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114TH CONGRESS
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H. R. 4697

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

IN THE HOUSE OF REPRESENTATIVES

MARCH 3, 2016

Ms. ESTY (for herself, Mr. COSTELLO of Pennsylvania, and Mr. KNIGHT) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means and the Judiciary, 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

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A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Prevent Drug Addiction Act of 2016''.

SEC. 2. CONSUMER EDUCATION CAMPAIGN.

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

"SEC. 506C. CONSUMER EDUCATION CAMPAIGN.

''(a) IN GENERAL.—The Administrator shall award grants to States and nonprofit entities for the purpose of conducting culturally sensitive consumer education about opioid addiction, including methadone addiction. Such education shall include information on the dangers of opioid addiction, how to prevent opioid addiction including through safe disposal of prescription medications and other safety precautions, and detection of early warning signs of addiction.

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

''(1) be a State or nonprofit entity; and

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

''(c) PRIORITY.—In awarding grants under this section, the Administrator shall give priority to applicants that are States or communities with a high incidence of addiction to methadone and other opioids, and opioid-related deaths.

''(d) EVALUATIONS.—The Administrator shall develop a process to evaluate the effectiveness of activities carried out by grantees under this section at reducing addiction to methadone and other opioids.

''(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $15,000,000 for each of fiscal years 2017 through 2021.''.

SEC. 3. PRACTITIONER EDUCATION.

(a) EDUCATION REQUIREMENTS.—

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

''(6) The applicant's compliance with the training requirements described in subsection (g)(3) during any previous period in which the applicant has been subject to such training requirements.''.

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

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

''(B) The training requirement of this subparagraph is that the practitioner has completed not less than 12 hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) with respect to—

''(i) the treatment and management of opioid-dependent patients;

''(ii) pain management treatment guidelines; and

''(iii) early detection of opioid addiction, including through such methods as Screening, Brief Intervention, and Referral to Treatment (SBIRT),

that is provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, the American Academy of Pain Management, the American Pain Society, the American Academy of Pain Medicine, the American Board of Pain Medicine, the American Society of Interventional Pain Physicians, or any other organization that the Secretary determines is appropriate for purposes of this subparagraph.''.

(b) REQUIREMENTS FOR PARTICIPATION IN OPIOID TREATMENT PROGRAMS.—Effective July 1, 2017, a physician practicing in an opioid treatment program shall

comply with the requirements of section 303(g)(3) of the Controlled Substances Act (as added by subsection (a)) with respect to required minimum training at least once during each 3-year period.

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

(d) FUNDING.—The Drug Enforcement Administration shall fund the enforcement of the requirements specified in section 303(g)(3) of the Controlled Substances Act (as added by subsection (a)) through the use of a portion of the licensing fees paid by controlled substance prescribers under the Controlled Substances Act (21 U.S.C. 801 et seq.).

SEC. 4. OPERATION OF OPIOID TREATMENT PROGRAMS.

Section 303 of the Controlled Substances Act (21 U.S.C. 823) is amended by adding at the end the following:

''(i)(1) An opioid treatment program that is registered under this section, and that closes for business on any weekday or weekend day, including a Federal or State holiday, shall comply with the requirements of this subsection.

''(2) The program shall make acceptable arrangements for each patient who is restricted, by Federal regulation or guideline or by the determination of the program medical director, from having a take-home dose of a controlled substance related to the treatment involved, to receive a dose of that substance under appropriate supervision during the closure.

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

SEC. 5. MORTALITY REPORTING.

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

''SEC. 506D. MORTALITY REPORTING.

''(a) MODEL OPIOID TREATMENT PROGRAM MORTALITY REPORT.—

''(1) IN GENERAL.—Not later than July 1, 2017, the Secretary, acting through the Administrator, shall require that a Model Opioid Treatment Program Mortality Report be completed and submitted to the Administrator for each individual who

dies while receiving treatment in an opioid treatment program.

''(2) REQUIREMENT OF STATES THAT RECEIVE FUNDING FOR THE CONTROLLED SUBSTANCE MONITORING PROGRAM.—As a condition for receiving funds under section 399O, each State shall require that any individual who signs a death certificate where an opioid drug is detected in the body of the deceased, or where such drug is otherwise associated with the death, report such death to the Administrator by submitting a Model Opioid Treatment Program Mortality Report described in paragraph (3). Such report shall be submitted to the Administrator on or before the later of—

''(A) 90 days after the date of signing the death certificate; or

''(B) as soon as practicable after the date on which the necessary postmortem and toxicology reports become available to such individual, as required by the Secretary.

