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111TH CONGRESS
2D SESSION

H. R. 4489

To amend chapter 89 of title 5, United States Code, to ensure program integrity, transparency, and cost savings in the pricing and contracting of prescription drug benefits under the Federal Employees Health Benefits Program.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 21, 2010

Mr. LYNCH (for himself, Mr. CONNOLLY of Virginia, and Mr. CUMMINGS) introduced the following bill; which was referred to the Committee on Oversight and Government Reform

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A BILL

To amend chapter 89 of title 5, United States Code, to ensure program integrity, transparency, and cost savings in the pricing and contracting of prescription drug benefits under the Federal Employees Health Benefits Program.

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 referred to as the ''FEHBP Prescription Drug Integrity, Transparency, and Cost Savings Act''.

SEC. 2. IMPROVED PROGRAM INTEGRITY, TRANSPARENCY, AND COST SAVINGS FOR PRESCRIPTION DRUG BENEFITS IN THE FEDERAL EMPLOYEES HEALTH BENEFITS PROGRAM.

(a) CHANGE IN CONTRACTING REQUIREMENTS.—Section 8902 of title 5, United States Code, is amended by adding at the end the following:

''(p) A contract may not be made or a plan approved under this chapter, with respect to a carrier that is a party to a PBM carrier arrangement, unless the PBM and the carrier comply with the requirements of section 8915. The Office shall terminate such contract or discontinue such plan for failure to comply with such requirements.''.

(b) REQUIREMENTS FOR PBMS AND RELATED REQUIREMENTS FOR CARRIERS.—Chapter 89 of title 5, United States Code, is amended by adding at the end the following:

''§ 8915. Requirements for PBM arrangements

''(a) LIMITATIONS ON CROSS-OWNERSHIP.—

''(1) IN GENERAL.—Under a PBM carrier arrangement under this chapter—

''(A) no pharmaceutical drug manufacturer or retail pharmacy may have a controlling interest in the PBM; and

''(B) the PBM may not have a controlling interest in a retail pharmacy.

''(2) COMPLIANCE.—Each carrier shall certify annually to the Office of Personnel Management that any PBM with which it has a PBM carrier arrangement meets the requirements of paragraph (1). The Office shall terminate any contract with a carrier with a PBM carrier arrangement that does not comply with such requirements.

''(3) PROFIT RESTRICTION ON CARRIER CONTROLLED PBMS.—The Office may not permit a carrier that has a controlling interest in a PBM to earn a profit from such interest with respect to a contract under this chapter.

''(b) DRUG SUBSTITUTION RESTRICTIONS.—Under a PBM carrier arrangement under this chapter—

''(1) the PBM shall allow a drug substitution, if it is not a generic drug substitution, only after the prescriber (or another individual authorized to prescribe drugs) provides the pharmacist with an express, verifiable authorization for such substitution;

''(2) to the extent appropriate, the PBM shall consult an enrollee concerning any drug substitution for a drug prescribed to such enrollee;

''(3) the PBM may not propose that the prescriber or pharmacist substitute a prescription drug

that has a higher net cost for a prescription drug in the same class with a lower net cost;

''(4) the PBM may not propose that the prescriber or pharmacist substitute a prescription drug that is a single source drug for a prescription drug in the same class that is a multiple source drug;

''(5) the PBM may not require a drug substitution if the prescriber determines that such substitution will endanger the health of the enrollee for whom the drug was prescribed;

''(6) the PBM will disclose to the prescriber of a drug, the carrier, and the enrollee for whom such drug was prescribed—

''(A) the reason why the PBM is suggesting a drug substitution for such drug; and

''(B) the financial impact of the drug substitution on the PBM, the carrier, and the patient; and

''(7) if a PBM has a controlling interest in a mail order pharmacy, such PBM shall ensure that any drug which is dispensed by such pharmacy to an enrollee as a result of a drug substitution shall be dispensed with a written notice that such drug substitution occurred and that such substitution occurred with the approval of the prescriber.

