

114TH CONGRESS
1ST SESSION

S. 1431

To provide for increased Federal oversight of prescription opioid treatment and assistance to States in reducing opioid abuse, diversion, and deaths.

IN THE SENATE OF THE UNITED STATES

MAY 21, 2015

Mr. MANCHIN (for himself, Mr. KING, and Mrs. CAPITO) introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

To provide for increased Federal oversight of prescription opioid treatment and assistance to States in reducing opioid abuse, diversion, and deaths.

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 “Prescription Drug
5 Abuse Prevention and Treatment Act of 2015”.

6 **SEC. 2. CONSUMER EDUCATION CAMPAIGN.**

7 Part A of title V of the Public Health Service Act
8 (42 U.S.C. 290aa et seq.) is amended by adding at the
9 end the following:

1 **“SEC. 506C. CONSUMER EDUCATION CAMPAIGN.**

2 “(a) IN GENERAL.—The Administrator shall award
3 grants to States and nonprofit entities for the purpose of
4 conducting culturally sensitive consumer education about
5 opioid abuse, including methadone abuse. Such education
6 shall include information on the dangers of opioid abuse,
7 how to prevent opioid abuse including through safe dis-
8 posal of prescription medications and other safety pre-
9 cautions, and detection of early warning signs of addic-
10 tion.

11 “(b) ELIGIBILITY.—To be eligible to receive a grant
12 under subsection (a), an entity shall—

13 “(1) be a State or nonprofit entity; and

14 “(2) submit to the Administrator an application
15 at such time, in such manner, and containing such
16 information as the Administrator may require.

17 “(c) PRIORITY.—In awarding grants under this sec-
18 tion, the Administrator shall give priority to applicants
19 that are States or communities with a high incidence of
20 abuse of methadone and other opioids, and opioid-related
21 deaths.

22 “(d) EVALUATIONS.—The Administrator shall de-
23 velop a process to evaluate the effectiveness of activities
24 carried out by grantees under this section at reducing
25 abuse of methadone and other opioids.

1 “(e) AUTHORIZATION OF APPROPRIATIONS.—There
 2 is authorized to be appropriated to carry out this section
 3 \$15,000,000 for each of fiscal years 2016 through 2020.”.

4 **SEC. 3. PRACTITIONER EDUCATION.**

5 (a) EDUCATION REQUIREMENTS.—

6 (1) REGISTRATION CONSIDERATION.—Section
 7 303(f) of the Controlled Substances Act (21 U.S.C.
 8 823(f)) is amended by inserting after paragraph (5)
 9 the following:

10 “(6) The applicant’s compliance with the train-
 11 ing requirements described in subsection (g)(3) dur-
 12 ing any previous period in which the applicant has
 13 been subject to such training requirements.”.

14 (2) TRAINING REQUIREMENTS.—Section 303(g)
 15 of the Controlled Substances Act (21 U.S.C. 823(g))
 16 is amended by adding at the end the following:

17 “(3)(A) To be registered to prescribe or otherwise
 18 dispense methadone or other opioids, a practitioner de-
 19 scribed in paragraph (1) shall comply with the 12-hour
 20 training requirement of subparagraph (B) at least once
 21 during each 3-year period.

22 “(B) The training requirement of this subparagraph
 23 is that the practitioner has completed not less than 12
 24 hours of training (through classroom situations, seminars

1 at professional society meetings, electronic communica-
2 tions, or otherwise) with respect to—

3 “(i) the treatment and management of opioid-
4 dependent patients;

5 “(ii) pain management treatment guidelines;
6 and

7 “(iii) early detection of opioid addiction, includ-
8 ing through such methods as Screening, Brief Inter-
9 vention, and Referral to Treatment (SBIRT),

10 that is provided by the American Society of Addiction
11 Medicine, the American Academy of Addiction Psychiatry,
12 the American Medical Association, the American Osteo-
13 pathic Association, the American Psychiatric Association,
14 the American Academy of Pain Management, the Amer-
15 ican Pain Society, the American Academy of Pain Medi-
16 cine, the American Board of Pain Medicine, the American
17 Society of Interventional Pain Physicians, or any other or-
18 ganization that the Secretary determines is appropriate
19 for purposes of this subparagraph.”.