''(3) DEVELOPMENT.—The Administrator, in consultation with State and local medical examiners, prescribing physicians, hospitals, and any other organization that the Administrator determines appropriate, shall develop a Model Opioid Treatment Pro-

gram Mortality Report to be used under paragraphs (1) and (2).

''(b) NATIONAL OPIOID DEATH REGISTRY.—

''(1) IN GENERAL.—Not later than July 1, 2017, the Administrator shall establish and implement, through the National Center for Health Statistics, a National Opioid Death Registry (referred to in this subsection as the 'Registry') to track opioid-related deaths and information related to such deaths.

''(2) CONSULTATION.—In establishing the uniform reporting criteria for the Registry, the Director of the Centers for Disease Control and Prevention shall consult with the Administrator, State and local medical examiners, prescribing physicians, hospitals, and any other organization that the Director determines is appropriate for purposes of this subsection.

''(3) REQUIREMENTS.—The registry shall be designed as a uniform reporting system for opioid-related deaths and shall require the reporting of information with respect to such deaths, including—

''(A) the particular drug formulation used at the time of death;

''(B) the dosage level;

"(C) a description of the circumstances surrounding the death in relation to the recommended dosage involved;

"(D) a disclosure of whether the medication involved can be traced back to a physician's prescription;

"(E) a disclosure of whether the individual was in an opioid treatment program at the time of death;

"(F) the age and sex of the individual; and

"(G) other nonpersonal information such as that included in filed National Association of Medical Examiners Pediatric Toxicology Registry case reports as required under the privacy standard for the de-identification of health information pursuant to the regulations contained in part 164 of title 45, Code of Federal Regulations.

"(4) AUTHORIZATION.—There is authorized to be appropriated $5,000,000 for each of fiscal years 2017 through 2021 to carry out this subsection.

"(c) REPORT ON REGISTRY INFORMATION.—Not later than the January 1 of the first fiscal year beginning 2 years after the date of enactment of this section, and each January 1 thereafter, the Director of the Centers for

Disease Control and Prevention shall submit to the Secretary a report, based on information contained in the Registry described in subsection (b), concerning the number of methadone-related deaths in the United States for the year for which the report is submitted.''.

SEC. 6. DEVELOPMENT OF PRESCRIPTION DRUG ADDICTION 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 ADDICTION 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 addiction pre-

vention and treatment quality measures for each relevant health care provider setting, as identified by the Director.

''(b) DISSEMINATION.—Not later than April 1, 2017, the Secretary shall disseminate the quality measure requirements developed under subsection (a) to all affected providers.

''(c) TYPES OF MEASURES.—Quality measures developed under this section may be structure-oriented (such as the required presence of a hospital-based treatment program), process-oriented (such as requiring patients to be informed of the addictive qualities of the medication being prescribed), or outcome-oriented (such as assessing family satisfaction with care).''.

SEC. 7. PROGRAMS TO PREVENT PRESCRIPTION DRUG ADDICTION UNDER MEDICARE PART D.

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

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

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

''(A) AUTHORITY TO ESTABLISH.—A PDP sponsor may establish a drug management program for at-risk beneficiaries under which, sub-

ject to subparagraph (B), the PDP sponsor may, in the case of an at-risk beneficiary for prescription drug addiction who is an enrollee in a prescription drug plan of such PDP sponsor, limit such beneficiary's access to coverage for addictive drugs under such plan to addictive drugs that are prescribed for such beneficiary by a prescriber selected under subparagraph (D), and dispensed for such beneficiary by a pharmacy selected under such subparagraph.

''(B) REQUIREMENT FOR NOTICES.—

''(i) IN GENERAL.—A PDP sponsor may not limit the access of an at-risk beneficiary for prescription drug addiction to coverage for addictive drugs under a prescription drug plan until such sponsor—

''(I) provides to the beneficiary an initial notice described in clause (ii) and a second notice described in clause (iii); and

''(II) verifies with the providers of the beneficiary that the beneficiary is an at-risk beneficiary for prescription drug addiction.