''(c) REIMBURSEMENT OF CARRIERS.—Under a PBM carrier arrangement under this chapter, by the last day of each quarter of the contract year—

''(1) the PBM shall pay to a carrier an amount that is at least 99 percent of the sum of—

''(A) all compensation that the PBM received during the previous quarter from a pharmaceutical drug manufacturer under a PBM manufacturer arrangement (to the extent such arrangement relates to the PBM carrier arrangement) including compensation that the Office categorizes (regardless of how such compensation is categorized by the PBM) as market share incentives, drug-switch programs, educational support, commissions, mail service purchase discounts, administrative or management fees, and all other forms of compensation (excluding rebates);

''(B) all compensation received by the PBM during the previous quarter for sales of utilization or claims data that the PBM possesses as a result of the PBM carrier arrangement; and

''(C) all rebates paid to the PBM during the previous quarter by a pharmaceutical drug

manufacturer to the extent that such rebates are based on drugs dispensed under the PBM carrier arrangement; and

''(2) the PBM shall disclose to the carrier and the Office, in a form and manner specified by the Office—

''(A) the compensation described in paragraph (1)(A), reported by the amount of compensation for each category recognized by the Office;

''(B) the compensation described in paragraph (1)(B); and

''(C) the rebates described in paragraph (1)(C), reported on a drug-by-drug basis.

''(d) SALE OF UTILIZATION AND CLAIMS DATA.—Under a PBM carrier arrangement under this chapter, if the PBM intends to sell utilization or claims data that the PBM possesses as a result of such arrangement—

''(1) the PBM shall notify the Office before selling such data and shall provide the Office with the name of the potential purchaser of such data and the expected use of any utilization or claims data by such purchaser; and

''(2) the PBM may not sell such data unless the sale complies with all Federal and State laws and

the PBM has received approval for such sale from the Office.

''(e) PRICING.—

''(1) SPREAD PRICING.—

''(A) LIMITATION ON CHARGES TO CARRIER.—The PBM shall not charge the carrier more for a drug that is covered under the PBM carrier arrangement than the amount that the PBM reimburses a pharmacy which dispensed such drug for the drug.

''(B) DISCLOSURES.—

''(i) INITIAL DISCLOSURE.—Before entering into a PBM carrier arrangement under this chapter, the PBM shall disclose to the carrier and the Office—

''(I) the reimbursement basis that the PBM uses (including the type of benchmark price and the source of the data for determining such price) for reimbursing retail and mail order pharmacies; and

''(II) the methodology that the PBM uses to compute reimbursements to retail and mail order pharmacies that dispense the drug.

"(ii) UPDATES.—Not later than 30 days after making a change to the reimbursement basis or methodology under clause (i), the PBM shall disclose such change to the carrier and the Office.

"(iii) TRANSITION RULE.—Under a PBM carrier arrangement under this chapter that is in effect on the effective date of the FEHBP Prescription Drug Integrity, Transparency, and Cost Savings Act, the PBM shall disclose the information under clause (i) not later than 1 year after such date.

"(2) MAXIMUM PRICE FOR PRESCRIPTION DRUGS.—

"(A) IN GENERAL.—Subject to subparagraph (B), a carrier under a PBM carrier arrangement under this chapter may not pay a PBM an amount for a prescription drug that is more than an amount that is equal to the average manufacturer price for the drug minus any cost-sharing for such drug that is the responsibility of an enrollee.

''(B) RULE OF CONSTRUCTION.—Subparagraph (A) shall not be construed to affect the payment—

''(i) of any applicable cost-sharing to a pharmacy by an enrollee; or

''(ii) subject to paragraph (3), the payment of any dispensing fee to a pharmacy by a PBM.

''(3) MAXIMUM DISPENSING FEE.—

''(A) IN GENERAL.—Under a PBM carrier arrangement, a PBM may not pay to a pharmacy a dispensing fee that exceeds the maximum dispensing fee determined under subparagraph (B).

''(B) DETERMINATION OF MAXIMUM DISPENSING FEE.—The Office shall, with respect to each drug covered by a health benefits plan under this chapter, determine the maximum dispensing fee.

''(f) RIGHT TO EXPLANATION OF BENEFITS.—Under a PBM carrier arrangement under this chapter, not later than 90 days after the date on which a pharmacy dispenses a prescription drug covered under the arrangement, the PBM shall provide (by mail or electronically) to the enrollee to whom such drug was dispensed an expla-

nation of benefits statement that contains the following information:

''(1) The date the claim for such prescription drug was made by the pharmacy.

''(2) The name of such drug and the strength and quantity dispensed to the enrollee.

''(3) The amount paid by the enrollee for the prescription drug.

''(4) The amount paid to the pharmacy by the PBM to reimburse such pharmacy for the prescription drug and the provision of any covered service related to dispensing such drug.

''(5) The amount paid by the carrier to the PBM for such prescription drug.

''(g) NON-DISCRIMINATORY CONTRACT.—Under a PBM carrier arrangement under this chapter, a PBM may not require that a pharmacy participate in a pharmacy network managed by such PBM in order for the pharmacy to participate in another network managed by such PBM.

