

114TH CONGRESS
1ST SESSION

H. R. 2298

To amend title XVIII of the Social Security Act to provide for programs to prevent prescription drug abuse under parts C and D of the Medicare program.

IN THE HOUSE OF REPRESENTATIVES

MAY 13, 2015

Mr. BILIRAKIS (for himself, Mr. BEN RAY LUJÁN of New Mexico, and Mr. LONG) 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 programs to prevent prescription drug abuse under parts C and D of the Medicare program.

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 “Medicare Patient Safe-
5 ty and Drug Abuse Prevention Act”.

1 **SEC. 2. PROGRAMS TO PREVENT PRESCRIPTION DRUG**
2 **ABUSE UNDER MEDICARE PARTS C AND D.**

3 (a) **DRUG MANAGEMENT PROGRAM FOR AT-RISK**
4 **BENEFICIARIES.—**

5 (1) **IN GENERAL.—**Section 1860D–4(c) of the
6 Social Security Act (42 U.S.C. 1395w–10(c)) is
7 amended by adding at the end the following:

8 “(5) **DRUG MANAGEMENT PROGRAM FOR AT-**
9 **RISK BENEFICIARIES.—**

10 “(A) **AUTHORITY TO ESTABLISH.—**A PDP
11 sponsor may establish a drug management pro-
12 gram for at-risk beneficiaries under which, sub-
13 ject to subparagraph (B), the PDP sponsor
14 may, in the case of an at-risk beneficiary for
15 prescription drug abuse who is an enrollee in a
16 prescription drug plan of such PDP sponsor,
17 limit such beneficiary’s access to coverage for
18 frequently abused drugs under such plan to fre-
19 quently abused drugs that are prescribed for
20 such beneficiary by a prescriber selected under
21 subparagraph (D), and dispensed for such bene-
22 ficiary by a pharmacy selected under such sub-
23 paragraph.

24 “(B) **REQUIREMENT FOR NOTICES.—**

25 “(i) **IN GENERAL.—**A PDP sponsor
26 may not limit the access of an at-risk ben-

1 beneficiary for prescription drug abuse to cov-
2 erage for frequently abused drugs under a
3 prescription drug plan until such spon-
4 sor—

5 “(I) provides to the beneficiary
6 an initial notice described in clause
7 (ii) and a second notice described in
8 clause (iii); and

9 “(II) verifies with the providers
10 of the beneficiary that the beneficiary
11 is an at-risk beneficiary for prescrip-
12 tion drug abuse.

13 “(ii) INITIAL NOTICE.—An initial no-
14 tice described in this clause is a notice that
15 provides to the beneficiary—

16 “(I) notice that the PDP sponsor
17 has identified the beneficiary as po-
18 tentially being an at-risk beneficiary
19 for prescription drug abuse;

20 “(II) information describing all
21 State and Federal public health re-
22 sources that are designed to address
23 prescription drug abuse to which the
24 beneficiary has access, including men-

1 tal health services and other coun-
2 seling services;

3 “(III) notice of, and information
4 about, the right of the beneficiary to
5 appeal such identification under sub-
6 section (h) and the option of an auto-
7 matic escalation to external review;

8 “(IV) a request for the bene-
9 ficiary to submit to the PDP sponsor
10 preferences for which prescribers and
11 pharmacies the beneficiary would pre-
12 fer the PDP sponsor to select under
13 subparagraph (D) in the case that the
14 beneficiary is identified as an at-risk
15 beneficiary for prescription drug
16 abuse as described in clause (iii)(I);

17 “(V) an explanation of the mean-
18 ing and consequences of the identi-
19 fication of the beneficiary as poten-
20 tially being an at-risk beneficiary for
21 prescription drug abuse, including an
22 explanation of the drug management
23 program established by the PDP
24 sponsor pursuant to subparagraph
25 (A);

1 “(VI) clear instructions that ex-
2 plain how the beneficiary can contact
3 the PDP sponsor in order to submit
4 to the PDP sponsor the preferences
5 described in subclause (IV) and any
6 other communications relating to the
7 drug management program for at-risk
8 beneficiaries established by the PDP
9 sponsor; and

10 “(VII) contact information for
11 other organizations that can provide
12 the beneficiary with assistance regard-
13 ing such drug management program
14 (similar to the information provided
15 by the Secretary in other standardized
16 notices provided to part D eligible in-
17 dividuals enrolled in prescription drug
18 plans under this part).

