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113TH CONGRESS
1ST SESSION

H. R. 3392

To amend title XVIII of the Social Security Act to provide for a PDP safety program to prevent fraud and abuse in the dispensing of controlled substances under part D of the Medicare program, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 30, 2013

Mr. BILIRAKIS (for himself and Mr. BEN RAY LUJÁN of New Mexico) 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 a PDP safety program to prevent fraud and abuse in the dispensing of controlled substances under part D of 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; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Medicare Part D Patient Safety and Drug Abuse Prevention Act of 2013''.

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

SEC. 2. ESTABLISHING PDP SAFETY PROGRAM TO PREVENT FRAUD AND ABUSE IN MEDICARE PRESCRIPTION DRUG PLANS.

(a) PDP SAFETY PROGRAM.—Section 1860D–4(c) of the Social Security Act (42 U.S.C. 1395w–104(c)) is amended—

(1) in paragraph (1)(D)—

(A) by inserting ", designed to" after "program"; and

(B) by inserting ", that includes the procedures described in paragraph (4)" after "waste"; and

(2) by adding at the end the following:

"(4) SAFE PHARMACY ACCESS PROGRAM.—

"(A) PDP SPONSOR PROCEDURES.—A PDP sponsor (or an MA organization offering an MA–PD plan) shall have in place procedures designed—

"(i) to identify an individual who has obtained coverage for a covered part D

drug that is a frequently abused schedule II, III, IV, or V controlled substance, as determined in accordance with utilization guidelines established by the Secretary and the sponsor (or MA organization), and to notify such individuals that they have been so identified;

''(ii) to contract with pharmacies authorized to dispense such controlled substances to create a safe pharmacy network that meets the criteria specified in subparagraph (C);

''(iii) taking into account the location of the individual's residence (or residences), work site, mobility, and other relevant factors, to limit coverage to schedule II, III, IV, or V controlled substances for some or all classes of covered part D drugs for an individual identified under clause (i) (or under subparagraph (B)) to drugs dispensed by one or more pharmacies contracted with under clause (ii);

''(iv) to provide to the Secretary the name, and other information that the Secretary may require, of individuals so iden-

tified and of the fact of such individual's disenrollment (if any) from the plan of the sponsor (or the MA–PD plan offered by the MA organization);

''(v) to provide for an appeals process whereby an individual so identified may appeal such identification on the basis that the identification was not appropriate;

''(vi) to provide for a process whereby an individual so identified may petition for the termination of such identification on the basis that the limitation on coverage is no longer necessary to prevent fraud and abuse by the individual; and

''(vii) to provide that coverage shall be provided for a schedule II, III, IV, or V controlled substance only if it prescribed in accordance with an electronic prescribing program under subsection (e), except in such exceptional circumstances as the Secretary may permit.

''(B) SHARING INFORMATION FOR SUBSEQUENT PLAN ENROLLMENTS.—The Secretary shall share information, with respect to the identity of an individual identified under sub-

paragraph (A)(i) who disenrolls from a plan under subparagraph (A)(iv), with a PDP sponsor (or MA organization) that subsequently enrolls such individual under another plan in order that the provisions of subparagraph (A)(iii) would apply under such subsequent enrollment.

''(C) SAFE PHARMACY NETWORK CRITERIA.—The criteria specified in this subparagraph for a safe pharmacy network are the following:

''(i) The pharmacies in the network are able to properly monitor the usage of schedule II, III, IV, and V controlled substances.

''(ii) Such pharmacies and network meet such other drug safety criteria as the Secretary or the PDP sponsor (or MA organization) determines to be appropriate, such as use of a State prescription drug monitoring program, if such a program is available in the State.''.

(b) 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 1860D–4(c)(4)(A)(i)'' after ''the Secretary''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to plan years beginning after the date that is 8 months after the date of the enactment of this Act.

SEC. 3. PART D SUSPENSION OF CLAIMS PAYMENT.

Amend 1860D–12(b)(4) of the Social Security Act (42 U.S.C. 1395w–112(b)(4)) is amended by adding at the end the following new subparagraph:

''(H) SUSPENSION OF PAYMENTS PENDING INVESTIGATION OF CREDIBLE ALLEGATIONS OF FRAUD BY PHARMACIES.—

''(i) IN GENERAL.—A PDP sponsor may suspend payments and clean claim notifications to a pharmacy pending an investigation of a credible allegation of fraud (as defined in clause (ii)) against the pharmacy, unless the Secretary determines there is a good cause not to suspend payments.

''(ii) CREDIBLE ALLEGATION OF FRAUD DEFINED.—In this subparagraph, the term 'credible allegation of fraud' includes—

''(I) a complaint made on the Medicare fraud hotline;

''(II) detection of potential fraud through the analysis of claims data;

''(III) detection of potential fraud through identification of inappropriate dispensing through audits, civil false claims cases, and law enforcement investigations; and

''(IV) claims referred to Medicare drug integrity contractors (MEDICs).

''(iii) RULE OF CONSTRUCTION.—Nothing in this subparagraph shall be construed as limited the authority of a PDP sponsor to conduct post-claim payment review.''.

SEC. 4. IMPROVING ACTIVITIES OF MEDICARE DRUG INTEGRITY CONTRACTORS (MEDICS).

(a) 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) IMPROVING ACTIVITIES OF MEDICARE DRUG INTEGRITY CONTRACTORS (MEDICS).—

''(1) ACCESS TO IN GENERAL.—Under contracts entered into under this section (each in this

subsection referred to as a 'MEDIC contract') with Medicare drug integrity contractors (each in this subsection referred to as a 'MEDIC'), the Secretary shall authorize MEDICs to directly obtain prescription and medical records from entities such as pharmacies, PDP and physicians.

''(2) REQUIREMENT FOR ACKNOWLEDGMENT OF REFERRALS.—If a PDP sponsor refers information to a MEDIC for investigation, under the MEDIC contract the MEDIC must acknowledge receipt of the referral and must report back to the sponsor the result of the MEDIC's investigation within 45 days of the date of the referral and share such results with appropriate agencies, such as law enforcement officials and State licensing authority.

''(3) UNIFORM ANNUAL REPORT CRITERIA.—In order to assess the performance of MEDICs, the Secretary shall develop a uniform reporting criteria for the annual reporting of the results of investigations by MEDICs to the Secretary and to Congress. Each such annual report shall include information on the number of referrals for investigation made to a MEDIC, the average time required for investigation, the results of the investigation, and the number of results that were referred to the Inspector Gen-

eral of the Department of Health and Human Services and to State licensing officials for further investigations.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on the date of the enactment of this Act and shall apply as quickly as possible to MEDIC contracts, including MEDIC contracts entered into before such date of enactment.

SEC. 5. REQUIRING E-PRESCRIBING FOR COVERAGE OF COVERED PART D CONTROLLED SUBSTANCES.

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

''(7) REQUIREMENT OF E-PRESCRIBING FOR CONTROLLED SUBSTANCES.—Except in such emergent circumstances as the Secretary may specify, coverage shall not be provided for a covered part D drug under a prescription drug plan (or under an MA–PD plan) for a schedule II, III, IV, or V controlled substance unless the prescription for the drug has been transmitted electronically in accordance with an electronic prescription drug program that meets the requirements of paragraph (2).''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to coverage of drugs prescribed on or after January 1, 2015.

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