20 (b) REQUIREMENTS FOR PARTICIPATION IN OPIOID
21 TREATMENT PROGRAMS.—Effective July 1, 2016, a phy-
22 sician practicing in an opioid treatment program shall
23 comply with the requirements of section 303(g)(3) of the
24 Controlled Substances Act (as added by subsection (a))

1 with respect to required minimum training at least once
2 during each 3-year period.

3 (c) DEFINITION.—In this section, the term “opioid
4 treatment program” has the meaning given such term in
5 section 8.2 of title 42, Code of Federal Regulations (or
6 any successor regulation).

7 (d) FUNDING.—The Drug Enforcement Administra-
8 tion shall fund the enforcement of the requirements speci-
9 fied in section 303(g)(3) of the Controlled Substances Act
10 (as added by subsection (a)) through the use of a portion
11 of the licensing fees paid by controlled substance pre-
12 scribers under the Controlled Substances Act (21 U.S.C.
13 801 et seq.).

14 **SEC. 4. OPERATION OF OPIOID TREATMENT PROGRAMS.**

15 Section 303 of the Controlled Substances Act (21
16 U.S.C. 823) is amended by adding at the end the fol-
17 lowing:

18 “(i)(1) An opioid treatment program that is reg-
19 istered under this section, and that closes for business on
20 any weekday or weekend day, including a Federal or State
21 holiday, shall comply with the requirements of this sub-
22 section.

23 “(2) The program shall make acceptable arrange-
24 ments for each patient who is restricted, by Federal regu-
25 lation or guideline or by the determination of the program

1 medical director, from having a take home dose of a con-
 2 trolled substance related to the treatment involved, to re-
 3 ceive a dose of that substance under appropriate super-
 4 vision during the closure.

5 “(3) The Administrator of the Substance Abuse and
 6 Mental Health Services Administration shall issue a notice
 7 that references regulations on acceptable arrangements
 8 under this subsection, or shall promulgate regulations on
 9 such acceptable arrangements.”.

10 **SEC. 5. MORTALITY REPORTING.**

11 Part A of title V of the Public Health Service Act
 12 (42 U.S.C. 290aa et seq.), as amended by section 3, is
 13 further amended by adding at the end the following:

14 **“SEC. 506D. MORTALITY REPORTING.**

15 “(a) MODEL OPIOID TREATMENT PROGRAM MOR-
 16 TALITY REPORT.—

17 “(1) IN GENERAL.—Not later than July 1,
 18 2016, the Secretary, acting through the Adminis-
 19 trator, shall require that a Model Opioid Treatment
 20 Program Mortality Report be completed and sub-
 21 mitted to the Administrator for each individual who
 22 dies while receiving treatment in an opioid treatment
 23 program.

24 “(2) REQUIREMENT OF STATES THAT RECEIVE
 25 FUNDING FOR THE CONTROLLED SUBSTANCE MONI-

1 TORING PROGRAM.—As a condition for receiving
2 funds under section 399O, each State shall require
3 that any individual who signs a death certificate
4 where an opioid drug is detected in the body of the
5 deceased, or where such drug is otherwise associated
6 with the death, report such death to the Adminis-
7 trator by submitting a Model Opioid Treatment Pro-
8 gram Mortality Report described in paragraph (3).
9 Such report shall be submitted to the Administrator
10 on or before the later of—

11 “(A) 90 days after the date of signing the
12 death certificate; or

13 “(B) as soon as practicable after the date
14 on which the necessary postmortem and tox-
15 ecology reports become available to such indi-
16 vidual, as required by the Secretary.

