing for coverage of covered part D controlled substances.

3 **SEC. 2. ESTABLISHING PDP SAFETY PROGRAM TO PREVENT**
 4 **FRAUD AND ABUSE IN MEDICARE PRESCRIP-**
 5 **TION DRUG PLANS.**

6 (a) PDP SAFETY PROGRAM.—Section 1860D–4(c) of
 7 the Social Security Act (42 U.S.C. 1395w–104(c)) is
 8 amended—

9 (1) in paragraph (1)(D)—

10 (A) by inserting “, designed to” after
 11 “program”; and

12 (B) by inserting “, that includes the proce-
 13 dures described in paragraph (4)” after
 14 “waste”; and

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

16 “(4) SAFE PHARMACY ACCESS PROGRAM.—

17 “(A) PDP SPONSOR PROCEDURES.—A
 18 PDP sponsor (or an MA organization offering
 19 an MA–PD plan) shall have in place procedures
 20 designed—

21 “(i) to identify an individual who has
 22 obtained coverage for a covered part D

1 drug that is a frequently abused schedule
2 II, III, IV, or V controlled substance, as
3 determined in accordance with utilization
4 guidelines established by the Secretary and
5 the sponsor (or MA organization), and to
6 notify such individuals that they have been
7 so identified;

8 “(ii) to contract with pharmacies au-
9 thorized to dispense such controlled sub-
10 stances to create a safe pharmacy network
11 that meets the criteria specified in sub-
12 paragraph (C);

13 “(iii) taking into account the location
14 of the individual’s residence (or resi-
15 dences), work site, mobility, and other rel-
16 evant factors, to limit coverage to schedule
17 II, III, IV, or V controlled substances for
18 some or all classes of covered part D drugs
19 for an individual identified under clause (i)
20 (or under subparagraph (B)) to drugs dis-
21 pensed by one or more pharmacies con-
22 tracted with under clause (ii);

23 “(iv) to provide to the Secretary the
24 name, and other information that the Sec-
25 retary may require, of individuals so iden-

1 tified and of the fact of such individual's
2 disenrollment (if any) from the plan of the
3 sponsor (or the MA–PD plan offered by
4 the MA organization);

5 “(v) to provide for an appeals process
6 whereby an individual so identified may
7 appeal such identification on the basis that
8 the identification was not appropriate;

9 “(vi) to provide for a process whereby
10 an individual so identified may petition for
11 the termination of such identification on
12 the basis that the limitation on coverage is
13 no longer necessary to prevent fraud and
14 abuse by the individual; and

15 “(vii) to provide that coverage shall be
16 provided for a schedule II, III, IV, or V
17 controlled substance only if it prescribed in
18 accordance with an electronic prescribing
19 program under subsection (e), except in
20 such exceptional circumstances as the Sec-
21 retary may permit.

22 “(B) SHARING INFORMATION FOR SUBSE-
23 QUENT PLAN ENROLLMENTS.—The Secretary
24 shall share information, with respect to the
25 identity of an individual identified under sub-

1 paragraph (A)(i) who disenrolls from a plan
2 under subparagraph (A)(iv), with a PDP spon-
3 sor (or MA organization) that subsequently en-
4 rolls such individual under another plan in
5 order that the provisions of subparagraph
6 (A)(iii) would apply under such subsequent en-
7 rollment.

8 “(C) SAFE PHARMACY NETWORK CRI-
9 TERIA.—The criteria specified in this subpara-
10 graph for a safe pharmacy network are the fol-
11 lowing:

12 “(i) The pharmacies in the network
13 are able to properly monitor the usage of
14 schedule II, III, IV, and V controlled sub-
15 stances.

16 “(ii) Such pharmacies and network
17 meet such other drug safety criteria as the
18 Secretary or the PDP sponsor (or MA or-
19 ganization) determines to be appropriate,
20 such as use of a State prescription drug
21 monitoring program, if such a program is
22 available in the State.”.

23 (b) DUAL ELIGIBLES.—Section 1860D–1(b)(3)(D) of
24 the Social Security Act (42 U.S.C. 1395w–101(b)(3)(D))
25 is amended by inserting “, subject to such limits as the

1 Secretary may establish for individuals identified pursuant
 2 to section 1860D–4(c)(4)(A)(i)” after “the Secretary”.

3 (c) EFFECTIVE DATE.—The amendments made by
 4 this section shall apply with respect to plan years begin-
 5 ning after the date that is 8 months after the date of the
 6 enactment of this Act.