19 “(iii) SECOND NOTICE.—A second no-
20 tice described in this clause is a notice that
21 provides to the beneficiary notice—

22 “(I) that the PDP sponsor has
23 identified the beneficiary as an at-risk
24 beneficiary for prescription drug
25 abuse;

1 “(II) that such beneficiary is
2 subject to the requirements of the
3 drug management program for at-risk
4 beneficiaries established by such PDP
5 sponsor for such plan;

6 “(III) of the prescriber and phar-
7 macy selected for such individual
8 under subparagraph (D);

9 “(IV) of, and information about,
10 the beneficiary’s right to appeal such
11 identification under subsection (h)
12 and the option of an automatic esca-
13 lation to external review;

14 “(V) that the beneficiary can, in
15 the case that the beneficiary has not
16 previously submitted to the PDP
17 sponsor preferences for which pre-
18 scribers and pharmacies the bene-
19 ficiary would prefer the PDP sponsor
20 select under subparagraph (D), sub-
21 mit such preferences to the PDP
22 sponsor; and

23 “(VI) that includes clear instruc-
24 tions that explain how the beneficiary
25 can contact the PDP sponsor.

1 “(iv) TIMING OF NOTICES.—

2 “(I) IN GENERAL.—Subject to
3 subclause (II), a second notice de-
4 scribed in clause (iii) shall be provided
5 to the beneficiary on a date that is
6 not less than 60 days after an initial
7 notice described in clause (ii) is pro-
8 vided to the beneficiary.

9 “(II) EXCEPTION.—In the case
10 that the PDP sponsor, in conjunction
11 with the Secretary, determines that
12 concerns identified through rule-
13 making by the Secretary regarding
14 the health or safety of the beneficiary
15 or regarding significant drug diversion
16 activities require the PDP sponsor to
17 provide a second notice described in
18 clause (iii) to the beneficiary on a
19 date that is earlier than the date de-
20 scribed in subclause (II), the PDP
21 sponsor may provide such second no-
22 tice on such earlier date.

23 “(C) AT-RISK BENEFICIARY FOR PRE-
24 SCRIPTIION DRUG ABUSE.—

1 “(i) IN GENERAL.—For purposes of
2 this paragraph, the term ‘at-risk bene-
3 ficiary for prescription drug abuse’ means
4 a part D eligible individual who is not an
5 exempted individual described in clause (ii)
6 and—

7 “(I) who is identified through the
8 use of clinical guidelines developed by
9 the Secretary in consultation with
10 PDP sponsors and other stakeholders
11 described in subsection (f)(2)(A); or

12 “(II) with respect to whom the
13 PDP sponsor of a prescription drug
14 plan, upon enrolling such individual in
15 such plan, received notice from the
16 Secretary that such individual was
17 identified under this paragraph to be
18 an at-risk beneficiary for prescription
19 drug abuse under the prescription
20 drug plan in which such individual
21 was most recently previously enrolled
22 and such identification has not been
23 terminated under subparagraph (F).

24 “(ii) EXEMPTED INDIVIDUAL DE-
25 SCRIBED.—An exempted individual de-

1 scribed in this clause is an individual
2 who—

3 “(I) an individual who receives
4 hospice care under this title; or

5 “(II) an individual, such as an
6 individual who is a resident of a long-
7 term care facility, who the Secretary
8 elects to treat as an exempted indi-
9 vidual for purposes of clause (i).

