

114TH CONGRESS
2D SESSION

H. R. 4876

To authorize the establishment of programs to prevent prescription drug abuse under the Medicare program, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 23, 2016

Mr. MEEHAN (for himself and Mr. NEAL) 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 authorize the establishment of programs to prevent prescription drug abuse under 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.**

4 This Act may be cited as the “Medicare Prescription
5 Drug Abuse Prevention Act of 2016”.

1 **SEC. 2. PROGRAMS TO PREVENT PRESCRIPTION DRUG**
2 **ABUSE UNDER THE MEDICARE PROGRAM.**

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–104(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 (or prescribers)
21 selected under subparagraph (D), and dis-
22 pensed for such beneficiary by a pharmacy (or
23 pharmacies) selected under such subparagraph.

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, as described in sub-
13 paragraph (C)(iv).

14 “(ii) INITIAL NOTICE.—An initial
15 written notice described in this clause is a
16 notice that provides to the beneficiary—

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

21 “(II) information, when possible,
22 describing State and Federal public
23 health resources that are designed to
24 address prescription drug abuse to
25 which the beneficiary may have ac-

cess, including substance use disorder treatment services, addiction treatment services, mental health services, and other counseling services;

“(III) a request for the beneficiary to submit to the PDP sponsor preferences for which prescribers and pharmacies the beneficiary would prefer the PDP sponsor to select under subparagraph (D) in the case that the beneficiary is identified as an at-risk beneficiary for prescription drug abuse as described in clause (iii)(I);

“(IV) an explanation of the meaning and consequences of the identification of the beneficiary as potentially being an at-risk beneficiary for prescription drug abuse, including an explanation of the drug management program established by the PDP sponsor pursuant to subparagraph (A);

“(V) clear instructions that explain how the beneficiary can contact the PDP sponsor in order to submit

1 to the PDP sponsor the preferences
2 described in subclause (IV) and any
3 other communications relating to the
4 drug management program for at-risk
5 beneficiaries established by the PDP
6 sponsor;

7 “(VI) contact information for
8 other organizations that can provide
9 the beneficiary with information re-
10 garding drug management program
11 for at-risk beneficiaries (similar to the
12 information provided by the Secretary
13 in other standardized notices to part
14 D eligible individuals enrolled in pre-
15 scription drug plans under this part);
16 and

17 “(VII) notice that the beneficiary
18 has a right to an appeal pursuant to
19 subparagraph (E).

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

24 “(I) that the PDP sponsor has
25 identified the beneficiary as an at-risk

1 beneficiary for prescription drug
2 abuse;

3 “(II) that such beneficiary has
4 been sent, or informed of, such identi-
5 fication in the initial notice and is
6 now subject to the requirements of the
7 drug management program for at-
8 risk beneficiaries established by such
9 PDP sponsor for such plan;

10 “(III) of the prescriber and phar-
11 macy selected for such individual
12 under subparagraph (D);

13 “(IV) of, and information about,
14 the right of the beneficiary to a recon-
15 sideration and an appeal under sub-
16 section (h) of such identification and
17 the prescribers and pharmacies se-
18 lected;

19 “(V) that the beneficiary can, in
20 the case that the beneficiary has not
21 previously submitted to the PDP
22 sponsor preferences for which pre-
23 scribers and pharmacies the bene-
24 ficiary would prefer the PDP sponsor
25 select under subparagraph (D), sub-

mit such preferences to the PDP sponsor; and

“(VI) that includes clear instructions that explain how the beneficiary can contact the PDP sponsor in order to submit to the PDP sponsor the preferences described in subclause (V).

“(iv) TIMING OF NOTICES.—

“(I) IN GENERAL.—Subject to subclause (II), a second written notice described in clause (iii) shall be provided to the beneficiary on a date that is not less than 30 days after an initial notice described in clause (ii) is provided to the beneficiary.

