

114TH CONGRESS
1ST SESSION

S. 1913

To amend title XVIII of the Social Security Act to establish programs to prevent prescription drug abuse under the Medicare program, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JULY 30, 2015

Mr. TOOMEY (for himself, Mr. BROWN, Mr. PORTMAN, and Mr. Kaine) introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

To amend title XVIII of the Social Security Act to establish 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 “Stopping Medication
5 Abuse and Protecting Seniors Act of 2015”.

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

8 (a) DRUG MANAGEMENT PROGRAM FOR AT-RISK
9 BENEFICIARIES.—

1 (1) IN GENERAL.—Section 1860D–4(c) of the
2 Social Security Act (42 U.S.C. 1395w–104(c)) is
3 amended by adding at the end the following:

4 “(5) DRUG MANAGEMENT PROGRAM FOR AT-
5 RISK BENEFICIARIES.—

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

20 “(B) REQUIREMENT FOR NOTICES.—

21 “(i) IN GENERAL.—A PDP sponsor
22 may not limit the access of an at-risk ben-
23 eficiary for prescription drug abuse to cov-
24 erage for frequently abused drugs under a

1 prescription drug plan until such spon-
2 sor—

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

7 “(II) verifies with the providers
8 of the beneficiary that the beneficiary
9 is an at-risk beneficiary for prescrip-
10 tion drug abuse, as described in sub-
11 paragraph (C)(iv).

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

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

19 “(II) information, when possible,
20 describing State and Federal public
21 health resources that are designed to
22 address prescription drug abuse to
23 which the beneficiary may have ac-
24 cess, including substance use disorder
25 treatment services, addiction treat-

1 ment services, mental health services,
2 and other counseling services;

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

12 “(IV) an explanation of the
13 meaning and consequences of the
14 identification of the beneficiary as po-
15 tentially being an at-risk beneficiary
16 for prescription drug abuse, including
17 an explanation of the drug manage-
18 ment program established by the PDP
19 sponsor pursuant to subparagraph
20 (A);

21 “(V) clear instructions that ex-
22 plain how the beneficiary can contact
23 the PDP sponsor in order to submit
24 to the PDP sponsor the preferences
25 described in subclause (IV) and any

1 other communications relating to the
2 drug management program for at-risk
3 beneficiaries established by the PDP
4 sponsor;

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

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

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

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

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

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

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

1 “(VI) that includes clear instruc-
2 tions that explain how the beneficiary
3 can contact the PDP sponsor in order
4 to submit to the PDP sponsor the
5 preferences described in subclause
6 (V).

7 “(iv) TIMING OF NOTICES.—

8 “(I) IN GENERAL.—Subject to
9 subclause (II), a second written notice
10 described in clause (iii) shall be pro-
11 vided to the beneficiary on a date that
12 is not less than 30 days after an ini-
13 tial notice described in clause (ii) is
14 provided to the beneficiary.

15 “(II) EXCEPTION.—In the case
16 that the PDP sponsor, in conjunction
17 with the Secretary, determines that
18 concerns identified through rule-
19 making by the Secretary regarding
20 the health or safety of the beneficiary
21 or regarding significant drug diversion
22 activities require the PDP sponsor to
23 provide a second notice described in
24 clause (iii) to the beneficiary on a
25 date that is earlier than the date de-

scribed in subclause (II), the PDP sponsor may provide such second notice on such earlier date.

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

“(C) AT-RISK BENEFICIARY FOR PRESCRIPTION DRUG ABUSE.—

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

“(I) who is identified through criteria developed by the Secretary in consultation with PDP sponsors and other stakeholders described in subsection section 2(g)(2)(A) of the Stopping Medication Abuse and Protecting Seniors Act of 2015 based on clinical factors indicating misuse or abuse of prescription drugs described in sub-

paragraph (G), including dosage, quantity, duration of use, number of prescribers, and number of pharmacies used to obtain such drug; or

“(II) with respect to whom the PDP sponsor of a prescription drug plan, upon enrolling such individual in such plan, received notice from the Secretary that such individual was identified under this paragraph to be an at-risk beneficiary for prescription drug abuse under a prescription drug plan in which such individual was previously enrolled and such identification has not been terminated under subparagraph (F).

“(ii) EXEMPTED INDIVIDUAL DESCRIBED.—An exempted individual described in this clause is an individual who—

“(I) receives hospice care under this title;

“(II) resides in a long-term care facility, a facility described in section

1 1905(d), or other facility under con-
 2 tract with a single pharmacy; or

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

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

15 “(iv) CLINICAL CONTACT.—With re-
 16 spect to each at-risk beneficiary for pre-
 17 scription drug abuse enrolled in a prescrip-
 18 tion drug plan offered by a PDP sponsor,
 19 the PDP sponsor shall contact the bene-
 20 ficiary’s physicians regarding whether pre-
 21 scribed medications are appropriate for
 22 such beneficiary’s medical conditions.

