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111TH CONGRESS
2D SESSION

H. R. 5234

To amend the Public Health Service Act, the Employee Retirement Income Security Act, the Internal Revenue Code of 1986, and title XVIII of the Social Security Act to ensure transparency and proper operation of pharmacy benefit managers.

IN THE HOUSE OF REPRESENTATIVES

MAY 6, 2010

Mr. WEINER (for himself and Mr. MORAN of Kansas) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means and Education and Labor, 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 the Public Health Service Act, the Employee Retirement Income Security Act, the Internal Revenue Code of 1986, and title XVIII of the Social Security Act to ensure transparency and proper operation of pharmacy benefit managers.

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 ''PBM Audit Reform and Transparency Act of 2010''.

SEC. 2. PHARMACY BENEFITS MANAGER TRANSPARENCY AND PROPER OPERATION REQUIREMENTS.

(a) IN GENERAL.—

(1) AMENDMENTS TO THE PUBLIC HEALTH SERVICE ACT RELATING TO THE GROUP MARKET.—Subpart 2 of part A of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–4 et seq.) is amended by adding at the end the following:

"SEC. 2729. PHARMACY BENEFITS MANAGER TRANSPARENCY AND PROPER OPERATION REQUIREMENTS.

''(a) IN GENERAL.—Notwithstanding any other provision of law, a group health plan, and a health insurance issuer providing health insurance coverage in connection with a group health plan, shall not enter into a contract with any pharmacy benefits manager to manage the prescription drug coverage provided under such plan or insurance coverage, or to control the costs of such prescription drug coverage, unless the PBM satisfies the following requirements:

''(1) REQUIRED DISCLOSURES TO GROUP HEALTH PLAN OR HEALTH INSURANCE ISSUER IN ANNUAL REPORT.—

''(A) IN GENERAL.—The PBM shall provide at least annually a report to each group

health plan and health insurance issuer with which the PBM has a contract.

"(B) CONTENTS.—With respect to the contract described under subparagraph (A), the report under subparagraph (A) shall include—

"(i) information on the number and total cost of prescriptions under the contract filled at each of the following types of pharmacies: mail order pharmacies, speciality pharmacies, and retail pharmacies;

"(ii) the aggregate average payments under the contract, per prescription (weighted by prescription volume), made to such pharmacies;

"(iii) the average amount, per prescription (weighted by prescription volume), that the PBM was paid by the plan or issuer for prescriptions filled at such pharmacies;

"(iv) the aggregate average payment per prescription (weighted by prescription volume) under the contract received from pharmaceutical manufacturers, including all rebates, discounts, price concessions, or administrative and other payments from

pharmaceutical manufacturers, and a description of the types of payments, the amount of these payments that were shared with the plan, and the percentage of prescriptions for which the PBM received such payments;

''(v) information on the overall percentage of generic drugs dispensed under the contract separately at retail and mail order pharmacies, and the percentage of cases in which a generic drug is dispensed when available; and

''(vi) information on the percentage and number of cases under the contract in which individuals were switched, because of the policies of the PBM, from the drug originally prescribed to such individual by the health care provider to a drug with a higher cost to the plan or issuer, the rationale for these switches, and a description of the policies of the PBM applicable to such switches.

''(2) PBM INTERACTIONS WITH PHARMACIES.—

''(A) OBLIGATIONS ON PBM.—A PBM shall—

"(i) provide to pharmacies that contract with the PBM—

"(I) the methodology and resources that the PBM utilizes to determine reimbursement (including to calculate the maximum allowable cost list); and

"(II) timely updates to pharmacy product reimbursement benchmarks used to calculate prescription reimbursement to pharmacies;

"(ii) not less than one time per week, update the maximum allowable cost list and the reimbursement benchmarks;

"(iii) establish a process for providing prompt notification of the updates under clause (ii) to the pharmacies; and

"(iv) pay pharmacies promptly for clean claims, in a manner that is similar to the manner in which claims are paid under section 1860D–12(b)(4) of the Social Security Act (42 U.S.C. 1395w–112(b)(4)).

"(B) PBM LIMITATIONS.—A PBM may not—

"(i) require that a pharmacy participate in one network of pharmacies managed by such PBM as a condition for the pharmacy to participate in another network managed by such PBM;

"(ii) exclude an otherwise qualified pharmacy from participation in a network of pharmacies managed by such PBM if the person or entity that owns the pharmacy accepts the terms, conditions and reimbursement rates of the PBM's contract; and

"(iii) automatically—

"(I) enroll a pharmacy in a contract with the PBM for participation in a pharmacy network; or

"(II) modify an existing contract regarding participation in a pharmacy network,

without a written agreement of the person or entity that owns the pharmacy.