17 “(3) DEVELOPMENT.—The Administrator, in
18 consultation with State and local medical examiners,
19 prescribing physicians, hospitals, and any other or-
20 ganization that the Administrator determines appro-
21 priate, shall develop a Model Opioid Treatment Pro-
22 gram Mortality Report to be used under paragraphs
23 (1) and (2).

24 “(b) NATIONAL OPIOID DEATH REGISTRY.—

1 “(1) IN GENERAL.—Not later than July 1,
 2 2016, the Administrator shall establish and imple-
 3 ment, through the National Center for Health Sta-
 4 tistics, a National Opioid Death Registry (referred
 5 to in this subsection as the ‘Registry’) to track
 6 opioid-related deaths and information related to such
 7 deaths.

8 “(2) CONSULTATION.—In establishing the uni-
 9 form reporting criteria for the Registry, the Director
 10 of the Centers for Disease Control and Prevention
 11 shall consult with the Administrator, State and local
 12 medical examiners, prescribing physicians, hospitals,
 13 and any other organization that the Director deter-
 14 mines is appropriate for purposes of this subsection.

15 “(3) REQUIREMENTS.—The registry shall be
 16 designed as a uniform reporting system for opioid-
 17 related deaths and shall require the reporting of in-
 18 formation with respect to such deaths, including—

19 “(A) the particular drug formulation used
 20 at the time of death;

21 “(B) the dosage level;

22 “(C) a description of the circumstances
 23 surrounding the death in relation to the rec-
 24 ommended dosage involved;

1 “(D) a disclosure of whether the medica-
 2 tion involved can be traced back to a physi-
 3 cian’s prescription;

4 “(E) a disclosure of whether the individual
 5 was in an opioid treatment program at the time
 6 of death;

7 “(F) the age and sex of the individual; and

8 “(G) other non-personal information such
 9 as that included in filed National Association of
 10 Medical Examiners Pediatric Toxicology Reg-
 11 istry case reports as required under the privacy
 12 standard for the de-identification of health in-
 13 formation pursuant to the regulations contained
 14 in part 164 of title 45, Code of Federal Regula-
 15 tions.

16 “(4) AUTHORIZATION.—There is authorized to
 17 be appropriated \$5,000,000 for each of fiscal years
 18 2016 through 2020 to carry out this subsection.

19 “(c) REPORT ON REGISTRY INFORMATION.—Not
 20 later than the January 1 of the first fiscal year beginning
 21 2 years after the date of enactment of this section, and
 22 each January 1 thereafter, the Director of the Centers for
 23 Disease Control and Prevention shall submit to the Sec-
 24 retary a report, based on information contained in the
 25 Registry described in subsection (b), concerning the num-

ber of methadone-related deaths in the United States for the year for which the report is submitted.”.

SEC. 6. DEVELOPMENT OF PRESCRIPTION DRUG ABUSE PREVENTION AND TREATMENT QUALITY MEASURES ACROSS EACH RELEVANT PROVIDER SETTING.

Subpart I of part D of title IX of the Public Health Service Act (42 U.S.C. 299b–31 et seq.) is amended by adding at the end the following:

“SEC. 932. DEVELOPMENT OF PRESCRIPTION DRUG ABUSE PREVENTION AND TREATMENT QUALITY MEASURES ACROSS EACH RELEVANT PROVIDER SETTING.

“(a) IN GENERAL.—The Secretary, acting through the Director of the Agency for Healthcare Research and Quality and in consultation with the Director of the Centers for Disease Control and Prevention, the Administrator of the Substance Abuse and Mental Health Services Administration, and the Director of the Centers for Medicare & Medicaid Services, shall require the development and application of specific prescription drug abuse prevention and treatment quality measures for each relevant health care provider setting, as identified by the Director.

