

112TH CONGRESS
1ST SESSION

S. 1058

To amend the Public Health Service Act to ensure transparency and proper operation of pharmacy benefit managers.

IN THE SENATE OF THE UNITED STATES

MAY 24, 2011

Mr. PRYOR (for himself and Mr. MORAN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Public Health Service Act to ensure transparency and proper operation of pharmacy benefit managers.

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 “Pharmacy Competition
5 and Consumer Choice Act of 2011”.

6 **SEC. 2. PHARMACY BENEFITS MANAGER TRANSPARENCY**
7 **AND PROPER OPERATION REQUIREMENTS.**

8 (a) AMENDMENT TO THE PUBLIC HEALTH SERVICE
9 ACT RELATING TO THE GROUP MARKET.—

1 (1) IN GENERAL.—Subpart 2 of part A of title
 2 XXVII of the Public Health Service Act (42 U.S.C.
 3 300gg–4 et seq.) is amended by adding at the end
 4 the following:

5 **“SEC. 2729. PHARMACY BENEFITS MANAGER TRANS-**
 6 **PARENCY AND PROPER OPERATION RE-**
 7 **QUIREMENTS.**

8 “(a) IN GENERAL.—Notwithstanding any other pro-
 9 vision of law, a group health plan, and a health insurance
 10 issuer providing health insurance coverage in connection
 11 with a group health plan (collectively, a ‘plan sponsor’),
 12 shall not enter into a contract with any pharmacy benefits
 13 manager (referred to in this section as a ‘PBM’) to man-
 14 age the prescription drug coverage provided under such
 15 plan or insurance coverage, or to control the costs of such
 16 prescription drug coverage, unless the PBM satisfies the
 17 following requirements:

18 “(1) REQUIRED DISCLOSURES TO PLAN SPON-
 19 SOR IN ANNUAL REPORT.—The PBM shall provide
 20 at least annually a report to each plan sponsor, in-
 21 cluding, at a minimum—

22 “(A) information on the number and total
 23 cost of prescriptions under the contract filled at
 24 mail order and at retail pharmacies;

1 “(B) an estimate of aggregate average
2 payments under the contract, per prescription
3 (weighted by prescription volume), made to mail
4 order and retail pharmacies, and the average
5 amount per prescription that the PBM was
6 paid by the plan for prescriptions filled at mail
7 order and retail pharmacies;

8 “(C) an estimate of the aggregate average
9 payment per prescription (weighted by prescrip-
10 tion volume) under the contract received from
11 pharmaceutical manufacturers, including all re-
12 bates, discounts, price concessions, or adminis-
13 trative and other payments from pharma-
14 ceutical manufacturers, and a description of the
15 types of payments, the amount of such pay-
16 ments that were shared with the plan, and the
17 percentage of prescriptions for which the PBM
18 received such payments;

19 “(D) information on the overall percentage
20 of generic drugs dispensed under the contract
21 separately at retail and mail order pharmacies,
22 and the percentage of cases in which a generic
23 drug is dispensed when available; and

24 “(E) information on the percentage and
25 number of cases under the contract in which in-

1 individuals who had been receiving a prescribed
2 drug that had a lower cost for the plan were
3 later given a drug with a higher cost for the
4 plan, because of PBM policies or at the direct
5 or indirect control of the PBM, and the ration-
6 ale for such changes and a description of the
7 applicable PBM policies.

8 “(2) PBM REQUIREMENTS WITH RESPECT TO
9 PHARMACIES.—With respect to contracts between a
10 PBM and a pharmacy, the PBM shall—

11 “(A) include in such contracts, the meth-
12 odology and resources utilized for the Maximum
13 Allowable Cost (referred to in this section as
14 ‘MAC’) pricing of the PBM, update pricing in-
15 formation on such list at least weekly, and es-
16 tablish a process for the prompt notification of
17 such pricing updates to network pharmacies;

18 “(B) agree to provide timely updates, not
19 less than once every 3 business days, to phar-
20 macy product pricing files used to calculate pre-
21 scription prices that will be used to reimburse
22 pharmacies;

23 “(C) agree to pay pharmacies promptly for
24 clean claims under section 1860D–12(b)(4) of

1 the Social Security Act (42 U.S.C. 1395w-
2 112(b)(4));

3 “(D) not require that a pharmacist or
4 pharmacy participate in a pharmacy network
5 managed by such PBM as a condition for the
6 pharmacy to participate in another network
7 managed by such PBM, and shall not exclude
8 an otherwise qualified pharmacist or pharmacy
9 from participation in a particular network pro-
10 vided that the pharmacist or pharmacy—

11 “(i) accepts the terms, conditions and
12 reimbursement rates of the PBM;

13 “(ii) meets all applicable Federal and
14 State licensure and permit requirements;
15 and

16 “(iii) has not been excluded from par-
17 ticipation in any Federal or State program;

18 “(E) not automatically enroll a pharmacy
19 in a contract or modify an existing contract
20 without written agreement from the pharmacy
21 or pharmacist; and

22 “(F) require each pharmacy to sign a con-
23 tract before assuming responsibility to fill pre-
24 scriptions for the PBM.

