113TH CONGRESS
1ST SESSION

S. 867

To amend title XVIII of the Social Security Act to provide for pharmacy benefits manager standards under the Medicare prescription drug program, to establish basic audit standards of pharmacies, to further transparency of payment methodology to pharmacies, and to provide for recoupment returns to Medicare.

IN THE SENATE OF THE UNITED STATES

MAY 6, 2013

Mr. PRYOR (for himself, Mr. MORAN, Mr. WICKER, and Mr. BOOZMAN) introduced the following bill; which was read twice and referred to the Committee on Finance

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A BILL

To amend title XVIII of the Social Security Act to provide for pharmacy benefits manager standards under the Medicare prescription drug program, to establish basic audit standards of pharmacies, to further transparency of payment methodology to pharmacies, and to provide for recoupment returns to Medicare.

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 Program Integrity and Transparency Act of 2013''.

SEC. 2. PHARMACY BENEFITS MANAGER STANDARDS UNDER THE MEDICARE PROGRAM.

(a) IN GENERAL.—Section 1860D–12(b) of the Social Security Act (42 U.S.C. 1395w–112(b)) is amended by adding at the end the following new paragraphs:

''(7) PHARMACY BENEFITS MANAGER TRANSPARENCY AND PROPER OPERATIONS REQUIREMENTS.—

''(A) IN GENERAL.—Each contract entered into with a PDP sponsor under this part with respect to a prescription drug plan offered by such sponsor shall provide that the PDP may not enter into a contract with any pharmacy benefits manager (referred to in this paragraph as a 'PBM') to manage the prescription drug coverage provided under such plan, or to control the costs of the prescription drug coverage under such plan, unless the PBM satisfies the requirements described in subparagraph (B).

''(B) REQUIREMENTS.—The requirements described in this subparagraph are as follows:

''(i) PROPER AUDIT PROCEDURES.—The following shall apply to each audit of a pharmacy conducted by or for the pharmacy benefits manager with respect to such prescription drug plan:

"(I) ASSURING RECOVERIES TO MEDICARE.—

"(aa) The PBM (or auditing entity) shall disclose the amount of each payment recovered pursuant to the audit to the PDP sponsor with a copy to the pharmacy.

"(bb) Any payment recovered by the PBM (or auditing entity) pursuant to the audit shall be returned to the PDP sponsor.

"(II) ASSURING CLINICAL DECISIONS IN AUDITS.—

"(aa) In the case the audit involves clinical or professional judgment, the audit shall be conducted by, or in consultation with, a pharmacist licensed in the State of the audit or the State board of pharmacy.

"(bb) The pharmacy, practice site, or other entity may use a nursing home's medication administration record (MAR), the

records of a hospital, physician, rehabilitation facility, State-licensed healthcare facility, or other authorized practitioner to validate the pharmacy records and any legal prescription (one that complies with State Board of Pharmacy requirements) may be used to validate claims submitted by the pharmacy in connection with prescriptions, refills, proof of delivery, or changes in prescriptions during any phase of the audit, including appeal.

''(III) ASSURING PROPER PROCEDURES.—

''(aa) The PBM (or auditing entity) may not apply record-keeping or other requirements on the pharmacy that are more stringent than such requirements applied under Federal law or the State law involved.

''(bb) The PBM (or auditing entity) shall accept all pharmacy

prescription records related to the audit in an electronic format or other digital media.

''(cc) The PBM (or auditing entity) may not, pursuant to the audit, disallow the entire payment with respect to a claim submitted by the pharmacy because of a clerical or recordkeeping error (such as a typographical error, scrivener's error, or computer error) if there is an absence of intent to commit fraud, as defined in section 1347 of title 18, United States Code. In the case of errors that have no financial harm to the patient or plan, the PBM shall not assess any chargebacks.

''(dd) The PBM (or auditing entity) may not use extrapolation or other statistical expansion techniques in calculating any recoupment or penalty pursuant to the audit.

"(ee) The period covered by the audit may not exceed 2 years from the date the claim involved was submitted to, or adjusted by, the PBM (or auditing entity).

"(ff) The PBM (or auditing entity) shall have in place a written appeals process that affords the pharmacy a minimum of 60 days to respond to the auditor findings, shall include procedures for appeals from preliminary reports and final reports related to such audit, and shall permit the pharmacy to introduce any documentation which would validate a claim contested in the audit until the final written decision is issued on appeal.

"(ii) BUSINESS PRACTICE PREDICTABILITY.—A PBM shall provide a particular aggregate average reimbursement rate for generics or a maximum average discount off of an accepted pharmaceutical pricing benchmark for multi-source

generics as a whole (often referred to as a 'generic effective rate') and provide a process for the generic effective rate to be appealed. For the purposes of this rate or benchmark amount, the PBM shall utilize a pharmaceutical pricing benchmark published by a nationally available compendium. The aggregate average reimbursement rate for generics (generic effective rate) shall be calculated using the actual amount paid to the pharmacy (typically the amount of reimbursement to the PBM plus the patient co-pay), excluding the dispensing fee, shall not be calculated solely according to the amount allowed by the plan, and shall include all generics dispensed, regardless of whether they are subject to MAC pricing.

''(iii) PROTECTING PATIENT AND CLAIMS RELATED DATA.—A PBM shall adhere to the following criteria when handling personally identifiable utilization and claims data or other sensitive patient data:

''(I) A PBM may not transmit any personally identifiable utilization

or claims data to a pharmacy owned by a PBM if the plan enrollee has not voluntarily elected in writing or via secure electronic means to fill that particular prescription at the PBM-owned pharmacy.

''(II) A PBM may not require that a plan enrollee use a retail pharmacy, mail order pharmacy, specialty pharmacy, or other pharmacy entity providing pharmacy services in which the PBM has an ownership interest or that has an ownership interest in the PBM or provide an incentive to a beneficiary to encourage the individual to use a retail pharmacy, mail order pharmacy, specialty pharmacy, or other pharmacy entity providing pharmacy services in which the PBM has an ownership interest or that has an ownership interest in the PBM, if the incentive is applicable only to such pharmacies.''.

(b) DISCLOSURE AND REGULAR UPDATE OF PRESCRIPTION DRUG REIMBURSEMENT.—Section 1860D–

12(b) of the Social Security Act (42 U.S.C. 1395w–112(b)) is amended to read as follows:

''(6) DISCLOSURE AND REGULAR UPDATE OF PRESCRIPTION DRUG REIMBURSEMENT.—Each contract entered into with a PDP sponsor under this part with respect to a prescription drug plan offered by such sponsor shall provide that the sponsor or subcontractor of such sponsor shall—

''(A) disclose to a pharmacy, at the time when a contract is offered, the methodology and actual per unit reimbursement amount for each covered drug for each such pharmacy; and

''(B) not less frequently than once every 7 days, beginning with an initial update on January 1 of each year—

''(i) update such reimbursement amount to accurately reflect the market price of acquiring the drug; and

''(ii) disclose to each contracted pharmacy such methodology and reimbursement amounts.''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to plan years beginning on or after January 1, 2015.

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