“(b) DISSEMINATION.—Not later than April 1, 2016, the Secretary shall disseminate the quality measure re-

1 requirements developed under subsection (a) to all affected
2 providers.

3 “(c) TYPES OF MEASURES.—Quality measures devel-
4 oped under this section may be structure-oriented (such
5 as the required presence of a hospital-based treatment
6 program), process-oriented (such as requiring patients to
7 be informed of the addictive qualities of the medication
8 being prescribed), or outcome-oriented (such as assessing
9 family satisfaction with care).”.

10 **SEC. 7. PROGRAMS TO PREVENT PRESCRIPTION DRUG**
11 **ABUSE UNDER MEDICARE PART D.**

12 (a) DRUG MANAGEMENT PROGRAM FOR AT-RISK
13 BENEFICIARIES.—

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

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

19 “(A) AUTHORITY TO ESTABLISH.—A PDP
20 sponsor may establish a drug management pro-
21 gram for at-risk beneficiaries under which, sub-
22 ject to subparagraph (B), the PDP sponsor
23 may, in the case of an at-risk beneficiary for
24 prescription drug abuse who is an enrollee in a
25 prescription drug plan of such PDP sponsor,

1 limit such beneficiary's access to coverage for
 2 frequently abused drugs under such plan to fre-
 3 quently abused drugs that are prescribed for
 4 such beneficiary by a prescriber selected under
 5 subparagraph (D), and dispensed for such bene-
 6 ficiary by a pharmacy selected under such sub-
 7 paragraph.

8 “(B) REQUIREMENT FOR NOTICES.—

9 “(i) IN GENERAL.—A PDP sponsor
 10 may not limit the access of an at-risk ben-
 11 eficiary for prescription drug abuse to cov-
 12 erage for frequently abused drugs under a
 13 prescription drug plan until such spon-
 14 sor—

15 “(I) provides to the beneficiary
 16 an initial notice described in clause
 17 (ii) and a second notice described in
 18 clause (iii); and

19 “(II) verifies with the providers
 20 of the beneficiary that the beneficiary
 21 is an at-risk beneficiary for prescrip-
 22 tion drug abuse.

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

1 “(I) notice that the PDP sponsor
2 has identified the beneficiary as po-
3 tentially being an at-risk beneficiary
4 for prescription drug abuse;

5 “(II) information describing all
6 State and Federal public health re-
7 sources that are designed to address
8 prescription drug abuse to which the
9 beneficiary has access, including men-
10 tal health services and other coun-
11 seling services;

12 “(III) notice of, and information
13 about, the right of the beneficiary to
14 appeal such identification under sub-
15 section (h) and the option of an auto-
16 matic escalation to external review;

17 “(IV) a request for the bene-
18 ficiary to submit to the PDP sponsor
19 preferences for which prescribers and
20 pharmacies the beneficiary would pre-
21 fer the PDP sponsor to select under
22 subparagraph (D) in the case that the
23 beneficiary is identified as an at-risk
24 beneficiary for prescription drug
25 abuse as described in clause (iii)(I);

1 “(V) an explanation of the mean-
2 ing and consequences of the identi-
3 fication of the beneficiary as poten-
4 tially being an at-risk beneficiary for
5 prescription drug abuse, including an
6 explanation of the drug management
7 program established by the PDP
8 sponsor pursuant to subparagraph
9 (A);

10 “(VI) clear instructions that ex-
11 plain how the beneficiary can contact
12 the PDP sponsor in order to submit
13 to the PDP sponsor the preferences
14 described in subclause (IV) and any
15 other communications relating to the
16 drug management program for at-risk
17 beneficiaries established by the PDP
18 sponsor; and

19 “(VII) contact information for
20 other organizations that can provide
21 the beneficiary with assistance regard-
22 ing such drug management program
23 (similar to the information provided
24 by the Secretary in other standardized
25 notices provided to part D eligible in-

1 individuals enrolled in prescription drug
2 plans under this part).