10 “(D) SELECTION OF PRESCRIBERS.—

11 “(i) IN GENERAL.—With respect to
12 each at-risk beneficiary for prescription
13 drug abuse enrolled in a prescription drug
14 plan offered by such sponsor, a PDP spon-
15 sor shall, based on the preferences sub-
16 mitted to the PDP sponsor by the bene-
17 ficiary pursuant to clauses (ii)(IV) and
18 (iii)(V) of subparagraph (B), select—

19 “(I) one or more individuals who
20 are authorized to prescribe frequently
21 abused drugs (referred to in this
22 paragraph as ‘prescribers’) who may
23 write prescriptions for such drugs for
24 such beneficiary; and

1 “(II) one or more pharmacies
2 that may dispense such drugs to such
3 beneficiary.

4 “(ii) REASONABLE ACCESS.—In mak-
5 ing the selection under this subparagraph,
6 a PDP sponsor shall ensure that the bene-
7 ficiary continues to have reasonable access
8 to drugs described in subparagraph (G),
9 taking into account geographic location,
10 beneficiary preference, impact on cost-
11 sharing, and reasonable travel time.

12 “(iii) BENEFICIARY PREFERENCES.—

13 “(I) IN GENERAL.—If an at-risk
14 beneficiary for prescription drug
15 abuse submits preferences for which
16 in-network prescribers and pharmacies
17 the beneficiary would prefer the PDP
18 sponsor select in response to a notice
19 under subparagraph (B), the PDP
20 sponsor shall—

21 “(aa) review such pref-
22 erences;

23 “(bb) select or change the
24 selection of a prescriber or phar-

1 macy for the beneficiary based on
2 such preferences; and

3 “(cc) inform the beneficiary
4 of such selection or change of se-
5 lection.

6 “(II) EXCEPTION.—In the case
7 that the PDP sponsor determines that
8 a change to the selection of a pre-
9 scriber or pharmacy under item (bb)
10 by the PDP sponsor is contributing or
11 would contribute to prescription drug
12 abuse or drug diversion by the bene-
13 ficiary, the PDP sponsor may change
14 the selection of a prescriber or phar-
15 macy for the beneficiary without re-
16 gard to the preferences of the bene-
17 ficiary described in subclause (I).

18 “(iv) CONFIRMATION.—Before select-
19 ing a prescriber or pharmacy under this
20 subparagraph, a PDP sponsor must re-
21 quest and receive confirmation from the
22 prescriber or pharmacy acknowledging and
23 accepting that the beneficiary involved is in
24 the drug management program for at-risk
25 beneficiaries.

1 “(E) TERMINATIONS AND APPEALS.—The
2 identification of an individual as an at-risk ben-
3 eficiary for prescription drug abuse under this
4 paragraph, a coverage determination made
5 under a drug management program for at-risk
6 beneficiaries, and the selection of a prescriber
7 or pharmacy under subparagraph (D) with re-
8 spect to such individual shall be subject to re-
9 consideration and appeal under subsection (h)
10 and the option of an automatic escalation to ex-
11 ternal review to the extent provided by the Sec-
12 retary.

13 “(F) TERMINATION OF IDENTIFICATION.—

14 “(i) IN GENERAL.—The Secretary
15 shall develop standards for the termination
16 of identification of an individual as an at-
17 risk beneficiary for prescription drug abuse
18 under this paragraph. Under such stand-
19 ards such identification shall terminate as
20 of the earlier of—

21 “(I) the date the individual dem-
22 onstrates that the individual is no
23 longer likely, in the absence of the re-
24 strictions under this paragraph, to be
25 an at-risk beneficiary for prescription

1 drug abuse described in subparagraph
2 (C)(i); or

3 “(II) the end of such maximum
4 period of identification as the Sec-
5 retary may specify.

6 “(ii) RULE OF CONSTRUCTION.—
7 Nothing in clause (i) shall be construed as
8 preventing a plan from identifying an indi-
9 vidual as an at-risk beneficiary for pre-
10 scription drug abuse under subparagraph
11 (C)(i) after such termination on the basis
12 of additional information on drug use oc-
13 ccurring after the date of notice of such ter-
14 mination.