23 “(D) SELECTION OF PRESCRIBERS.—

24 “(i) IN GENERAL.—With respect to
 25 each at-risk beneficiary for prescription

1 drug abuse enrolled in a prescription drug
2 plan offered by such sponsor, a PDP spon-
3 sor shall, based on the preferences sub-
4 mitted to the PDP sponsor by the bene-
5 ficiary pursuant to clauses (ii)(III) and
6 (iii)(V) of subparagraph (B) if applicable,
7 select—

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

18 “(II) one, or, if the PDP sponsor
19 reasonably determines it necessary to
20 provide the beneficiary with reason-
21 able access under clause (ii), more
22 than one, pharmacy that may dis-
23 pense such drugs to such beneficiary.

24 “(ii) REASONABLE ACCESS.—In mak-
25 ing the selection under this subparagraph,

1 a PDP sponsor shall ensure, taking into
2 account geographic location, beneficiary
3 preference, impact on cost-sharing, and
4 reasonable travel time, that the beneficiary
5 continues to have reasonable access to
6 drugs described in subparagraph (G), in-
7 cluding—

8 “(I) for individuals with multiple
9 residences; and

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

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. If the PDP
16 sponsor changes the selection pursu-
17 ant to the preceding sentence, the
18 PDP sponsor shall provide the bene-
19 ficiary with—

20 “(aa) at least 30 days writ-
21 ten notice of the change of selec-
22 tion; and

23 “(bb) a rationale for the
24 change.

1 “(III) TIMING.—An at-risk bene-
2 ficiary for prescription drug abuse
3 may choose to express their prescriber
4 and pharmacy preference at any date
5 while enrolled in the program, includ-
6 ing after a second notice under sub-
7 paragraph (B)(iii) has been provided.

8 “(iv) CONFIRMATION.—Before select-
9 ing a prescriber or pharmacy under this
10 subparagraph, a PDP sponsor must notify
11 the prescriber and pharmacy that the bene-
12 ficiary involved has been identified for in-
13 clusion in the drug management program
14 for at-risk beneficiaries and that the pre-
15 scriber and pharmacy has been selected as
16 the beneficiary’s designated prescriber and
17 pharmacy.

18 “(E) APPEALS.—The identification of an
19 individual as an at-risk beneficiary for prescrip-
20 tion drug abuse under this paragraph, a cov-
21 erage determination made under a drug man-
22 agement program for at-risk beneficiaries, and
23 the selection of a prescriber or pharmacy under
24 subparagraph (D) with respect to such indi-

vidual shall be subject to an expedited reconsideration and appeal pursuant to subsection (h).

“(F) TERMINATION OF IDENTIFICATION.—

“(i) IN GENERAL.—The Secretary shall develop standards for the termination of identification of an individual as an at-risk beneficiary for prescription drug abuse under this paragraph. Under such standards such identification shall terminate as of the earlier of—

“(I) the date the individual demonstrates that the individual is no longer likely, in the absence of the restrictions under this paragraph, to be an at-risk beneficiary for prescription drug abuse described in subparagraph (C)(i); or

“(II) the end of such maximum period of identification as the Secretary may specify.

“(ii) RULE OF CONSTRUCTION.—Nothing in clause (i) shall be construed as preventing a plan from identifying an individual as an at-risk beneficiary for prescription drug abuse under subparagraph

(C)(i) after such termination on the basis of additional information on drug use occurring after the date of notice of such termination.

“(G) FREQUENTLY ABUSED DRUG.—For purposes of this subsection, the term ‘frequently abused drug’ means a drug that is determined by the Secretary to be frequently abused or diverted and that is—

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

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

“(H) DATA DISCLOSURE.—

“(i) DATA ON DECISION TO IMPOSE LIMITATION.—In the case of an at-risk beneficiary for prescription drug abuse (or an individual who is a potentially at-risk beneficiary for prescription drug abuse) whose access to coverage for frequently abused drugs under a prescription drug plan has been limited by a PDP sponsor under this paragraph, the Secretary shall

1 establish rules and procedures to require
2 such PDP sponsor to disclose data, includ-
3 ing necessary individually identifiable
4 health information, about the decision to
5 impose such limitations and the limitations
6 imposed by the PDP sponsor under this
7 part.