7 **SEC. 3. PART D SUSPENSION OF CLAIMS PAYMENT.**

8 Amend 1860D–12(b)(4) of the Social Security Act
 9 (42 U.S.C. 1395w–112(b)(4)) is amended by adding at
 10 the end the following new subparagraph:

11 “(H) SUSPENSION OF PAYMENTS PENDING
 12 INVESTIGATION OF CREDIBLE ALLEGATIONS OF
 13 FRAUD BY PHARMACIES.—

14 “(i) IN GENERAL.—A PDP sponsor
 15 may suspend payments and clean claim no-
 16 tifications to a pharmacy pending an inves-
 17 tigation of a credible allegation of fraud
 18 (as defined in clause (ii)) against the phar-
 19 macy, unless the Secretary determines
 20 there is a good cause not to suspend pay-
 21 ments.

22 “(ii) CREDIBLE ALLEGATION OF
 23 FRAUD DEFINED.—In this subparagraph,
 24 the term ‘credible allegation of fraud’ in-
 25 cludes—

1 “(I) a complaint made on the
2 Medicare fraud hotline;

3 “(II) detection of potential fraud
4 through the analysis of claims data;

5 “(III) detection of potential fraud
6 through identification of inappropriate
7 dispensing through audits, civil false
8 claims cases, and law enforcement in-
9 vestigations; and

10 “(IV) claims referred to Medicare
11 drug integrity contractors (MEDICs).

12 “(iii) RULE OF CONSTRUCTION.—
13 Nothing in this subparagraph shall be con-
14 strued as limited the authority of a PDP
15 sponsor to conduct post-claim payment re-
16 view.”.

17 **SEC. 4. IMPROVING ACTIVITIES OF MEDICARE DRUG IN-**
18 **TEGRITY CONTRACTORS (MEDICS).**

19 (a) IN GENERAL.—Section 1893 of the Social Secu-
20 rity Act (42 U.S.C. 1395ddd) is amended by adding at
21 the end the following new subsection:

22 “(j) IMPROVING ACTIVITIES OF MEDICARE DRUG IN-
23TEGRITY CONTRACTORS (MEDICS).—

24 “(1) ACCESS TO IN GENERAL.—Under con-
25 tracts entered into under this section (each in this

1 subsection referred to as a ‘MEDIC contract’) with
2 Medicare drug integrity contractors (each in this
3 subsection referred to as a ‘MEDIC’), the Secretary
4 shall authorize MEDICs to directly obtain prescrip-
5 tion and medical records from entities such as phar-
6 macies, PDP and physicians.

7 “(2) REQUIREMENT FOR ACKNOWLEDGMENT
8 OF REFERRALS.—If a PDP sponsor refers informa-
9 tion to a MEDIC for investigation, under the
10 MEDIC contract the MEDIC must acknowledge re-
11 ceipt of the referral and must report back to the
12 sponsor the result of the MEDIC’s investigation
13 within 45 days of the date of the referral and share
14 such results with appropriate agencies, such as law
15 enforcement officials and State licensing authority.

16 “(3) UNIFORM ANNUAL REPORT CRITERIA.—In
17 order to assess the performance of MEDICs, the
18 Secretary shall develop a uniform reporting criteria
19 for the annual reporting of the results of investiga-
20 tions by MEDICs to the Secretary and to Congress.
21 Each such annual report shall include information
22 on the number of referrals for investigation made to
23 a MEDIC, the average time required for investiga-
24 tion, the results of the investigation, and the number
25 of results that were referred to the Inspector Gen-

1 eral of the Department of Health and Human Serv-
2 ices and to State licensing officials for further inves-
3 tigations.”.

4 (b) EFFECTIVE DATE.—The amendment made by
5 subsection (a) shall take effect on the date of the enact-
6 ment of this Act and shall apply as quickly as possible
7 to MEDIC contracts, including MEDIC contracts entered
8 into before such date of enactment.

9 **SEC. 5. REQUIRING E-PRESCRIBING FOR COVERAGE OF**
10 **COVERED PART D CONTROLLED SUB-**
11 **STANCES.**

12 (a) IN GENERAL.—Section 1860D–4(e) of the Social
13 Security Act (42 U.S.C. 1395w–104(e)) is amended by
14 adding at the end the following:

15 “(7) REQUIREMENT OF E-PRESCRIBING FOR
16 CONTROLLED SUBSTANCES.—Except in such emer-
17 gent circumstances as the Secretary may specify,
18 coverage shall not be provided for a covered part D
19 drug under a prescription drug plan (or under an
20 MA–PD plan) for a schedule II, III, IV, or V con-
21 trolled substance unless the prescription for the drug
22 has been transmitted electronically in accordance
23 with an electronic prescription drug program that
24 meets the requirements of paragraph (2).”.

1 (b) EFFECTIVE DATE.—The amendment made by
2 subsection (a) shall apply to coverage of drugs prescribed
3 on or after January 1, 2015.

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