“(II) EXCEPTION.—In the case that the PDP sponsor, in conjunction with the Secretary, determines that concerns identified through rule-making by the Secretary regarding the health or safety of the beneficiary or regarding significant drug diversion activities require the PDP sponsor to provide a second notice described in

1 clause (iii) to the beneficiary on a
2 date that is earlier than the date de-
3 scribed in subclause (II), the PDP
4 sponsor may provide such second no-
5 tice on such earlier date.

6 “(III) FORM OF NOTICE.—The
7 written notices under clauses (ii) and
8 (iii) shall be in a format determined
9 appropriate by the Secretary, taking
10 into account beneficiary preferences.

11 “(C) AT-RISK BENEFICIARY FOR PRE-
12SCRIPTION DRUG ABUSE.—

13 “(i) IN GENERAL.—For purposes of
14 this paragraph, the term ‘at-risk bene-
15 ficiary for prescription drug abuse’ means
16 a part D eligible individual who is not an
17 exempted individual described in clause (ii)
18 and—

19 “(I) who is identified through cri-
20 teria developed by the Secretary in
21 consultation with PDP sponsors and
22 other stakeholders described in section
23 2(g)(2)(A) of the Medicare Prescrip-
24 tion Drug Abuse Prevention Act of
25 2016 based on clinical factors indi-

1 cating misuse or abuse of prescription
2 drugs described in subparagraph (G),
3 including dosage, quantity, duration
4 of use, number of and reasonable ac-
5 cess to prescribers, and number of
6 and reasonable access to pharmacies
7 used to obtain such drug; or

8 “(II) with respect to whom the
9 PDP sponsor of a prescription drug
10 plan, upon enrolling such individual in
11 such plan, received notice from the
12 Secretary that such individual was
13 identified under this paragraph to be
14 an at- risk beneficiary for prescription
15 drug abuse under a prescription drug
16 plan in which such individual was pre-
17 viously enrolled and such identifica-
18 tion has not been terminated under
19 subparagraph (F).

20 “(ii) EXEMPTED INDIVIDUAL DE-
21 SCRIBED.—An exempted individual de-
22 scribed in this clause is an individual
23 who—

24 “(I) receives hospice care under
25 this title;

1 “(II) resides in a long-term care
2 facility, a facility described in section
3 1905(d), or other facility under con-
4 tract with a single pharmacy; or

5 “(III) the Secretary elects to
6 treat as an exempted individual for
7 purposes of clause (i).

8 “(iii) PROGRAM SIZE.—The Secretary
9 shall establish policies, including the cri-
10 teria developed under clause (i)(I) and the
11 exemptions under clause (ii)(III), to ensure
12 that the population of enrollees in a drug
13 management program for at-risk bene-
14 ficiaries operated by a prescription drug
15 plan can be effectively managed by such
16 plans.

17 “(iv) CLINICAL CONTACT.—With re-
18 spect to each at-risk beneficiary for pre-
19 scription drug abuse enrolled in a prescrip-
20 tion drug plan offered by a PDP sponsor,
21 the PDP sponsor shall contact the bene-
22 ficiary’s providers who have prescribed fre-
23 quently abused drugs regarding whether
24 prescribed medications are appropriate for
25 such beneficiary’s medical conditions.

1 “(D) SELECTION OF PRESCRIBERS.—

2 “(i) IN GENERAL.—With respect to
3 each at-risk beneficiary for prescription
4 drug abuse enrolled in a prescription drug
5 plan offered by such sponsor, a PDP spon-
6 sor shall, based on the preferences sub-
7 mitted to the PDP sponsor by the bene-
8 ficiary pursuant to clauses (ii)(III) and
9 (iii)(V) of subparagraph (B) if applicable,
10 select—

11 “(I) one, or, if the PDP sponsor
12 reasonably determines it necessary to
13 provide the beneficiary with reason-
14 able access under clause (ii), more
15 than one, individual who is authorized
16 to prescribe frequently abused drugs
17 (referred to in this paragraph as a
18 ‘prescriber’) who may write prescrip-
19 tions for such drugs for such bene-
20 ficiary; and

21 “(II) one, or, if the PDP sponsor
22 reasonably determines it necessary to
23 provide the beneficiary with reason-
24 able access under clause (ii), more

1 than one, pharmacy that may dis-
2 pense such drugs to such beneficiary.