8 “(ii) DATA TO REDUCE FRAUD,
9 ABUSE, AND WASTE.—The Secretary shall
10 establish rules and procedures to require
11 PDP sponsors operating a drug manage-
12 ment program for at-risk beneficiaries
13 under this paragraph to provide the Sec-
14 retary with such data as the Secretary de-
15 termines appropriate for purposes of iden-
16 tifying patterns of prescription drug utili-
17 zation for plan enrollees that are outside
18 normal patterns and that may indicate
19 fraudulent, medically unnecessary, or un-
20 safe use.

21 “(I) SHARING OF INFORMATION FOR SUB-
22 SEQUENT PLAN ENROLLMENTS.—The Secretary
23 shall establish procedures under which PDP
24 sponsors who offer prescription drug plans shall
25 share information with respect to individuals

1 who are at-risk beneficiaries for prescription
2 drug abuse (or individuals who are potentially
3 at-risk beneficiaries for prescription drug
4 abuse) and enrolled in a prescription drug plan
5 and who subsequently disenroll from such plan
6 and enroll in another prescription drug plan of-
7 fered by another PDP sponsor.

8 “(J) PRIVACY ISSUES.—Prior to the imple-
9 mentation of the rules and procedures under
10 this paragraph, the Secretary shall clarify pri-
11 vacy requirements, including requirements
12 under the regulations promulgated pursuant to
13 section 264(c) of the Health Insurance Port-
14 ability and Accountability Act of 1996 (42
15 U.S.C. 1320d–2 note), related to the sharing of
16 data under subparagraphs (H) and (I) by PDP
17 sponsors. Such clarification shall provide that
18 the sharing of such data shall be considered to
19 be protected health information in accordance
20 with the requirements of the regulations pro-
21 mulgated pursuant to such section 264(c).

22 “(K) EDUCATION.—The Secretary shall
23 provide education to enrollees in prescription
24 drug plans of PDP sponsors and providers re-
25 garding the drug management program for at-

1 risk beneficiaries described in this paragraph,
 2 including education—

3 “(i) provided through the improper
 4 payment outreach and education program
 5 described in section 1874A(h); and

6 “(ii) through current education efforts
 7 (such as State health insurance assistance
 8 programs described in subsection (a)(1)(A)
 9 of section 119 of the Medicare Improve-
 10 ments for Patients and Providers Act of
 11 2008 (42 U.S.C. 1395b–3 note)) and ma-
 12 terials directed toward such enrollees.

13 “(L) CMS COMPLIANCE REVIEW.—The
 14 Secretary shall ensure that existing plan spon-
 15 sor compliance reviews and audit processes in-
 16 clude the drug management programs for at-
 17 risk beneficiaries under this paragraph, includ-
 18 ing appeals processes under such programs.”.

19 (2) INFORMATION FOR CONSUMERS.—Section
 20 1860D–4(a)(1)(B) of the Social Security Act (42
 21 U.S.C. 1395w–104(a)(1)(B)) is amended by adding
 22 at the end the following:

23 “(v) The drug management program
 24 for at-risk beneficiaries under subsection
 25 (c)(5).”.

1 (3) DUAL ELIGIBLES.—Section 1860D–
 2 1(b)(3)(D) of the Social Security Act (42 U.S.C.
 3 1395w–101(b)(3)(D)) is amended by inserting “,
 4 subject to such limits as the Secretary may establish
 5 for individuals identified pursuant to section
 6 1860D–4(c)(5)” after “the Secretary”.

7 (b) UTILIZATION MANAGEMENT PROGRAMS.—Sec-
 8 tion 1860D–4(c) of the Social Security Act (42 U.S.C.
 9 1395w–104(c)), as amended by subsection (a)(1), is
 10 amended—

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

13 “(E) A utilization management tool to pre-
 14 vent drug abuse (as described in paragraph
 15 (5)(A)).”; and

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

18 “(6) UTILIZATION MANAGEMENT TOOL TO PRE-
 19 VENT DRUG ABUSE.—

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

22 “(i) A utilization tool designed to pre-
 23 vent the abuse of frequently abused drugs
 24 by individuals and to prevent the diversion
 25 of such drugs at pharmacies.

1 “(ii) Retrospective utilization review
2 to identify—

3 “(I) individuals that receive fre-
4 quently abused drugs at a frequency
5 or in amounts that are not clinically
6 appropriate; and

7 “(II) providers of services or sup-
8 pliers that may facilitate the abuse or
9 diversion of frequently abused drugs
10 by beneficiaries.