15 “(G) FREQUENTLY ABUSED DRUG.—For
16 purposes of this subsection, the term ‘frequently
17 abused drug’ means a drug that is a controlled
18 substance that the Secretary determines to be
19 frequently abused or diverted.

20 “(H) DATA DISCLOSURE.—In the case of
21 an at-risk beneficiary for prescription drug
22 abuse whose access to coverage for frequently
23 abused drugs under a prescription drug plan
24 has been limited by a PDP sponsor under this
25 paragraph, such PDP sponsor shall disclose

1 data, including any necessary individually iden-
2 tifiable health information, in a form and man-
3 ner specified by the Secretary, about the deci-
4 sion to impose such limitations and the limita-
5 tions imposed by the sponsor under this part.

6 “(I) EDUCATION.—The Secretary shall
7 provide education to enrollees in prescription
8 drug plans of PDP sponsors and providers re-
9 garding the drug management program for at-
10 risk beneficiaries described in this paragraph,
11 including education—

12 “(i) provided by medicare administra-
13 tive contractors through the improper pay-
14 ment outreach and education program de-
15 scribed in section 1874A(h); and

16 “(ii) through current education efforts
17 (such as State health insurance assistance
18 programs described in subsection (a)(1)(A)
19 of section 119 of the Medicare Improve-
20 ments for Patients and Providers Act of
21 2008 (42 U.S.C. 1395b–3 note)) and ma-
22 terials directed toward such enrollees.

23 “(J) APPLICATION UNDER MA–PD
24 PLANS.—Pursuant to section 1860D–21(c)(1),
25 the provisions of this paragraph apply under

1 part D to MA organizations offering MA–PD
2 plans to MA eligible individuals in the same
3 manner as such provisions apply under this
4 part to a PDP sponsor offering a prescription
5 drug plan to a part D eligible individual.”.

6 (2) INFORMATION FOR CONSUMERS.—Section
7 1860D–4(a)(1)(B) of the Social Security Act (42
8 U.S.C. 1395w–104(a)(1)(B)) is amended by adding
9 at the end the following:

10 “(v) The drug management program
11 for at-risk beneficiaries under subsection
12 (c)(5).”.

13 (b) UTILIZATION MANAGEMENT PROGRAMS.—Sec-
14 tion 1860D–4(c) of the Social Security Act (42 U.S.C.
15 1395w–104(c)), as amended by subsection (a)(1), is fur-
16 ther amended—

17 (1) in paragraph (1), by inserting after sub-
18 paragraph (D) the following new subparagraph:

19 “(E) A utilization management tool to pre-
20 vent drug abuse (as described in paragraph
21 (6)(A)).”; and

22 (2) by adding at the end the following new
23 paragraph:

24 “(6) UTILIZATION MANAGEMENT TOOL TO PRE-
25 VENT DRUG ABUSE.—

1 “(A) IN GENERAL.—A tool described in
2 this paragraph is any of the following:

3 “(i) A utilization tool designed to pre-
4 vent the abuse of frequently abused drugs
5 by individuals and to prevent the diversion
6 of such drugs at pharmacies.

7 “(ii) Retrospective utilization review
8 to identify—

9 “(I) individuals that receive fre-
10 quently abused drugs at a frequency
11 or in amounts that are not clinically
12 appropriate; and

13 “(II) providers of services or sup-
14 pliers that may facilitate the abuse or
15 diversion of frequently abused drugs
16 by beneficiaries.

17 “(iii) Consultation with the Con-
18 tractor described in subparagraph (B) to
19 verify if an individual enrolling in a pre-
20 scription drug plan offered by a PDP
21 sponsor has been previously identified by
22 another PDP sponsor as an individual de-
23 scribed in clause (ii)(I).

24 “(B) REPORTING.—A PDP sponsor offer-
25 ing a prescription drug plan (and an MA orga-

1 nization offering an MA–PD plan) in a State
 2 shall submit to the Secretary and the Medicare
 3 drug integrity contractor with which the Sec-
 4 retary has entered into a contract under section
 5 1893 with respect to such State a report, on a
 6 monthly basis, containing information on—

7 “(i) any provider of services or sup-
 8 plier described in subparagraph (A)(ii)(II)
 9 that is identified by such plan sponsor (or
 10 organization) during the 30-day period be-
 11 fore such report is submitted; and

12 “(ii) the name and prescription
 13 records of individuals described in para-
 14 graph (5)(C).”.