"(C) CONTRACT REQUIRED.—The person or entity that owns a pharmacy shall sign a contract with a PBM before assuming responsi-

bility to participate in a network managed by a PBM.

''(3) PBM OWNERSHIP INTERESTS AND CONFLICTS OF INTEREST.—With respect to an individual who is a beneficiary of pharmacy benefits managed by a PBM, the PBM may not mandate that such individual use a specific pharmacy or entity to fill a prescription if—

''(A) the PBM has an ownership interest in the pharmacy or entity; or

''(B) the pharmacy or entity has an ownership interest in the PBM.

''(4) PHARMACY CHOICE.—With respect to an individual who is a beneficiary of pharmacy benefits managed by a PBM, such PBM may not provide incentives to such individual (including variations in premiums, deductibles, co-payments, or co-insurance rates) to encourage such individual to utilize a specific pharmacy or other entity to fill a prescription, if such incentives only apply—

''(A) to a pharmacy or entity that the PBM has an ownership interest in; or

''(B) to a pharmacy or entity that has an ownership interest in the PBM.

''(5) PBM AUDIT OF PHARMACIES.—With respect to an audit by a PBM (or an entity acting on behalf of the PBM) of a pharmacy or other entity (referred to in this paragraph as a 'dispensing entity') that contracts with a PBM to receive reimbursement for dispensing prescription drugs to individuals covered by benefits managed by such PBM, the audit must comply with the following:

''(A) The PBM (or an entity acting on behalf of the PBM) shall give the pharmacy or other dispensing entity at least 15 days written notice prior to commencing an audit.

''(B) The time period covered by the audit may not exceed one year from the date the claim being audited was submitted to or adjudicated by the PBM.

''(C) To the extent that the audit requires the application of clinical or professional judgment, such audit shall be conducted by or in consultation with a pharmacist who is licensed in the State in which the audit is being conducted.

''(D) The PBM cannot require more stringent record keeping by a pharmacy or dis-

pensing entity than is required by State and Federal law and regulation.

''(E) The PBM (or an entity acting on behalf of the PBM) shall establish a written appeals process that shall include procedures to allow pharmacies and other dispensing entities to appeal to the PBM the preliminary reports and final reports resulting from the audit and any resulting recoupment or penalty.

''(F) The PBM (or an entity acting on behalf of the PBM) shall accept records of a hospital, physician, or other authorized practitioner that are made available to such PBM or entity by the pharmacy or dispensing entity to validate pharmacy records and prescriptions with respect to confirming the validity of claims in connection with prescriptions, refills, or changes in prescriptions.

''(G) To the extent that an audit results in the identification of any clerical or record-keeping errors (such as typographical errors, scrivener's error, or computer error) in a required document or record, the pharmacy or dispensing entity shall not be subject to recoupment of funds by the PBM unless—

''(i) the PBM can provide proof of intent to commit fraud; or

''(ii) such error results in actual financial harm to the PBM, a health insurance plan managed by the PBM, or a consumer.

''(H) The PBM (or an entity acting on behalf of the PBM) shall not use extrapolation or other statistical expansion techniques in calculating the amount of any recoupment or penalty resulting from an audit of a pharmacy or dispensing entity.

''(I) With respect to prescriptions covered by a group health plan or health insurance issuer, after the conclusion of any appeals under subparagraph (E), a PBM shall—

''(i) disclose any recoupment of funds from a pharmacy or dispensing entity that—

''(I) results from an audit; and

''(II) is related to prescriptions covered by such plan or issuer; and

''(ii) shall provide a copy of such disclosure to the pharmacy or dispensing entity.

"(6) PBM CONDUCT REGARDING COVERED INDIVIDUALS.—

"(A) TREATMENT OF DATA.—

"(i) NOTICE OF SALE.—The PBM shall notify a group health plan or health insurance issuer, in writing, at least 30 days before selling, leasing, or renting any utilization or claims data that the PBM possesses as a result of a contract between such PBM and plan or issuer, of—

"(I) the PBM's intent to sell, lease, or rent such data;

"(II) the name of the potential buyer, lessor, or renter of such data; and

"(III) the expected use of any utilization or claims data by such buyer, lessor, or renter.

"(ii) LIMITATIONS ON SALE.—The PBM may not sell, lease, or rent utilization or claims data that the PBM possesses as a result of a contract between such PBM and a group health plan or health insurance issuer unless the PBM has received

written approval for such transaction from the plan or issuer.

