

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

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Medicare Prescription
5 Drug Program Integrity and Transparency Act of 2013”.

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

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

6 “(7) PHARMACY BENEFITS MANAGER TRANS-
7 PARENCY AND PROPER OPERATIONS REQUIRE-
8 MENTS.—

9 “(A) IN GENERAL.—Each contract entered
10 into with a PDP sponsor under this part with
11 respect to a prescription drug plan offered by
12 such sponsor shall provide that the PDP may
13 not enter into a contract with any pharmacy
14 benefits manager (referred to in this paragraph
15 as a ‘PBM’) to manage the prescription drug
16 coverage provided under such plan, or to con-
17 trol the costs of the prescription drug coverage
18 under such plan, unless the PBM satisfies the
19 requirements described in subparagraph (B).

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

22 “(i) PROPER AUDIT PROCEDURES.—
23 The following shall apply to each audit of
24 a pharmacy conducted by or for the phar-
25 macy benefits manager with respect to
26 such prescription drug plan:

1 “(I) ASSURING RECOVERIES TO
2 MEDICARE.—

3 “(aa) The PBM (or auditing
4 entity) shall disclose the amount
5 of each payment recovered pursu-
6 ant to the audit to the PDP
7 sponsor with a copy to the phar-
8 macy.

9 “(bb) Any payment recov-
10 ered by the PBM (or auditing en-
11 tity) pursuant to the audit shall
12 be returned to the PDP sponsor.

13 “(II) ASSURING CLINICAL DECI-
14 SIONS IN AUDITS.—

15 “(aa) In the case the audit
16 involves clinical or professional
17 judgment, the audit shall be con-
18 ducted by, or in consultation
19 with, a pharmacist licensed in the
20 State of the audit or the State
21 board of pharmacy.

22 “(bb) The pharmacy, prac-
23 tice site, or other entity may use
24 a nursing home’s medication ad-
25 ministration record (MAR), the

1 records of a hospital, physician,
2 rehabilitation facility, State-li-
3 censed healthcare facility, or
4 other authorized practitioner to
5 validate the pharmacy records
6 and any legal prescription (one
7 that complies with State Board
8 of Pharmacy requirements) may
9 be used to validate claims sub-
10 mitted by the pharmacy in con-
11 nection with prescriptions, refills,
12 proof of delivery, or changes in
13 prescriptions during any phase of
14 the audit, including appeal.

15 “(III) ASSURING PROPER PROCE-
16 DURES.—

17 “(aa) The PBM (or auditing
18 entity) may not apply record-
19 keeping or other requirements on
20 the pharmacy that are more
21 stringent than such requirements
22 applied under Federal law or the
23 State law involved.

24 “(bb) The PBM (or auditing
25 entity) shall accept all pharmacy

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

4 “(cc) The PBM (or auditing
5 entity) may not, pursuant to the
6 audit, disallow the entire pay-
7 ment with respect to a claim sub-
8 mitted by the pharmacy because
9 of a clerical or recordkeeping
10 error (such as a typographical
11 error, scrivener’s error, or com-
12 puter error) if there is an ab-
13 sence of intent to commit fraud,
14 as defined in section 1347 of title
15 18, United States Code. In the
16 case of errors that have no finan-
17 cial harm to the patient or plan,
18 the PBM shall not assess any
19 chargebacks.

20 “(dd) The PBM (or auditing
21 entity) may not use extrapolation
22 or other statistical expansion
23 techniques in calculating any
24 recoupment or penalty pursuant
25 to the audit.

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

6 “(ff) The PBM (or auditing
7 entity) shall have in place a writ-
8 ten appeals process that affords
9 the pharmacy a minimum of 60
10 days to respond to the auditor
11 findings, shall include procedures
12 for appeals from preliminary re-
13 ports and final reports related to
14 such audit, and shall permit the
15 pharmacy to introduce any docu-
16 mentation which would validate a
17 claim contested in the audit until
18 the final written decision is
19 issued on appeal.

20 “(ii) BUSINESS PRACTICE PREDICT-
21 ABILITY.—A PBM shall provide a par-
22 ticular aggregate average reimbursement
23 rate for generics or a maximum average
24 discount off of an accepted pharmaceutical
25 pricing benchmark for multi-source

1 generics as a whole (often referred to as a
2 ‘generic effective rate’) and provide a pro-
3 cess for the generic effective rate to be ap-
4 pealed. For the purposes of this rate or
5 benchmark amount, the PBM shall utilize
6 a pharmaceutical pricing benchmark pub-
7 lished by a nationally available compen-
8 dium. The aggregate average reimburse-
9 ment rate for generics (generic effective
10 rate) shall be calculated using the actual
11 amount paid to the pharmacy (typically the
12 amount of reimbursement to the PBM plus
13 the patient co-pay), excluding the dis-
14 pensing fee, shall not be calculated solely
15 according to the amount allowed by the
16 plan, and shall include all generics dis-
17 pensed, regardless of whether they are sub-
18 ject to MAC pricing.

19 “(iii) PROTECTING PATIENT AND
20 CLAIMS RELATED DATA.—A PBM shall ad-
21 here to the following criteria when han-
22 dling personally identifiable utilization and
23 claims data or other sensitive patient data:

24 “(I) A PBM may not transmit
25 any personally identifiable utilization

1 or claims data to a pharmacy owned
2 by a PBM if the plan enrollee has not
3 voluntarily elected in writing or via se-
4 cure electronic means to fill that par-
5 ticular prescription at the PBM-owned
6 pharmacy.

7 “(II) A PBM may not require
8 that a plan enrollee use a retail phar-
9 macy, mail order pharmacy, specialty
10 pharmacy, or other pharmacy entity
11 providing pharmacy services in which
12 the PBM has an ownership interest or
13 that has an ownership interest in the
14 PBM or provide an incentive to a ben-
15 eficiary to encourage the individual to
16 use a retail pharmacy, mail order
17 pharmacy, specialty pharmacy, or
18 other pharmacy entity providing phar-
19 macy services in which the PBM has
20 an ownership interest or that has an
21 ownership interest in the PBM, if the
22 incentive is applicable only to such
23 pharmacies.”.

24 (b) DISCLOSURE AND REGULAR UPDATE OF PRE-
25 SCRIPTON DRUG REIMBURSEMENT.—Section 1860D—

1 12(b) of the Social Security Act (42 U.S.C. 1395w-
2 112(b)) is amended to read as follows:

3 “(6) DISCLOSURE AND REGULAR UPDATE OF
4 PRESCRIPTION DRUG REIMBURSEMENT.—Each con-
5 tract entered into with a PDP sponsor under this
6 part with respect to a prescription drug plan offered
7 by such sponsor shall provide that the sponsor or
8 subcontractor of such sponsor shall—

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

13 “(B) not less frequently than once every 7
14 days, beginning with an initial update on Janu-
15 ary 1 of each year—

16 “(i) update such reimbursement
17 amount to accurately reflect the market
18 price of acquiring the drug; and

19 “(ii) disclose to each contracted phar-
20 macy such methodology and reimburse-
21 ment amounts.”.

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

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