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

6 “(I) that the PDP sponsor has
7 identified the beneficiary as an at-risk
8 beneficiary for prescription drug
9 abuse;

10 “(II) that such beneficiary is
11 subject to the requirements of the
12 drug management program for at-risk
13 beneficiaries established by such PDP
14 sponsor for such plan;

15 “(III) of the prescriber and phar-
16 macy selected for such individual
17 under subparagraph (D);

18 “(IV) of, and information about,
19 the beneficiary’s right to appeal such
20 identification under subsection (h)
21 and the option of an automatic esca-
22 lation to external review;

23 “(V) that the beneficiary can, in
24 the case that the beneficiary has not
25 previously submitted to the PDP

1 sponsor preferences for which pre-
2 scribers and pharmacies the bene-
3 ficiary would prefer the PDP sponsor
4 select under subparagraph (D), sub-
5 mit such preferences to the PDP
6 sponsor; and

7 “(VI) that includes clear instruc-
8 tions that explain how the beneficiary
9 can contact the PDP sponsor.

10 “(iv) TIMING OF NOTICES.—

11 “(I) IN GENERAL.—Subject to
12 subclause (II), a second notice de-
13 scribed in clause (iii) shall be provided
14 to the beneficiary on a date that is
15 not less than 60 days after an initial
16 notice described in clause (ii) is pro-
17 vided to the beneficiary.

18 “(II) EXCEPTION.—In the case
19 that the PDP sponsor, in conjunction
20 with the Secretary, determines that
21 concerns identified through rule-
22 making by the Secretary regarding
23 the health or safety of the beneficiary
24 or regarding significant drug diversion
25 activities require the PDP sponsor to

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

7 “(C) AT-RISK BENEFICIARY FOR PRE-
 8 SCRIPTIION DRUG ABUSE.—

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

15 “(I) who is identified through the
 16 use of guidelines developed by the
 17 Secretary in consultation with PDP
 18 sponsors and other stakeholders de-
 19 scribed in section 10(f)(2)(A) of the
 20 Prescription Drug Abuse Prevention
 21 and Treatment Act of 2015; or

22 “(II) with respect to whom the
 23 PDP sponsor of a prescription drug
 24 plan, upon enrolling such individual in
 25 such plan, received notice from the

1 Secretary that such individual was
2 identified under this paragraph to be
3 an at-risk beneficiary for prescription
4 drug abuse under the prescription
5 drug plan in which such individual
6 was most recently previously enrolled
7 and such identification has not been
8 terminated under subparagraph (F).

9 “(ii) EXEMPTED INDIVIDUAL DE-
10 SCRIBED.—An exempted individual de-
11 scribed in this clause is an individual
12 who—

13 “(I) receives hospice care under
14 this title; or

15 “(II) the Secretary elects to treat
16 as an exempted individual for pur-
17 poses of clause (i).

18 “(D) SELECTION OF PRESCRIBERS.—

19 “(i) IN GENERAL.—With respect to
20 each at-risk beneficiary for prescription
21 drug abuse enrolled in a prescription drug
22 plan offered by such sponsor, a PDP spon-
23 sor shall, based on the preferences sub-
24 mitted to the PDP sponsor by the bene-

1 beneficiary pursuant to clauses (ii)(IV) and
 2 (iii)(V) of subparagraph (B), select—

3 “(I) one or more individuals who
 4 are authorized to prescribe frequently
 5 abused drugs (referred to in this
 6 paragraph as ‘prescribers’) who may
 7 write prescriptions for such drugs for
 8 such beneficiary; and

9 “(II) one or more pharmacies
 10 that may dispense such drugs to such
 11 beneficiary.

12 “(ii) REASONABLE ACCESS.—In mak-
 13 ing the selection under this subparagraph,
 14 a PDP sponsor shall ensure that the bene-
 15 ficiary continues to have reasonable access
 16 to drugs described in subparagraph (G),
 17 taking into account geographic location,
 18 beneficiary preference, affordability, and
 19 reasonable travel time.