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

12 “(I) for individuals with multiple
13 residences; and

14 “(II) in the case of natural disas-
15 ters and similar emergency situations.

16 “(iii) BENEFICIARY PREFERENCES.—

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

1 “(aa) review such pref-
2 erences;

3 “(bb) select or change the
4 selection of a prescriber or phar-
5 macy for the beneficiary based on
6 such preferences; and

7 “(cc) inform the beneficiary
8 of such selection or change of se-
9 lection.

10 “(II) EXCEPTION.—In the case
11 that the PDP sponsor determines that
12 a change to the selection of a pre-
13 scriber or pharmacy under item (bb)
14 by the PDP sponsor is contributing or
15 would contribute to prescription drug
16 abuse or drug diversion by the bene-
17 ficiary, the PDP sponsor may change
18 the selection of a prescriber or phar-
19 macy for the beneficiary. If the PDP
20 sponsor changes the selection pursu-
21 ant to the preceding sentence, the
22 PDP sponsor shall provide the bene-
23 ficiary with—

1 “(aa) at least 30 days writ-
2 ten notice of the change of selec-
3 tion; and

4 “(bb) a rationale for the
5 change.

6 “(III) TIMING.—An at-risk bene-
7 ficiary for prescription drug abuse
8 may choose to express their prescriber
9 and pharmacy preference and commu-
10 nicate such preference to their PDP
11 sponsor at any date while enrolled in
12 the program, including after a second
13 notice under subparagraph (B)(iii)
14 has been provided.

15 “(iv) CONFIRMATION.—Before select-
16 ing a prescriber or pharmacy under this
17 subparagraph, a PDP sponsor must notify
18 the prescriber and pharmacy that the bene-
19 ficiary involved has been identified for in-
20 clusion in the drug management program
21 for at-risk beneficiaries and that the pre-
22 scriber and pharmacy has been selected as
23 the beneficiary’s designated prescriber and
24 pharmacy.

1 “(E) APPEALS.—The identification of an
2 individual as an at-risk beneficiary for prescrip-
3 tion drug abuse under this paragraph, a cov-
4 erage determination made under a drug man-
5 agement program for at-risk beneficiaries, and
6 the selection of a prescriber or pharmacy under
7 subparagraph (D) with respect to such indi-
8 vidual shall be subject to an expedited reconsid-
9 eration and appeal pursuant to subsection (h).

10 “(F) TERMINATION OF IDENTIFICATION.—

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

18 “(I) the date the individual dem-
19 onstrates that the individual is no
20 longer likely, in the absence of the re-
21 strictions under this paragraph, to be
22 an at-risk beneficiary for prescription
23 drug abuse described in subparagraph
24 (C)(i); or

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

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

13 “(G) FREQUENTLY ABUSED DRUG.—For
14 purposes of this subsection, the term ‘frequently
15 abused drug’ means a drug that is determined
16 by the Secretary to be frequently abused or di-
17 verted and that is—

18 “(i) a Controlled Drug Substance in
19 Schedule CII; or

20 “(ii) within the same class or category
21 of drugs as a Controlled Drug Substance
22 in Schedule CII, as determined through
23 notice and comment rulemaking.

24 “(H) DATA DISCLOSURE.—

1 “(i) DATA ON DECISION TO IMPOSE
2 LIMITATION.—In the case of an at-risk
3 beneficiary for prescription drug abuse (or
4 an individual who is a potentially at-risk
5 beneficiary for prescription drug abuse)
6 whose access to coverage for frequently
7 abused drugs under a prescription drug
8 plan has been limited by a PDP sponsor
9 under this paragraph, the Secretary shall
10 establish rules and procedures to require
11 such PDP sponsor to disclose data, includ-
12 ing necessary individually identifiable
13 health information, about the decision to
14 impose such limitations and the limitations
15 imposed by the PDP sponsor under this
16 part.