"(ii) INITIAL NOTICE.—An initial notice described in this clause is a notice that provides to the beneficiary—

"(I) notice that the PDP sponsor has identified the beneficiary as potentially being an at-risk beneficiary for prescription drug addiction;

"(II) information describing all State and Federal public health resources that are designed to address prescription drug addiction to which the beneficiary has access, including mental health services and other counseling services;

"(III) notice of, and information about, the right of the beneficiary to appeal such identification under subsection (h) and the option of an automatic escalation to external review;

"(IV) 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 addiction as described in clause (iii)(I);

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

''(VI) 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 (IV) and any other communications relating to the drug management program for at-risk beneficiaries established by the PDP sponsor; and

''(VII) contact information for other organizations that can provide the beneficiary with assistance regarding such drug management program

(similar to the information provided by the Secretary in other standardized notices provided to part D eligible individuals enrolled in prescription drug plans under this part).

''(iii) SECOND NOTICE.—A second notice described in this clause is a notice that provides to the beneficiary notice—

''(I) that the PDP sponsor has identified the beneficiary as an at-risk beneficiary for prescription drug addiction;

''(II) that such beneficiary is subject to the requirements of the drug management program for at-risk beneficiaries established by such PDP sponsor for such plan;

''(III) of the prescriber and pharmacy selected for such individual under subparagraph (D);

''(IV) of, and information about, the beneficiary's right to appeal such identification under subsection (h) and the option of an automatic escalation to external review;

''(V) that the beneficiary can, in the case that the beneficiary has not previously submitted to the PDP sponsor preferences for which prescribers and pharmacies the beneficiary would prefer the PDP sponsor select under subparagraph (D), submit such preferences to the PDP sponsor; and

''(VI) that includes clear instructions that explain how the beneficiary can contact the PDP sponsor.

''(iv) TIMING OF NOTICES.—

''(I) IN GENERAL.—Subject to subclause (II), a second notice described in clause (iii) shall be provided to the beneficiary on a date that is not less than 60 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 rulemaking 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 clause (iii) to the beneficiary on a date that is earlier than the date described in subclause (II), the PDP sponsor may provide such second notice on such earlier date.

''(C) AT-RISK BENEFICIARY FOR PRESCRIPTION DRUG ADDICTION.—

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

''(I) who is identified through the use of guidelines developed by the Secretary in consultation with PDP sponsors and other stakeholders described in section 10(f)(2)(A) of the Prevent Drug Addiction Act of 2016; 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 addiction under the prescription drug plan in which such individual was most recently 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; or

''(II) the Secretary elects to treat as an exempted individual for purposes of clause (i).

''(D) SELECTION OF PRESCRIBERS.—

''(i) IN GENERAL.—With respect to each at-risk beneficiary for prescription drug addiction enrolled in a prescription

drug plan offered by such sponsor, a PDP sponsor shall, based on the preferences submitted to the PDP sponsor by the beneficiary pursuant to clauses (ii)(IV) and (iii)(V) of subparagraph (B), select—

"(I) one or more individuals who are authorized to prescribe addictive drugs (referred to in this paragraph as 'prescribers') who may write prescriptions for such drugs for such beneficiary; and

"(II) one or more pharmacies that may dispense such drugs to such beneficiary.

"(ii) REASONABLE ACCESS.—In making the selection under this subparagraph, a PDP sponsor shall ensure that the beneficiary continues to have reasonable access to drugs described in subparagraph (G), taking into account geographic location, beneficiary preference, affordability, and reasonable travel time.

"(iii) BENEFICIARY PREFERENCES.—

"(I) IN GENERAL.—If an at-risk beneficiary for prescription drug ad-

diction submits preferences for which in-network prescribers and pharmacies the beneficiary would prefer the PDP sponsor select in response to a notice under subparagraph (B), the PDP sponsor shall—

"(aa) review such preferences;

"(bb) select or change the selection of a prescriber or pharmacy for the beneficiary based on such preferences; and

"(cc) inform the beneficiary of such selection or change of selection.

"(II) EXCEPTION.—In the case that the PDP sponsor determines that a change to the selection of a prescriber or pharmacy under item (bb) by the PDP sponsor is contributing or would contribute to prescription drug addiction or drug diversion by the beneficiary, the PDP sponsor may change the selection of a prescriber or pharmacy for the beneficiary without

regard to the preferences of the beneficiary described in subclause (I).