20 “(iii) BENEFICIARY PREFERENCES.—

21 “(I) IN GENERAL.—If an at-risk
 22 beneficiary for prescription drug
 23 abuse submits preferences for which
 24 in-network prescribers and pharmacies
 25 the beneficiary would prefer the PDP

1 sponsor select in response to a notice
2 under subparagraph (B), the PDP
3 sponsor shall—

4 “(aa) review such pref-
5 erences;

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

10 “(cc) inform the beneficiary
11 of such selection or change of se-
12 lection.

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

1 “(iv) CONFIRMATION.—Before select-
2 ing a prescriber or pharmacy under this
3 subparagraph, a PDP sponsor must re-
4 quest and receive confirmation from the
5 prescriber or pharmacy acknowledging and
6 accepting that the beneficiary involved is in
7 the drug management program for at-risk
8 beneficiaries.

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

21 “(F) TERMINATION OF IDENTIFICATION.—

22 “(i) IN GENERAL.—The Secretary
23 shall develop standards for the termination
24 of identification of an individual as an at-
25 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

1 by the Secretary to be frequently abused or di-
2 verted and that is—

3 “(i) a Controlled Drug Substance in
4 Schedule CII–CIV;

5 “(ii) within the same class or category
6 of drugs as a Controlled Drug Substance
7 in Schedule CII–CIV; or

8 “(iii) within another class or category
9 of drugs that the Secretary determines, in
10 consultation with the Inspector General of
11 the Department of Health and Human
12 Services, is at high risk for diversion or
13 abuse.

14 “(H) DATA DISCLOSURE.—In the case of
15 an at-risk beneficiary for prescription drug
16 abuse whose access to coverage for frequently
17 abused drugs under a prescription drug plan
18 has been limited by a PDP sponsor under this
19 paragraph, such PDP sponsor shall disclose
20 data, including any necessary individually iden-
21 tifiable health information, in a form and man-
22 ner specified by the Secretary, about the deci-
23 sion to impose such limitations and the limita-
24 tions imposed by the sponsor under this part.

1 “(I) EDUCATION.—The Secretary shall
 2 provide education to enrollees in prescription
 3 drug plans of PDP sponsors and providers re-
 4 garding the drug management program for at-
 5 risk beneficiaries described in this paragraph,
 6 including education—

7 “(i) provided by Medicare administra-
 8 tive contractors through the improper pay-
 9 ment outreach and education program de-
 10 scribed in section 1874A(h); and

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

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

22 “(v) The drug management program
 23 for at-risk beneficiaries under subsection
 24 (c)(4).”.

1 (b) UTILIZATION MANAGEMENT PROGRAMS.—Sec-
 2 tion 1860D–4(c) of the Social Security Act (42 U.S.C.
 3 1395w–104(c)), as amended by subsection (a), is amend-
 4 ed—

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

7 “(E) A utilization management tool to pre-
 8 vent drug abuse (as described in paragraph
 9 (5)(A)).”; and

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

12 “(5) UTILIZATION MANAGEMENT TOOL TO PRE-
 13 VENT DRUG ABUSE.—

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

16 “(i) A utilization tool designed to pre-
 17 vent the abuse of frequently abused drugs
 18 by individuals and to prevent the diversion
 19 of such drugs at pharmacies.

20 “(ii) Retrospective utilization review
 21 to identify—

22 “(I) individuals that receive fre-
 23 quently abused drugs at a frequency
 24 or in amounts that are not clinically
 25 appropriate; and

1 “(II) providers of services or sup-
 2 pliers that may facilitate the abuse or
 3 diversion of frequently abused drugs
 4 by beneficiaries.