''(iii) OPT OUT FOR CONSUMERS.—Before a PBM sells, leases, or rents utilization or claims data that the PBM possesses as a result of a contract between such PBM and a group health plan or health insurance issuer, the PBM shall provide each individual who is covered by benefits managed by the PBM with an opportunity to affirmatively opt out of the sale, leasing, or renting of data related to such individual.

''(B) CONTACT WITH BENEFICIARIES.—A PBM may not directly contact, by any means (including via electronic delivery, telephonic, SMS text or direct mail), an individual who is covered by benefits managed by the PBM on behalf of a group health plan or health insurance issuer unless the PBM has the express written permission of the group health plan or health insurance issuer and the covered individual (through a request by the plan sponsor) to engage in such contact.

''(C) LIMITS ON SHARING DATA.—With respect to an individual covered by a benefit managed by a PBM, unless a patient has voluntarily elected to fill a prescription at a pharmacy, a PBM shall not transmit personally identifiable utilization or claims data related to such individual to such pharmacy if—

''(i) the PBM has an ownership interest in the pharmacy; or

''(ii) the pharmacy has an ownership interest in the PBM.

''(b) PHARMACY BENEFIT MANAGER; PBM DEFINED.—For purposes of this section, the terms 'pharmacy benefit manager' and 'PBM' mean an entity that provides pharmacy benefit management services on behalf of a group health plan or a health insurance issuer.''.

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

(A) IN GENERAL.—The subpart 2 of part B of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–51 et seq.) is amended by adding at the end the following:

''SEC. 2754. PHARMACY BENEFITS MANAGER TRANSPARENCY AND PROPER OPERATION REQUIREMENTS.

''The provisions of section 2729 shall apply to health insurance coverage offered by a health insurance issuer in the individual market in the same manner as such provisions apply to a group health plan and a health insurance issuer providing health insurance coverage under that section.''.

(3) CONFORMING AMENDMENTS.—

(A) ERISA AMENDMENT.—

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

''SEC. 715. PHARMACY BENEFITS MANAGER TRANSPARENCY AND PROPER OPERATION REQUIREMENTS.

''The provisions of section 2729 of the Public Health Service Act shall apply to a group health plan, and a health insurance issuer providing health insurance coverage in connection with a group health plan, in the same manner as such provisions apply to a group health plan and a health insurance issuer providing health insurance coverage under that section.''.

(ii) CLERICAL AMENDMENT.—The table of contents in section 1 of the Employee Retirement Income Security Act of 1974 is amended by inserting after the item relating to section 714 the following:

''Sec. 715. Pharmacy benefits manager transparency and proper operation requirements.''.

(B) IRC AMENDMENT.—

(i) IN GENERAL.—Subpart B of chapter 100 of the Internal Revenue Code of 1986 (26 U.S.C. 9811 et seq.) is amended by adding at the end the following:

''SEC. 9814. PHARMACY BENEFITS MANAGER TRANSPARENCY AND PROPER OPERATION REQUIREMENTS.

''The provisions of section 2729 of the Public Health Service Act shall apply to a group health plan, and a health insurance issuer providing health insurance coverage in connection with a group health plan, in the same manner as such provisions apply to a group health plan and a health insurance issuer providing health insurance coverage under that section.''.

(ii) CLERICAL AMENDMENT.—The table of sections for subpart B of chapter 100 of the Internal Revenue Code of 1986 is amended by inserting after the item re-

lating to section 9813 the following new item:

"Sec. 9814. Pharmacy benefits manager transparency and proper operation requirements.".

(b) PBMs and Medicare Part D.—Subpart 2 of part D of title XVIII of the Social Security Act is amended by adding at the end the following new section:

"SEC. 1860D–17. PHARMACY BENEFITS MANAGER TRANSPARENCY AND PROPER OPERATION REQUIREMENTS.

"The provisions of section 2729 of the Public Health Service Act shall apply to health insurance coverage offered by a prescription drug plan under this part in the same manner as such provisions apply to a group health plan and a health insurance issuer providing health insurance coverage under that section.".

(c) Effective Dates.—

(1) Group market and medicare.—The amendments made by paragraphs (1) and (3) of subsection (a) and by subsection (b) shall apply to group health plan or health insurance issuers for plan years beginning on or after the date of enactment of this Act.

(2) Individual market.—The amendment made by subsection (a)(2) shall apply with respect to health insurance coverage offered, sold, issued, re-

newed, in effect, or operated in the individual market on or after the date of enactment of this Act.

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