15 (c) EXPANDING ACTIVITIES OF MEDICARE DRUG IN-
 16 TEGRITY CONTRACTORS (MEDICS).—

17 (1) IN GENERAL.—Section 1893 of the Social
 18 Security Act (42 U.S.C. 1395ddd) is amended by
 19 adding at the end the following new subsection:

20 “(j) EXPANDING ACTIVITIES OF MEDICARE DRUG
 21 INTEGRITY CONTRACTORS (MEDICS).—

22 “(1) ACCESS TO INFORMATION.—Under con-
 23 tracts entered into under this section with Medicare
 24 drug integrity contractors, the Secretary shall au-
 25 thorize such contractors to directly accept prescrip-

1 tion and necessary medical records from entities
2 such as pharmacies, prescription drug plans, MA-
3 PD plans, and physicians with respect to an indi-
4 vidual in order for such contractors to provide infor-
5 mation relevant to the determination of whether
6 such individual is an at-risk beneficiary for prescrip-
7 tion drug abuse, as defined in section 1860D-
8 4(c)(5)(C).

9 “(2) REQUIREMENT FOR ACKNOWLEDGMENT
10 OF REFERRALS.—If a PDP sponsor or MA organiza-
11 tion refers information to a contractor described in
12 paragraph (1) in order for such contractor to assist
13 in the determination described in such paragraph,
14 the contractor shall—

15 “(A) acknowledge to the sponsor or organi-
16 zation receipt of the referral; and

17 “(B) in the case that any PDP sponsor or
18 MA organization contacts the contractor re-
19 questing to know the determination by the con-
20 tractor of whether or not an individual has been
21 determined to be an individual described such
22 paragraph, shall inform such sponsor or organi-
23 zation of such determination on a date that is
24 not later than 15 days after the date on which

1 the sponsor or organization contacts the con-
2 tractor.

3 “(3) MAKING DATA AVAILABLE TO OTHER EN-
4 TITIES.—

5 “(A) IN GENERAL.—For purposes of car-
6 rying out this subsection, subject to subpara-
7 graph (B), the Secretary shall authorize MED-
8 ICs to respond to requests for information from
9 PDP sponsors and MA organizations, State
10 prescription drug monitoring programs, and
11 other entities delegated by such sponsors or or-
12 ganizations using available programs and sys-
13 tems in the effort to prevent fraud, waste, and
14 abuse.

15 “(B) HIPAA COMPLIANT INFORMATION
16 ONLY.—Information may only be disclosed by a
17 MEDIC under subparagraph (A) if the disclo-
18 sure of such information is permitted under the
19 Federal regulations (concerning the privacy of
20 individually identifiable health information) pro-
21 mulgated under section 264(c) of the Health
22 Insurance Portability and Accountability Act of
23 1996 (42 U.S.C. 1320d–2 note).”.

24 (2) OIG STUDY AND REPORT ON EFFECTIVE-
25 NESS OF MEDICS.—

1 (A) STUDY.—The Inspector General of the
2 Department of Health and Human Services
3 shall conduct a study on the effectiveness of
4 Medicare drug integrity contractors in identi-
5 fying combating, and preventing fraud under
6 the Medicare program, including under the au-
7 thority provided under section 1893(j) of the
8 Social Security Act, as added by paragraph (1).

9 (B) REPORT.—Not later than 1 year after
10 the date of the enactment of this Act, the In-
11 spector General shall submit to Congress a re-
12 port on the study conducted under subpara-
13 graph (A). Such report shall include such rec-
14 ommendations for improvements in the effec-
15 tiveness of such contractors as the Inspector
16 General determines appropriate.