5 “(iii) Consultation with the Con-
 6 tractor described in subparagraph (B) to
 7 verify if an individual enrolling in a pre-
 8 scription drug plan offered by a PDP
 9 sponsor has been previously identified by
 10 another PDP sponsor as an individual de-
 11 scribed in clause (ii)(I).

12 “(B) REPORTING.—A PDP sponsor offer-
 13 ing a prescription drug plan in a State shall
 14 submit to the Secretary and the Medicare drug
 15 integrity contractor with which the Secretary
 16 has entered into a contract under section 1893
 17 with respect to such State a report, on a
 18 monthly basis, containing information on—

19 “(i) any provider of services or sup-
 20 plier described in subparagraph (A)(ii)(II)
 21 that is identified by such plan sponsor dur-
 22 ing the 30-day period before such report is
 23 submitted; and

1 “(ii) the name and prescription
2 records of individuals described in para-
3 graph (4)(C).”.

4 (c) EXPANDING ACTIVITIES OF MEDICARE DRUG IN-
5 INTEGRITY CONTRACTORS (MEDICs).—Section 1893 of the
6 Social Security Act (42 U.S.C. 1395ddd) is amended by
7 adding at the end the following new subsection:

8 “(j) EXPANDING ACTIVITIES OF MEDICARE DRUG
9 INTEGRITY CONTRACTORS (MEDICs).—

10 “(1) ACCESS TO INFORMATION.—Under con-
11 tracts entered into under this section with Medicare
12 drug integrity contractors, the Secretary shall au-
13 thorize such contractors to directly accept prescrip-
14 tion and necessary medical records from entities
15 such as pharmacies, prescription drug plans, and
16 physicians with respect to an individual in order for
17 such contractors to provide information relevant to
18 the determination of whether such individual is an
19 at-risk beneficiary for prescription drug abuse, as
20 defined in section 1860D–4(c)(4)(C).

21 “(2) REQUIREMENT FOR ACKNOWLEDGMENT
22 OF REFERRALS.—If a PDP sponsor refers informa-
23 tion to a contractor described in paragraph (1) in
24 order for such contractor to assist in the determina-

1 tion described in such paragraph, the contractor
2 shall—

3 “(A) acknowledge to the PDP sponsor re-
4 ceipt of the referral; and

5 “(B) in the case that any PDP sponsor
6 contacts the contractor requesting to know the
7 determination by the contractor of whether or
8 not an individual has been determined to be an
9 individual described such paragraph, shall in-
10 form such PDP sponsor of such determination
11 on a date that is not later than 15 days after
12 the date on which the PDP sponsor contacts
13 the contractor.

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

16 “(A) IN GENERAL.—For purposes of car-
17 rying out this subsection, subject to subpara-
18 graph (B), the Secretary shall authorize MED-
19 ICs to respond to requests for information from
20 PDP sponsors, State prescription drug moni-
21 toring programs, and other entities delegated by
22 PDP sponsors using available programs and
23 systems in the effort to prevent fraud, waste,
24 and abuse.

1 “(B) HIPAA COMPLIANT INFORMATION
 2 ONLY.—Information may only be disclosed by a
 3 MEDIC under subparagraph (A) if the disclo-
 4 sure of such information is permitted under the
 5 Federal regulations (concerning the privacy of
 6 individually identifiable health information) pro-
 7 mulgated under section 264(c) of the Health
 8 Insurance Portability and Accountability Act of
 9 1996 (42 U.S.C. 1320d–2 note).”.

10 (d) TREATMENT OF CERTAIN COMPLAINTS FOR PUR-
 11 POSES OF QUALITY OR PERFORMANCE ASSESSMENT.—
 12 Section 1860D–42 of the Social Security Act (42 U.S.C.
 13 1395w–152) is amended by adding at the end the fol-
 14 lowing new subsection:

15 “(d) TREATMENT OF CERTAIN COMPLAINTS FOR
 16 PURPOSES OF QUALITY OR PERFORMANCE ASSESS-
 17 MENT.—In conducting a quality or performance assess-
 18 ment of a PDP sponsor, the Secretary shall develop or
 19 utilize existing screening methods for reviewing and con-
 20 sidering complaints that are received from enrollees in a
 21 prescription drug plan offered by such PDP sponsor and
 22 that are complaints regarding the lack of access by the
 23 individual to prescription drugs due to a drug manage-
 24 ment program for at-risk beneficiaries.”.