''(iv) CONFIRMATION.—Before selecting a prescriber or pharmacy under this subparagraph, a PDP sponsor must request and receive confirmation from the prescriber or pharmacy acknowledging and accepting that the beneficiary involved is in the drug management program for at-risk beneficiaries.

''(E) TERMINATIONS AND APPEALS.—The identification of an individual as an at-risk beneficiary for prescription drug addiction under this paragraph, a coverage determination made under a drug management program for at-risk beneficiaries, and the selection of a prescriber or pharmacy under subparagraph (D) with respect to such individual shall be subject to reconsideration and appeal under subsection (h) and the option of an automatic escalation to external review to the extent provided by the Secretary.

''(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 addiction 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 addiction 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 addiction 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) ADDICTIVE DRUG.—For purposes of this subsection, the term 'addictive drug' means a drug that is determined by the Secretary to be addictive or frequently diverted and that is—

"(i) a Controlled Drug Substance in Schedule CII–CIV;

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

"(iii) within another class or category of drugs that the Secretary determines, in consultation with the Inspector General of the Department of Health and Human Services, is at high risk for diversion or addiction.

"(H) DATA DISCLOSURE.—In the case of an at-risk beneficiary for prescription drug addiction whose access to coverage for addictive drugs under a prescription drug plan has been limited by a PDP sponsor under this paragraph, such PDP sponsor shall disclose data, including any necessary individually identifiable health information, in a form and manner specified by the Secretary, about the decision to im-

pose such limitations and the limitations imposed by the sponsor under this part.

''(I) EDUCATION.—The Secretary shall provide education to enrollees in prescription drug plans of PDP sponsors and providers regarding the drug management program for at-risk beneficiaries described in this paragraph, including education—

''(i) provided by Medicare administrative contractors through the improper payment outreach and education program described in section 1874A(h); and

''(ii) through current education efforts (such as State health insurance assistance programs described in subsection (a)(1)(A) of section 119 of the Medicare Improvements for Patients and Providers Act of 2008 (42 U.S.C. 1395b–3 note)) and materials directed toward such enrollees.''.

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

"(v) The drug management program for at-risk beneficiaries under subsection (c)(4).".

(b) UTILIZATION MANAGEMENT PROGRAMS.—Section 1860D–4(c) of the Social Security Act (42 U.S.C. 1395w–104(c)), as amended by subsection (a), is amended—

(1) in paragraph (1), by inserting after subparagraph (D) the following new subparagraph:

"(E) A utilization management tool to prevent drug addiction (as described in paragraph (5)(A)).''; and

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

"(5) UTILIZATION MANAGEMENT TOOL TO PREVENT DRUG ADDICTION.—

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

"(i) A utilization tool designed to prevent addiction to addictive drugs by individuals and to prevent the diversion of such drugs at pharmacies.

"(ii) Retrospective utilization review to identify—

"(I) individuals that receive addictive drugs at a frequency or in amounts that are not clinically appropriate; and

"(II) providers of services or suppliers that may facilitate the addiction to or diversion of addictive drugs by beneficiaries.

"(iii) Consultation with the Contractor described in subparagraph (B) to verify if an individual enrolling in a prescription drug plan offered by a PDP sponsor has been previously identified by another PDP sponsor as an individual described in clause (ii)(I).

"(B) REPORTING.—A PDP sponsor offering a prescription drug plan in a State shall submit to the Secretary and the Medicare drug integrity contractor with which the Secretary has entered into a contract under section 1893 with respect to such State a report, on a monthly basis, containing information on—

"(i) any provider of services or supplier described in subparagraph (A)(ii)(II) that is identified by such plan sponsor dur-

ing the 30-day period before such report is submitted; and

"(ii) the name and prescription records of individuals described in paragraph (4)(C).".

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

"(j) EXPANDING ACTIVITIES OF MEDICARE DRUG INTEGRITY CONTRACTORS (MEDICS).—

"(1) ACCESS TO INFORMATION.—Under contracts entered into under this section with Medicare drug integrity contractors, the Secretary shall authorize such contractors to directly accept prescription and necessary medical records from entities such as pharmacies, prescription drug plans, and physicians with respect to an individual in order for such contractors to provide information relevant to the determination of whether such individual is an at-risk beneficiary for prescription drug addiction, as defined in section 1860D–4(c)(4)(C).

