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114TH CONGRESS
1ST SESSION

H. R. 2298

To amend title XVIII of the Social Security Act to provide for programs to prevent prescription drug abuse under parts C and D of the Medicare program.

IN THE HOUSE OF REPRESENTATIVES

MAY 13, 2015

Mr. BILIRAKIS (for himself, Mr. BEN RAY LUJÁN of New Mexico, and Mr. LONG) 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 amend title XVIII of the Social Security Act to provide for programs to prevent prescription drug abuse under parts C and D of the Medicare program.

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 Patient Safety and Drug Abuse Prevention Act''.

SEC. 2. PROGRAMS TO PREVENT PRESCRIPTION DRUG ABUSE UNDER MEDICARE PARTS C AND 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:

"(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 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 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.

''(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 abuse;

''(II) information describing all State and Federal public health resources that are designed to address prescription drug abuse to which the beneficiary has access, including men-

tal 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 abuse 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 abuse, 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 abuse;

''(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 rule-making by the Secretary regarding the health or safety of the beneficiary or regarding significant drug diversion activities require the PDP sponsor to provide a second notice described in 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 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 the use of clinical guidelines developed by the Secretary in consultation with PDP sponsors and other stakeholders described in subsection (f)(2)(A); 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 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 de-

scribed in this clause is an individual who—

"(I) an individual who receives hospice care under this title; or

"(II) an individual, such as an individual who is a resident of a long-term care facility, who 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 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)(IV) and (iii)(V) of subparagraph (B), select—

"(I) one or more individuals who are authorized to prescribe frequently abused 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, impact on cost-sharing, and reasonable travel time.

"(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 phar-

macy 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 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 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 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 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 a controlled substance that the Secretary determines to be frequently abused or diverted.

"(H) DATA DISCLOSURE.—In the case of an 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, 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 impose 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.

''(J) APPLICATION UNDER MA–PD PLANS.—Pursuant to section 1860D–21(c)(1), the provisions of this paragraph apply under

part D to MA organizations offering MA–PD plans to MA eligible individuals in the same manner as such provisions apply under this part to a PDP sponsor offering a prescription drug plan to a part D eligible individual.''.

(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).''.

(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 further 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 (6)(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 (and an MA orga-

nization offering an MA–PD 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 (or organization) 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) EXPANDING ACTIVITIES OF MEDICARE DRUG INTEGRITY CONTRACTORS (MEDICS).—

(1) IN GENERAL.—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 prescrip-

tion and necessary medical records from entities such as pharmacies, prescription drug plans, MA–PD 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 abuse, as defined in section 1860D–4(c)(5)(C).

''(2) REQUIREMENT FOR ACKNOWLEDGMENT OF REFERRALS.—If a PDP sponsor or MA organization 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 sponsor or organization receipt of the referral; and

''(B) in the case that any PDP sponsor or MA organization 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 sponsor or organization of such determination on a date that is not later than 15 days after the date on which

the sponsor or organization 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 and MA organizations, State prescription drug monitoring programs, and other entities delegated by such sponsors or organizations 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).''.

(2) OIG STUDY AND REPORT ON EFFECTIVENESS OF MEDICS.—

(A) STUDY.—The Inspector General of the Department of Health and Human Services shall conduct a study on the effectiveness of Medicare drug integrity contractors in identifying combating, and preventing fraud under the Medicare program, including under the authority provided under section 1893(j) of the Social Security Act, as added by paragraph (1).

(B) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Inspector General shall submit to Congress a report on the study conducted under subparagraph (A). Such report shall include such recommendations for improvements in the effectiveness of such contractors as the Inspector General determines appropriate.

(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) 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.

(f) EFFECTIVE DATE.—

(1) IN GENERAL.—The amendments made by this section shall apply to prescription drug plans (and MA–PD plans) for plan years beginning more than 1 year after the date of the enactment of this Act.

(2) STAKEHOLDER MEETINGS PRIOR TO EFFECTIVE DATE.—

(A) IN GENERAL.—Not later than January 1, 2016, 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, entities delegated by plan sponsors, and biopharmaceutical manufacturers for input regarding the topics described in subparagraph (B).

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

(i) the impact on cost-sharing and ensuring accessibility to prescription drugs for enrollees in prescription drug plans of PDP sponsors, and enrollees in MA–PD plans, who are at-risk beneficiaries for prescription drug abuse (as defined in subparagraph (C) of paragraph (5) 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 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 subparagraph (C)(ii) of such paragraph;

(iv) the manner in which terms and definitions in such paragraph 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;

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

(vi) with respect to a PDP sponsor (or Medicare Advantage organization) that establishes a drug management program for at-risk beneficiaries under such paragraph, the responsibilities of such PDP sponsor (or organization) with respect to the implementation of such program.

(g) RULEMAKING.—The Secretary of Health and Human Services shall promulgate regulations based on the input gathered pursuant to subsection (f)(2)(A).

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