1 “(3) PBM OWNERSHIP INTERESTS AND CON-
2 FLICTS OF INTEREST; PHARMACY CHOICE.—A PBM
3 shall not—

4 “(A) mandate that a covered individual use
5 a specific retail pharmacy, mail order phar-
6 macy, specialty pharmacy, or other pharmacy
7 practice site or entity if the PBM has an own-
8 ership interest in such pharmacy, practice site,
9 or entity or the pharmacy, practice site, or enti-
10 ty has an ownership interest in the PBM; or

11 “(B) provide incentives to covered plan
12 beneficiaries, in the form of variations in pre-
13 miums, deductibles, co-payments, or co-insur-
14 ance rates, to encourage plan beneficiaries to
15 use a specific pharmacy if such incentives are
16 only applicable to a pharmacy, practice site, or
17 entity that the PBM has an ownership interest
18 in, unless such incentives are applicable to all
19 network pharmacies.

20 “(4) PBM AUDIT OF PHARMACY PROVIDERS.—
21 The following shall apply to audits of pharmacy pro-
22 viders by a PBM:

23 “(A) The period covered by an audit may
24 not exceed 2 years from the date the claim was
25 submitted to or adjusted by the PBM.

1 “(B) An audit that involves clinical or pro-
2 fessional judgment shall be conducted by, or in
3 consultation with, a pharmacist licensed in the
4 State of the audit or the State board of phar-
5 macy.

6 “(C) The PBM may not require more
7 stringent recordkeeping than that required by
8 State or Federal law.

9 “(D) The PBM or the entity conducting
10 an audit for the PBM shall establish a written
11 appeals process that shall include procedures
12 for appeals for preliminary reports and final re-
13 ports.

14 “(E) The pharmacy, practice site, or other
15 entity may use the records of a hospital, physi-
16 cian, or other authorized practitioner to validate
17 the pharmacy records and any legal prescription
18 (one that complies with State Board of Phar-
19 macy requirements) may be used to validate
20 claims in connection with prescriptions, refills,
21 or changes in prescriptions.

22 “(F) Any clerical or recordkeeping error,
23 such as a typographical error, scrivener’s error,
24 or computer error, regarding a required docu-
25 ment or record shall not be subject to

1 recoupment unless proof of intent to commit
2 fraud or unless such discrepancy results in ac-
3 tual financial harm to an interested party.

4 “(G) The entity conducting the audit shall
5 not use extrapolation or other statistical expan-
6 sion techniques in calculating the recoupment
7 or penalties for audits.

8 “(H) The PBM shall disclose any audit
9 recoupment to the group health plan or health
10 insurance issuer with a copy to the pharmacy.

11 “(5) PBM CONDUCT REGARDING COVERED IN-
12 DIVIDUALS.—A PBM shall—

13 “(A) notify a plan sponsor if such PBM in-
14 tends to sell utilization or claims data that the
15 PBM possesses as a result of an arrangement
16 described in this section;

17 “(B) notify the plan sponsor in writing at
18 least 30 days before selling, leasing, or renting
19 such data and shall provide the plan sponsor
20 with the name of the potential purchaser of
21 such data and the expected use of any utiliza-
22 tion or claims data by such purchaser;

23 “(C) not sell such data unless the sale
24 complies with all Federal and State laws and

1 the PBM has received written approval for such
2 sale from the plan sponsor;

3 “(D) not directly contact a covered indi-
4 vidual by any means (including via electronic
5 delivery, telephonic, SMS text or direct mail)
6 without the express written permission of the
7 plan sponsor and the covered individual;

8 “(E) not transmit any personally identifi-
9 able utilization or claims data to a pharmacy
10 owned by the PBM if the patient has not volun-
11 tarily elected in writing to fill that particular
12 prescription at the PBM-owned pharmacy; and

13 “(F) provide each covered individual with
14 an opportunity to affirmatively opt out of the
15 sale of his or her data prior to entering into
16 any arrangement for the lease, rental, or sale of
17 such information.

18 “(b) DEFINITION.—For purposes of this section, the
19 term ‘fraud’ has the meaning given the term ‘health care
20 fraud’ in section 1347 of title 18, United States Code.”.

