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114TH CONGRESS
2D SESSION

H. R. 4876

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

IN THE HOUSE OF REPRESENTATIVES

MARCH 23, 2016

Mr. MEEHAN (for himself and Mr. NEAL) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

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

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 ''Medicare Prescription Drug Abuse Prevention Act of 2016''.

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

(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–104(c)) is amended by adding at the end the following:

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

''(B) REQUIREMENT FOR NOTICES.—

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

eficiary for prescription drug abuse to coverage for frequently abused 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 abuse, as described in subparagraph (C)(iv).

''(ii) INITIAL NOTICE.—An initial written 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 abuse;

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

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

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

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

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

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;

''(VI) contact information for other organizations that can provide the beneficiary with information regarding drug management program for at-risk beneficiaries (similar to the information provided by the Secretary in other standardized notices to part D eligible individuals enrolled in prescription drug plans under this part); and

''(VII) notice that the beneficiary has a right to an appeal pursuant to subparagraph (E).

''(iii) SECOND NOTICE.—A second written 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 abuse;

''(II) that such beneficiary has been sent, or informed of, such identification in the initial notice and is now 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 right of the beneficiary to a reconsideration and an appeal under subsection (h) of such identification and the prescribers and pharmacies selected;

''(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), sub-

mit such preferences to the PDP sponsor; and

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

''(iv) TIMING OF NOTICES.—

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

''(II) EXCEPTION.—In the case that the PDP sponsor, in conjunction with the Secretary, determines that concerns identified through 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.

''(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 section 2(g)(2)(A) of the Medicare Prescription Drug Abuse Prevention Act of 2016 based on clinical factors indi-

cating misuse or abuse of prescription drugs described in subparagraph (G), including dosage, quantity, duration of use, number of and reasonable access to prescribers, and number of and reasonable access to 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 1905(d), or other facility under contract with a single pharmacy; or

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

''(iii) PROGRAM SIZE.—The Secretary shall establish policies, including the criteria developed under clause (i)(I) and the exemptions under clause (ii)(III), to ensure that the population of enrollees in a drug management program for at-risk beneficiaries operated by a prescription drug plan can be effectively managed by such plans.

''(iv) CLINICAL CONTACT.—With respect to each at-risk beneficiary for prescription drug abuse enrolled in a prescription drug plan offered by a PDP sponsor, the PDP sponsor shall contact the beneficiary's providers who have prescribed frequently abused drugs regarding whether prescribed medications are appropriate for such beneficiary's medical conditions.

''(D) SELECTION OF PRESCRIBERS.—

''(i) IN GENERAL.—With respect to each at-risk beneficiary for prescription drug abuse 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)(III) and (iii)(V) of subparagraph (B) if applicable, select—

''(I) one, or, if the PDP sponsor reasonably determines it necessary to provide the beneficiary with reasonable access under clause (ii), more than one, individual who is authorized to prescribe frequently abused drugs (referred to in this paragraph as a 'prescriber') who may write prescriptions for such drugs for such beneficiary; and

''(II) one, or, if the PDP sponsor reasonably determines it necessary to provide the beneficiary with reasonable access under clause (ii), more

than one, pharmacy that may dispense such drugs to such beneficiary.

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

''(I) for individuals with multiple residences; and

''(II) in the case of natural disasters and similar emergency situations.

''(iii) BENEFICIARY PREFERENCES.—

''(I) IN GENERAL.—If an at-risk beneficiary for prescription drug abuse 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 abuse or drug diversion by the beneficiary, the PDP sponsor may change the selection of a prescriber or pharmacy for the beneficiary. If the PDP sponsor changes the selection pursuant to the preceding sentence, the PDP sponsor shall provide the beneficiary with—

"(aa) at least 30 days written notice of the change of selection; and

"(bb) a rationale for the change.

"(III) TIMING.—An at-risk beneficiary for prescription drug abuse may choose to express their prescriber and pharmacy preference and communicate such preference to their PDP sponsor at any date while enrolled in the program, including after a second notice under subparagraph (B)(iii) has been provided.

"(iv) CONFIRMATION.—Before selecting a prescriber or pharmacy under this subparagraph, a PDP sponsor must notify the prescriber and pharmacy that the beneficiary involved has been identified for inclusion in the drug management program for at-risk beneficiaries and that the prescriber and pharmacy has been selected as the beneficiary's designated prescriber and pharmacy.

"(E) APPEALS.—The identification of an individual as an at-risk beneficiary for prescription drug abuse 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 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 establish rules and procedures to require such PDP sponsor to disclose data, including necessary individually identifiable health information, about the decision to impose such limitations and the limitations imposed by the PDP sponsor under this part.