17 “(ii) DATA TO REDUCE FRAUD,
18 ABUSE, AND WASTE.—The Secretary shall
19 establish rules and procedures to require
20 PDP sponsors operating a drug manage-
21 ment program for at-risk beneficiaries
22 under this paragraph to provide the Sec-
23 retary with such data as the Secretary de-
24 termines appropriate for purposes of iden-
25 tifying patterns of prescription drug utili-

1 zation for plan enrollees that are outside
2 normal patterns and that may indicate
3 fraudulent, medically unnecessary, or un-
4 safe use.

5 “(I) SHARING OF INFORMATION FOR SUB-
6 SEQUENT PLAN ENROLLMENTS.—The Secretary
7 shall establish procedures under which PDP
8 sponsors who offer prescription drug plans shall
9 share information with respect to individuals
10 who are at-risk beneficiaries for prescription
11 drug abuse (or individuals who are potentially
12 at-risk beneficiaries for prescription drug
13 abuse) and enrolled in a prescription drug plan
14 and who subsequently disenroll from such plan
15 and enroll in another prescription drug plan of-
16 fered by another PDP sponsor.

17 “(J) PRIVACY ISSUES.—Prior to the imple-
18 mentation of the rules and procedures under
19 this paragraph, the Secretary shall clarify pri-
20 vacy requirements, including requirements
21 under the regulations promulgated pursuant to
22 section 264(c) of the Health Insurance Port-
23 ability and Accountability Act of (42 U.S.C.
24 1320d–2 note), related to the sharing of data
25 under subparagraphs (H) and (I) by PDP

1 sponsors. Such clarification shall provide that
2 the sharing of such data shall be considered to
3 be protected health information in accordance
4 with the requirements of the regulations pro-
5 mulgated pursuant to such section 264(c).

6 “(K) 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 through the improper
13 payment outreach and education program
14 described in section 1874A(h); and

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

22 “(L) CMS COMPLIANCE REVIEW.—The
23 Secretary shall ensure that existing plan spon-
24 sor compliance reviews and audit processes in-
25 clude the drug management programs for at-

1 risk beneficiaries under this paragraph, includ-
 2 ing appeals processes under such programs.”.

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

7 “(v) The drug management program
 8 for at-risk beneficiaries under subsection
 9 (c)(5).”.

10 (3) DUAL ELIGIBLES.—Section 1860D–
 11 1(b)(3)(D) of the Social Security Act (42 U.S.C.
 12 1395w–101(b)(3)(D)) is amended by inserting “,
 13 subject to such limits as the Secretary may establish
 14 for individuals identified pursuant to section D–
 15 4(c)(5)” after “the Secretary”.

16 (b) UTILIZATION MANAGEMENT PROGRAMS.—Sec-
 17 tion 1860D–4(c) of the Social Security Act (42 U.S.C.
 18 1395w–104(c)), as amended by subsection (a)(1), is
 19 amended—

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

22 “(E) A utilization management tool to pre-
 23 vent drug abuse (as described in paragraph
 24 (5)(A)).”; and

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

3 “(6) UTILIZATION MANAGEMENT TOOL TO PRE-
4 VENT DRUG ABUSE.—

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

7 “(i) A utilization tool designed to pre-
8 vent the abuse of frequently abused drugs
9 by individuals and to prevent the diversion
10 of such drugs at pharmacies.

11 “(ii) Retrospective utilization review
12 to identify—

13 “(I) individuals that receive fre-
14 quently abused drugs at a frequency
15 or in amounts that are not clinically
16 appropriate; and

17 “(II) providers of services or sup-
18 pliers that may facilitate the abuse or
19 diversion of frequently abused drugs
20 by beneficiaries.

21 “(iii) Consultation with the contractor
22 described in subparagraph (B) to verify if
23 an individual enrolling in a prescription
24 drug plan offered by a PDP sponsor has
25 been previously identified by another PDP

1 sponsor as an individual described in
2 clause (ii)(I).