11 “(iii) Consultation with the contractor
12 described in subparagraph (B) to verify if
13 an individual enrolling in a prescription
14 drug plan offered by a PDP sponsor has
15 been previously identified by another PDP
16 sponsor as an individual described in
17 clause (ii)(I).

18 “(B) REPORTING.—A PDP sponsor offer-
19 ing a prescription drug plan in a State shall
20 submit to the Secretary and the Medicare drug
21 integrity contractor with which the Secretary
22 has entered into a contract under section 1893
23 with respect to such State a report, on a
24 monthly basis, containing information on—

1 “(i) any provider of services or sup-
 2 plier described in subparagraph (A)(ii)(II)
 3 that is identified by such plan sponsor dur-
 4 ing the 30-day period before such report is
 5 submitted; and

6 “(ii) the name and prescription
 7 records of individuals described in para-
 8 graph (5)(C).

9 “(C) CMS COMPLIANCE REVIEW.—The
 10 Secretary shall ensure that plan sponsor annual
 11 compliance reviews and program audits include
 12 a certification that utilization management tools
 13 under this paragraph are in compliance with
 14 the requirements for such tools.”.

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

20 “(d) TREATMENT OF CERTAIN COMPLAINTS FOR
 21 PURPOSES OF QUALITY OR PERFORMANCE ASSESS-
 22 MENT.—In conducting a quality or performance assess-
 23 ment of a PDP sponsor, the Secretary shall develop or
 24 utilize existing screening methods for reviewing and con-
 25 sidering complaints that are received from enrollees in a

1 prescription drug plan offered by such PDP sponsor and
 2 that are complaints regarding the lack of access by the
 3 individual to prescription drugs due to a drug manage-
 4 ment program for at-risk beneficiaries.”.

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

12 (e) GAO STUDY AND REPORT.—

13 (1) STUDY.—The Comptroller General of the
 14 United States shall conduct a study on the imple-
 15 mentation of the amendments made by this section,
 16 including the effectiveness of the at-risk beneficiaries
 17 for prescription drug abuse drug management pro-
 18 grams authorized by section 1860D–4(c)(5) of the
 19 Social Security Act (42 U.S.C. 1395w–10(c)(5)), as
 20 added by subsection (a)(1). Such study shall include
 21 an analysis of—

22 (A) the impediments, if any, that impair
 23 the ability of individuals described in subpara-
 24 graph (C) of such section 1860D–4(c)(5) to ac-

cess clinically appropriate levels of prescription
drugs;

(B) the types of—

(i) individuals who, in the implementation of such section, are determined to be individuals described in such subparagraph; and

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

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

(D) other areas determined appropriate by the Comptroller General.

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

(f) REPORT BY SECRETARY.—

1 (1) IN GENERAL.—Not later than 12 months
2 after the date of the enactment of this Act, the Sec-
3 retary of Health and Human Services shall submit
4 to the appropriate committees of jurisdiction of Con-
5 gress a report on ways to improve upon the appeals
6 process for Medicare beneficiaries with respect to
7 prescription drug coverage under part D of title
8 XVIII of the Social Security Act. Such report shall
9 include an analysis comparing appeals processes
10 under parts C and D of such title XVIII.

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

19 (g) EFFECTIVE DATE.—

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

24 (2) STAKEHOLDER MEETINGS PRIOR TO EFFEC-
25 TIVE DATE.—

(A) IN GENERAL.—Not later than January 1, 2017, the Secretary of Health and Human Services shall convene stakeholders, including individuals entitled to benefits under part A of title XVIII of the Social Security Act or enrolled under part B of such title of such Act, advocacy groups representing such individuals, clinicians, plan sponsors, pharmacists, retail pharmacies, entities delegated by plan sponsors, and biopharmaceutical manufacturers for input regarding the topics described in subparagraph (B).

(B) TOPICS DESCRIBED.—The topics described in this subparagraph are the topics of—

(i) the impact on cost-sharing and ensuring accessibility to prescription drugs for enrollees in prescription drug plans of PDP sponsors who are at-risk beneficiaries for prescription drug abuse (as defined in paragraph (5)(C) of section 1860D–4(c) of the Social Security Act (42 U.S.C. 1395w–10(c)));

(ii) the use of an expedited appeals process under which such an enrollee may appeal an identification of such enrollee as

1 an at-risk beneficiary for prescription drug
2 abuse under such paragraph (similar to the
3 processes established under the Medicare
4 Advantage program under part C of title
5 XVIII of the Social Security Act);

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

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

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

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

1 PDP sponsor with respect to the imple-
2 mentation of such program;

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

8 (viii) evidence-based prescribing guide-
9 lines for opiates.

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).

○