25 (e) GAO STUDIES AND REPORTS.—

1 (1) STUDIES.—The Comptroller General of the
2 United States shall conduct a study on each of the
3 following:

4 (A) The implementation of the amend-
5 ments made by this section.

6 (B) The effectiveness of the at-risk bene-
7 ficiaries for prescription drug abuse drug man-
8 agement programs authorized by section
9 1860D–4(c)(4) of the Social Security Act (42
10 U.S.C. 1395w–10(c)(4)), as added by sub-
11 section (a)(1), including an analysis of—

12 (i) the impediments, if any, that im-
13 pair the ability of individuals described in
14 subparagraph (C) of such section 1860D–
15 4(c)(4) to access clinically appropriate lev-
16 els of prescription drugs; and

17 (ii) the types of—

18 (I) individuals who, in the imple-
19 mentation of such section, are deter-
20 mined to be individuals described in
21 such subparagraph; and

22 (II) prescribers and pharmacies
23 that are selected under subparagraph
24 (D) of such section.

1 (2) REPORTS.—Not later than January 1,
2 2016, the Comptroller General of the United States
3 shall begin work, with respect to each study de-
4 scribed in paragraph (1), on a report that describes
5 the result of such study. Upon the completion of
6 each such report, such Comptroller General shall
7 submit the report to each of the committees de-
8 scribed in paragraph (3).

9 (3) COMMITTEES DESCRIBED.—The committees
10 described in this paragraph are the following:

11 (A) The Committee on Ways and Means of
12 the House of Representatives.

13 (B) The Committee on Energy and Com-
14 merce of the House of Representatives.

15 (C) The Committee on Finance of the Sen-
16 ate.

17 (D) The Committee on Health, Education,
18 Labor, and Pensions of the Senate.

19 (E) The Special Committee on Aging of
20 the Senate.

21 (f) EFFECTIVE DATE.—

22 (1) IN GENERAL.—The amendments made by
23 this section shall apply to prescription drug plans for
24 plan years beginning on or after January 1, 2017.

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

3 (A) IN GENERAL.—Not later than January
4 1, 2016, the Secretary shall convene stake-
5 holders, including individuals entitled to bene-
6 fits under part A of title XVIII of the Social
7 Security Act or enrolled under part B of such
8 title of such Act, advocacy groups representing
9 such individuals, clinicians, plan sponsors, and
10 entities delegated by plan sponsors, for input
11 regarding the topics described in subparagraph
12 (B).

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

15 (i) ensuring affordability and accessi-
16 bility to prescription drugs for enrollees in
17 prescription drug plans of PDP sponsors
18 who are at-risk beneficiaries for prescrip-
19 tion drug abuse (as defined in paragraph
20 (4)(C) of section 1860D–4(c) of the Social
21 Security Act (42 U.S.C. 1395w–10(c)), as
22 added by subsection (a)(1));

23 (ii) the use of an expedited appeals
24 process under which such an enrollee may
25 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 that allow
6 an automatic escalation to external review
7 of claims submitted under such part);

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

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

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

23 (vi) with respect to a PDP sponsor
24 that establishes a drug management pro-
25 gram for at-risk beneficiaries under such

1 paragraph (4), the responsibilities of such
2 PDP sponsor with respect to the imple-
3 mentation of such program.

4 (C) RULEMAKING.—The Secretary shall
5 promulgate regulations based on the input
6 gathered pursuant to subparagraph (A).

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