3 “(B) REPORTING.—A PDP sponsor offer-
4 ing a prescription drug plan in a State shall
5 submit to the Secretary and the Medicare drug
6 integrity contractor with which the Secretary
7 has entered into a contract under section 1893
8 with respect to such State a report, on a
9 monthly basis, containing information on—

10 “(i) any provider of services or sup-
11 plier described in subparagraph (A)(ii)(II)
12 that is identified by such plan sponsor dur-
13 ing the 30-day period before such report is
14 submitted; and

15 “(ii) the name and prescription
16 records of individuals described in para-
17 graph (5)(C).

18 “(C) CMS COMPLIANCE REVIEW.—The
19 Secretary shall ensure that plan sponsor annual
20 compliance reviews and program audits include
21 a certification that utilization management tools
22 under this paragraph are in compliance with
23 the requirements for such tools.”.

24 (c) TREATMENT OF CERTAIN COMPLAINTS FOR PUR-
25 POSES OF QUALITY OR PERFORMANCE ASSESSMENT.—

1 Section 1860D–42 of the Social Security Act (42 U.S.C.
2 1395w–152) is amended by adding at the end the fol-
3 lowing new subsection:

4 “(d) TREATMENT OF CERTAIN COMPLAINTS FOR
5 PURPOSES OF QUALITY OR PERFORMANCE ASSESS-
6 MENT.—In conducting a quality or performance assess-
7 ment of a PDP sponsor, the Secretary shall develop or
8 utilize existing screening methods for reviewing and con-
9 sidering complaints that are received from enrollees in a
10 prescription drug plan offered by such PDP sponsor and
11 that are complaints regarding the lack of access by the
12 individual to prescription drugs due to a drug manage-
13 ment program for at-risk beneficiaries.”.

14 (d) SENSE OF CONGRESS REGARDING USE OF TECH-
15 NOLOGY TOOLS TO COMBAT FRAUD.—It is the sense of
16 Congress that MA organizations and PDP sponsors
17 should consider using e-prescribing and other health infor-
18 mation technology tools to support combating fraud under
19 MA–PD plans and prescription drug plans under parts C
20 and D of the Medicare program.

21 (e) GAO STUDY AND REPORT.—

22 (1) STUDY.—The Comptroller General of the
23 United States shall conduct a study on the imple-
24 mentation of the amendments made by this section,
25 including the effectiveness of the at-risk beneficiaries

1 for prescription drug abuse drug management pro-
2 grams authorized by paragraph (5) of section
3 1860D–4(c) of the Social Security Act (42 U.S.C.
4 1395w–104(c)), as added by subsection (a)(1). Such
5 study shall include an analysis of—

6 (A) the impediments, if any, that impair
7 the ability of individuals described in subpara-
8 graph (C) of such section D–4(c)(5) to access
9 clinically appropriate levels of prescription
10 drugs;

11 (B) the effectiveness of the reasonable ac-
12 cess protections under subparagraph (D)(ii) of
13 such section 1860D–4(c)(5), including the im-
14 pact on beneficiary access and health;

15 (C) how best to define the term “des-
16 ignated pharmacy”, including whether the defi-
17 nition of such term should include an entity
18 that is comprised of a number of locations that
19 are under common ownership and that elec-
20 tronically share a real-time, online database and
21 whether such a definition would help to protect
22 and improve beneficiary access;

23 (D) the types of—

24 (i) individuals who, in the implemen-
25 tation of such section, are determined to be

1 individuals described in such subpara-
2 graph; and

3 (ii) prescribers and pharmacies that
4 are selected under subparagraph (D) of
5 such section;

6 (E) the extent of prescription drug abuse
7 beyond Controlled Drug Substances in Schedule
8 CII in parts C and D of the Medicare program;
9 and

10 (F) other areas determined appropriate by
11 the Comptroller General.

12 (2) REPORT.—Not later than July 1, 2019, the
13 Comptroller General of the United States shall sub-
14 mit to the appropriate committees of jurisdiction of
15 Congress a report on the study conducted under
16 paragraph (1), together with recommendations for
17 such legislation and administrative action as the
18 Comptroller General determines to be appropriate.