17 (d) TREATMENT OF CERTAIN COMPLAINTS FOR PUR-
18 POSES OF QUALITY OR PERFORMANCE ASSESSMENT.—
19 Section 1860D–42 of the Social Security Act (42 U.S.C.
20 1395w–152) is amended by adding at the end the fol-
21 lowing new subsection:

22 “(d) TREATMENT OF CERTAIN COMPLAINTS FOR
23 PURPOSES OF QUALITY OR PERFORMANCE ASSESS-
24 MENT.—In conducting a quality or performance assess-
25 ment of a PDP sponsor, the Secretary shall develop or

1 utilize existing screening methods for reviewing and con-
2 sidering complaints that are received from enrollees in a
3 prescription drug plan offered by such PDP sponsor and
4 that are complaints regarding the lack of access by the
5 individual to prescription drugs due to a drug manage-
6 ment program for at-risk beneficiaries.”.

7 (e) SENSE OF CONGRESS REGARDING USE OF TECH-
8 NOLOGY TOOLS TO COMBAT FRAUD.—It is the sense of
9 Congress that MA organizations and PDP sponsors
10 should consider using e-prescribing and other health infor-
11 mation technology tools to support combating fraud under
12 MA–PD plans and prescription drug plans under parts C
13 and D of the Medicare program.

14 (f) EFFECTIVE DATE.—

15 (1) IN GENERAL.—The amendments made by
16 this section shall apply to prescription drug plans
17 (and MA–PD plans) for plan years beginning more
18 than 1 year after the date of the enactment of this
19 Act.

20 (2) STAKEHOLDER MEETINGS PRIOR TO EFFEC-
21 TIVE DATE.—

22 (A) IN GENERAL.—Not later than January
23 1, 2016, the Secretary of Health and Human
24 Services shall convene stakeholders, including
25 individuals entitled to benefits under part A of

1 title XVIII of the Social Security Act or en-
2 rolled under part B of such title of such Act,
3 advocacy groups representing such individuals,
4 clinicians, plan sponsors, entities delegated by
5 plan sponsors, and biopharmaceutical manufac-
6 turers for input regarding the topics described
7 in subparagraph (B).

8 (B) TOPICS DESCRIBED.—The topics de-
9 scribed in this subparagraph are the topics of—

10 (i) the impact on cost-sharing and en-
11 suring accessibility to prescription drugs
12 for enrollees in prescription drug plans of
13 PDP sponsors, and enrollees in MA–PD
14 plans, who are at-risk beneficiaries for pre-
15 scription drug abuse (as defined in sub-
16 paragraph (C) of paragraph (5) of section
17 1860D–4(c) of the Social Security Act (42
18 U.S.C. 1395w–104(c));

19 (ii) the use of an expedited appeals
20 process under which such an enrollee may
21 appeal an identification of such enrollee as
22 an at-risk beneficiary for prescription drug
23 abuse under such paragraph (similar to the
24 processes established under the Medicare
25 Advantage program under part C of title

1 XVIII of the Social Security Act that allow
2 an automatic escalation to external review
3 of claims submitted under such part);

4 (iii) the types of enrollees that should
5 be treated as exempted individuals, as de-
6 scribed in subparagraph (C)(ii) of such
7 paragraph;

8 (iv) the manner in which terms and
9 definitions in such paragraph should be ap-
10 plied, such as the use of clinical appro-
11 priateness in determining whether an en-
12 rollee is an at-risk beneficiary for prescrip-
13 tion drug abuse as defined in subpara-
14 graph (C) of such paragraph;

15 (v) the information to be included in
16 the notices described in subparagraph (B)
17 of such paragraph and the standardization
18 of such notices; and

19 (vi) with respect to a PDP sponsor
20 (or Medicare Advantage organization) that
21 establishes a drug management program
22 for at-risk beneficiaries under such para-
23 graph, the responsibilities of such PDP
24 sponsor (or organization) with respect to
25 the implementation of such program.

1 (g) RULEMAKING.—The Secretary of Health and
2 Human Services shall promulgate regulations based on the
3 input gathered pursuant to subsection (f)(2)(A).

○