21 (2) EFFECTIVE DATE.—The amendment made
22 by this subsection shall apply to plan sponsors for
23 plan years beginning on or after the date of enact-
24 ment of this Act.

1 (b) AMENDMENTS TO THE PUBLIC HEALTH SERVICE
2 ACT RELATING TO THE INDIVIDUAL MARKET.—

3 (1) IN GENERAL.—Subpart 2 of part B of title
4 XXVII of the Public Health Service Act (42 U.S.C.
5 300gg–51 et seq.) is amended by adding at the end
6 the following:

7 **“SEC. 2754. PHARMACY BENEFITS MANAGER TRANS-**
8 **PARENCY AND PROPER OPERATION RE-**
9 **QUIREMENTS.**

10 “The provisions of section 2729 of the Public Health
11 Service Act shall apply to health insurance coverage of-
12 fered by a health insurance issuer in the individual market
13 in the same manner as they apply to a group health plan
14 and a health insurance issuer providing health insurance
15 coverage under that section.”.

16 (2) CONFORMING AMENDMENTS.—

17 (A) ERISA AMENDMENT.—

18 (i) IN GENERAL.—Subpart B of part
19 7 of subtitle B of title I of the Employee
20 Retirement Income Security Act of 1974
21 (29 U.S.C. 1185 et seq.) is amended by
22 adding at the end the following:

1 **“SEC. 716. PHARMACY BENEFITS MANAGER TRANS-**
 2 **PARENCY AND PROPER OPERATION RE-**
 3 **QUIREMENTS.**

4 “The provisions of section 2729 of the Public Health
 5 Service Act shall apply to a group health plan, and a
 6 health insurance issuer providing health insurance cov-
 7 erage in connection with a group health plan, in the same
 8 manner as such provisions apply to a group health plan
 9 and a health insurance issuer providing health insurance
 10 coverage under that section.”.

11 (ii) **CLERICAL AMENDMENT.**—The
 12 table of contents in section 1 of the Em-
 13 ployee Retirement Income Security Act of
 14 1974 is amended by inserting after the
 15 item relating to section 714 the following:

“Sec. 715. Additional market reforms.

“Sec. 716. Pharmacy benefits manager transparency and proper operation re-
 quirements.”.

16 (B) **IRC AMENDMENT.**—

17 (i) **IN GENERAL.**—Subpart B of chap-
 18 ter 100 of the Internal Revenue Code of
 19 1986 (26 U.S.C. 9811 et seq.) is amended
 20 by adding at the end the following:

1 **“SEC. 9814. PHARMACY BENEFITS MANAGER TRANS-**
 2 **PARENCY AND PROPER OPERATION RE-**
 3 **QUIREMENTS.**

4 “The provisions of section 2729 of the Public Health
 5 Service Act shall apply to a group health plan, and a
 6 health insurance issuer providing health insurance cov-
 7 erage in connection with a group health plan, in the same
 8 manner as such provisions apply to a group health plan
 9 and a health insurance issuer providing health insurance
 10 coverage under that section.”.

11 (ii) **CLERICAL AMENDMENT.**—The
 12 table of sections for subpart B of chapter
 13 100 of the Internal Revenue Code of 1986
 14 is amended by inserting after the item re-
 15 lating to section 9813 the following new
 16 item:

“Sec. 9814. Pharmacy benefits manager transparency and proper operation re-
 quirements.”.

17 (3) **EFFECTIVE DATE.**—The amendments made
 18 by paragraphs (1) and (2) shall apply with respect
 19 to health insurance coverage offered, sold, issued, re-
 20 newed, in effect, or operated in the individual mar-
 21 ket on or after the date of enactment of this Act.

22 (c) **MEDICARE PRESCRIPTION DRUG PLANS.**—

23 (1) **IN GENERAL.**—Subpart 2 of part D of title
 24 XVIII of the Social Security Act (42 U.S.C. 1395w–

1 111 et seq.) is amended by adding at the end the
2 following:

3 **“SEC. 1860D–17. PHARMACY BENEFITS MANAGER TRANS-**
4 **PARENCY AND PROPER OPERATION RE-**
5 **QUIREMENTS.**

6 “The provisions of section 2729 of the Public Health
7 Service Act shall apply to health insurance coverage of-
8 fered by a prescription drug plan under this part in the
9 same manner as such provisions apply to a group health
10 plan and a health insurance issuer providing health insur-
11 ance coverage under that section.”.

12 (2) EFFECTIVE DATE.—The amendment made
13 by this subsection shall apply with respect to plan
14 years beginning on or after the date of enactment of
15 this Act.

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