19 (f) REPORT BY SECRETARY.—

20 (1) IN GENERAL.—Not later than 12 months
21 after the date of the enactment of this Act, the Sec-
22 retary of Health and Human Services shall submit
23 to the appropriate committees of jurisdiction of Con-
24 gress a report on ways to improve upon the appeals
25 process for Medicare beneficiaries with respect to

1 prescription drug coverage under part D of title
2 XVIII of the Social Security Act. Such report shall
3 include an analysis comparing appeals processes
4 under parts C and D of such title XVIII.

5 (2) FEEDBACK.—In development of the report
6 described in paragraph (1), the Secretary of Health
7 and Human Services shall solicit feedback on the
8 current appeals process from stakeholders, such as
9 beneficiaries, consumer advocates, plan sponsors,
10 pharmacy benefit managers, pharmacists, providers,
11 independent review entity evaluators, and pharma-
12 ceutical manufacturers.

13 (g) EFFECTIVE DATE.—

14 (1) IN GENERAL.—Except as provided in sub-
15 section (d)(2), the amendments made by this section
16 shall apply to prescription drug plans for plan years
17 beginning on or after January 1, 2018.

18 (2) STAKEHOLDER MEETINGS PRIOR TO EFFEC-
19 TIVE DATE.—

20 (A) IN GENERAL.—Not later than January
21 1, 2017, the Secretary of Health and Human
22 Services shall convene stakeholders, including
23 individuals entitled to benefits under part A of
24 title XVIII of the Social Security Act or en-
25 rolled under part B of such title of such Act,

1 advocacy groups representing such individuals,
2 clinicians, plan sponsors, pharmacists, retail
3 pharmacies, entities delegated by plan sponsors,
4 and biopharmaceutical manufacturers for input
5 regarding the topics described in subparagraph
6 (B). The input described in the preceding sen-
7 tence shall be provided to the Secretary in suffi-
8 cient time in order for the Secretary to take
9 such input into account in promulgating the
10 regulations pursuant to subparagraph (C).

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

13 (i) the impact on cost-sharing and en-
14 suring accessibility to prescription drugs
15 for enrollees in prescription drug plans of
16 PDP sponsors who are at-risk beneficiaries
17 for prescription drug abuse (as defined in
18 paragraph (5)(C) of section 1860D–4(c) of
19 the Social Security Act (42 U.S.C. 1395w–
20 104(c)));

21 (ii) the use of an expedited appeals
22 process under which such an enrollee may
23 appeal an identification of such enrollee as
24 an at-risk beneficiary for prescription drug
25 abuse under such paragraph (similar to the

1 processes established under the Medicare
2 Advantage program under part C of title
3 XVIII of the Social Security Act);

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

7 (iv) the manner in which terms and
8 definitions in paragraph (5) of such section
9 1860D–4(c) should be applied, such as the
10 use of clinical appropriateness in deter-
11 mining whether an enrollee is an at-risk
12 beneficiary for prescription drug abuse as
13 defined in subparagraph (C) of such para-
14 graph (5);

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

19 (vi) with respect to a PDP sponsor
20 that establishes a drug management pro-
21 gram for at-risk beneficiaries under such
22 paragraph (5), the responsibilities of such
23 PDP sponsor with respect to the imple-
24 mentation of such program;

1 (vii) notices for plan enrollees at the
2 point of sale that would explain why an at-
3 risk beneficiary has been prohibited from
4 receiving a prescription at a location out-
5 side of the designated pharmacy;

6 (viii) evidence-based prescribing guide-
7 lines for opiates; and

8 (ix) the sharing of claims data under
9 parts A and B with PDP sponsors.

10 (C) RULEMAKING.—The Secretary of
11 Health and Human Services shall, taking into
12 account the input gathered pursuant to sub-
13 paragraph (A) and after providing notice and
14 an opportunity to comment, promulgate regula-
15 tions to carry out the provisions of, and amend-
16 ments made by subsections (a) and (b).

○