"(ii) DATA TO REDUCE FRAUD, ABUSE, AND WASTE.—The Secretary shall establish rules and procedures to require PDP sponsors operating a drug management program for at-risk beneficiaries under this paragraph to provide the Secretary with such data as the Secretary determines appropriate for purposes of identifying patterns of prescription drug utili-

zation for plan enrollees that are outside normal patterns and that may indicate fraudulent, medically unnecessary, or unsafe use.

''(I) SHARING OF INFORMATION FOR SUBSEQUENT PLAN ENROLLMENTS.—The Secretary shall establish procedures under which PDP sponsors who offer prescription drug plans shall share information with respect to individuals who are at-risk beneficiaries for prescription drug abuse (or individuals who are potentially at-risk beneficiaries for prescription drug abuse) and enrolled in a prescription drug plan and who subsequently disenroll from such plan and enroll in another prescription drug plan offered by another PDP sponsor.

''(J) PRIVACY ISSUES.—Prior to the implementation of the rules and procedures under this paragraph, the Secretary shall clarify privacy requirements, including requirements under the regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of (42 U.S.C. 1320d–2 note), related to the sharing of data under subparagraphs (H) and (I) by PDP

sponsors. Such clarification shall provide that the sharing of such data shall be considered to be protected health information in accordance with the requirements of the regulations promulgated pursuant to such section 264(c).

''(K) 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 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.

''(L) CMS COMPLIANCE REVIEW.—The Secretary shall ensure that existing plan sponsor compliance reviews and audit processes include the drug management programs for at-

risk beneficiaries under this paragraph, including appeals processes under such programs.''.

(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)(5).''.

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

(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)(1), is amended—

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

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

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

''(6) UTILIZATION MANAGEMENT TOOL TO PREVENT DRUG ABUSE.—

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

''(i) A utilization tool designed to prevent the abuse of frequently abused drugs by individuals and to prevent the diversion of such drugs at pharmacies.

''(ii) Retrospective utilization review to identify—

''(I) individuals that receive frequently abused drugs at a frequency or in amounts that are not clinically appropriate; and

''(II) providers of services or suppliers that may facilitate the abuse or diversion of frequently abused 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 during the 30-day period before such report is submitted; and

''(ii) the name and prescription records of individuals described in paragraph (5)(C).

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

(c) 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.''.

(d) SENSE OF CONGRESS REGARDING USE OF TECHNOLOGY TOOLS TO COMBAT FRAUD.—It is the sense of Congress that MA organizations and PDP sponsors should consider using e-prescribing and other health information technology tools to support combating fraud under MA–PD plans and prescription drug plans under parts C and D of the Medicare program.

(e) GAO STUDY AND REPORT.—

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

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

(A) the impediments, if any, that impair the ability of individuals described in subparagraph (C) of such section D–4(c)(5) to access clinically appropriate levels of prescription drugs;

(B) the effectiveness of the reasonable access protections under subparagraph (D)(ii) of such section 1860D–4(c)(5), including the impact on beneficiary access and health;

(C) how best to define the term ''designated pharmacy'', including whether the definition of such term should include an entity that is comprised of a number of locations that are under common ownership and that electronically share a real-time, online database and whether such a definition would help to protect and improve beneficiary access;

(D) 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;

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

(F) 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) IN GENERAL.—Not later than 12 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to the appropriate committees of jurisdiction of Congress a report on ways to improve upon the appeals process for Medicare beneficiaries with respect to

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

(2) FEEDBACK.—In development of the report described in paragraph (1), the Secretary of Health and Human Services shall solicit feedback on the current appeals process from stakeholders, such as beneficiaries, consumer advocates, plan sponsors, pharmacy benefit managers, pharmacists, providers, independent review entity evaluators, and pharmaceutical manufacturers.

(g) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided in subsection (d)(2), 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 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). The input described in the preceding sentence shall be provided to the Secretary in sufficient time in order for the Secretary to take such input into account in promulgating the regulations pursuant to subparagraph (C).

(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–104(c)));

(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 abuse under such paragraph (similar to the

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

(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 (5) 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 abuse as defined in subparagraph (C) of such paragraph (5);

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

(vi) with respect to a PDP sponsor that establishes a drug management program for at-risk beneficiaries under such paragraph (5), the responsibilities of such PDP sponsor with respect to the implementation of such program;

(vii) notices for plan enrollees at the point of sale that would explain why an at-risk beneficiary has been prohibited from receiving a prescription at a location outside of the designated pharmacy;

(viii) evidence-based prescribing guidelines for opiates; and

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

(C) RULEMAKING.—The Secretary of Health and Human Services shall, taking into account the input gathered pursuant to subparagraph (A) and after providing notice and an opportunity to comment, promulgate regulations to carry out the provisions of, and amendments made by subsections (a) and (b).

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