"(2) REQUIREMENT FOR ACKNOWLEDGMENT OF REFERRALS.—If a PDP sponsor refers information to a contractor described in paragraph (1) in

order for such contractor to assist in the determination described in such paragraph, the contractor shall—

"(A) acknowledge to the PDP sponsor receipt of the referral; and

"(B) in the case that any PDP sponsor contacts the contractor requesting to know the determination by the contractor of whether or not an individual has been determined to be an individual described such paragraph, shall inform such PDP sponsor of such determination on a date that is not later than 15 days after the date on which the PDP sponsor contacts the contractor.

"(3) MAKING DATA AVAILABLE TO OTHER ENTITIES.—

"(A) IN GENERAL.—For purposes of carrying out this subsection, subject to subparagraph (B), the Secretary shall authorize MEDICs to respond to requests for information from PDP sponsors, State prescription drug monitoring programs, and other entities delegated by PDP sponsors using available programs and systems in the effort to prevent fraud, waste, and abuse.

''(B) HIPAA COMPLIANT INFORMATION ONLY.—Information may only be disclosed by a MEDIC under subparagraph (A) if the disclosure of such information is permitted under the Federal regulations (concerning the privacy of individually identifiable health information) promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).''.

(d) TREATMENT OF CERTAIN COMPLAINTS FOR PURPOSES OF QUALITY OR PERFORMANCE ASSESSMENT.—Section 1860D–42 of the Social Security Act (42 U.S.C. 1395w–152) is amended by adding at the end the following new subsection:

''(d) TREATMENT OF CERTAIN COMPLAINTS FOR PURPOSES OF QUALITY OR PERFORMANCE ASSESSMENT.—In conducting a quality or performance assessment of a PDP sponsor, the Secretary shall develop or utilize existing screening methods for reviewing and considering complaints that are received from enrollees in a prescription drug plan offered by such PDP sponsor and that are complaints regarding the lack of access by the individual to prescription drugs due to a drug management program for at-risk beneficiaries.''.

(e) GAO STUDIES AND REPORTS.—

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

(A) The implementation of the amendments made by this section.

(B) The effectiveness of the at-risk beneficiaries for prescription drug addiction drug management programs authorized by section 1860D–4(c)(4) of the Social Security Act (42 U.S.C. 1395w–10(c)(4)), as added by subsection (a)(1), including an analysis of—

(i) the impediments, if any, that impair the ability of individuals described in subparagraph (C) of such section 1860D–4(c)(4) to access clinically appropriate levels of prescription drugs; and

(ii) 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.

(2) REPORTS.—Not later than January 1, 2017, the Comptroller General of the United States shall begin work, with respect to each study described in paragraph (1), on a report that describes the result of such study. Upon the completion of each such report, such Comptroller General shall submit the report to each of the committees described in paragraph (3).

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

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

(B) The Committee on Energy and Commerce of the House of Representatives.

(C) The Committee on Finance of the Senate.

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

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

(f) EFFECTIVE DATE.—

(1) IN GENERAL.—The amendments made by this section shall apply to prescription drug plans for plan years beginning on or after January 1, 2018.

(2) STAKEHOLDER MEETINGS PRIOR TO EFFECTIVE DATE.—

(A) IN GENERAL.—Not later than January 1, 2017, the Secretary 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, and entities delegated by plan sponsors, for input regarding the topics described in subparagraph (B).

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

(i) ensuring affordability and accessibility to prescription drugs for enrollees in prescription drug plans of PDP sponsors who are at-risk beneficiaries for prescription drug addiction (as defined in paragraph (4)(C) of section 1860D–4(c) of the Social Security Act (42 U.S.C. 1395w–10(c)), as added by subsection (a)(1));

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

an at-risk beneficiary for prescription drug addiction under such paragraph (similar to the processes established under the Medicare Advantage program under part C of title XVIII of the Social Security Act that allow an automatic escalation to external review of claims submitted under such part);

(iii) the types of enrollees that should be treated as exempted individuals, as described in clause (ii) of such paragraph;

(iv) the manner in which terms and definitions in paragraph (4) of such section 1860D–4(c) should be applied, such as the use of clinical appropriateness in determining whether an enrollee is an at-risk beneficiary for prescription drug addiction as defined in subparagraph (C) of such paragraph (4);

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

(vi) with respect to a PDP sponsor that establishes a drug management pro-

gram for at-risk beneficiaries under such paragraph (4), the responsibilities of such PDP sponsor with respect to the implementation of such program.

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

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