''(h) ACCESS TO PBM CONTRACT INFORMATION.—

''(1) IN GENERAL.—Under a PBM carrier arrangement under this chapter, on the request of the Office of Personnel Management, a PBM shall provide to the Office and to the Office of Inspector General of the Office of Personnel Management full

access to information relating to contracts entered into by such PBM under such arrangement (such as PBM manufacturer arrangements and contracts with pharmacies). Such information shall include—

"(A) corporate-wide rebate receipt aging reports that cover all of the PBM's lines of business;

"(B) information and methodology used to calculate and allocate rebates between the PBM's lines of business;

"(C) information on average wholesale prices, wholesale acquisition costs, and maximum allowable costs;

"(D) information on dispensing fees paid; and

"(E) information and methodologies used to calculate additional administrative and service fees charged to the carrier.

"(2) CONFIDENTIALITY.—Information disclosed by a health benefits plan or PBM under this subsection is confidential and shall not be disclosed by the Office or by a plan receiving the information, except that nothing in this paragraph shall prevent—

"(A) a disclosure requird under the Inspector General Act of 1978; or

''(B) any disclosure which the Office, in its sole discretion, considers necessary in order to carry out this section, if such disclosure is made in a form which does not disclose the identity of a specific PBM or plan or the price charged for a particular drug.

''(3) EXEMPTION FROM FOIA.—Any information obtained under this subsection shall be exempt from disclosure under section 552 (commonly referred to as the 'Freedom of Information Act').

''(i) CIVIL MONETARY PENALTIES.—

''(1) IN GENERAL.—A PBM or a carrier that makes a false statement or false claim to the Government of the United States with respect to the disclosure of information required under this section shall be considered in violation of section 3729 of title 31.

''(2) USE OF COLLECTIONS.—Any monetary penalty collected under paragraph (1) shall be deposited into the Employees Health Benefits Fund under section 8909.

''(j) COLLECTION OF DATA ON AVERAGE MANUFACTURER PRICE.—

''(1) MASTER AGREEMENT.—For quarters beginning on or after January 1, 2011—

"(A) each manufacturer of covered drugs shall enter into a master agreement with the Office under which, not later than 60 days after the last day of each quarter for which the agreement is in effect, the manufacturer reports to the Office the average manufacturer price for the drug during such quarter; and

"(B) unless the manufacturer meets the requirement of subparagraph (A) for a quarter, the manufacturer may not receive payment from a carrier under this chapter or from a PBM under a PBM carrier arrangement under this chapter for the purchase of such drugs dispensed during the period—

"(i) beginning with the second subsequent quarter; and

"(ii) ending with the second quarter after the next quarter for which such requirement is met).

"(2) APPLICATION OF PROVISIONS.—The provisions of subparagraphs (B), (C), and (D) of section 1927(b)(3) of the Social Security Act shall apply to covered drugs and the Office under this section with respect to information required to be reported under paragraph (1)(A) in the same manner as such provi-

sions apply to covered outpatient drugs and the Secretary of Health and Human Services with respect to information required to be reported under subparagraph (A) of such section 1927(b)(3).

''(3) COVERED DRUG DEFINED.—For purposes of this subsection, the term 'covered drug' means a covered outpatient drug (as defined in section 1927(k) of the Social Security Act) for which benefits are payable under a health benefits plan under this chapter.

''(k) DEFINITIONS.—For purposes of this section and section 8902(p):

''(1) AVERAGE MANUFACTURER PRICE.—The term 'average manufacturer price' means the average price for a drug that is paid to a manufacturer by wholesalers, retail pharmacies, and mail order pharmacies that buy directly from the manufacturer.

''(2) AVERAGE WHOLESALE PRICE.—The term 'average wholesale price' means a publicly available, suggested list price for a prescription drug that is provided by a wholesaler to a pharmacy or other entity that provides prescription drugs directly to consumers.

''(3) CONTROLLING INTEREST.—An entity that has a 'controlling interest' in a second entity owns

or otherwise controls at least 20 percent of the second entity.

''(4) DISPENSING FEE.—The term 'dispensing fee' means a fee paid to a pharmacy for the service of filling or dispensing prescriptions (excluding the cost of the drug dispensed).

''(5) DRUG SUBSTITUTION.—The term 'drug substitution' means any change from one prescription drug to another prescription drug that is intended to address or treat the same illness or condition.

''(6) MAXIMUM ALLOWABLE COST.—The term 'maximum allowable cost' means a cost that is set by a PBM as the upper payment limit on the ingredient costs for a multiple source drug.

''(7) MULTIPLE SOURCE DRUG.—The term 'multiple source drug' has the meaning given such term in section 1927(k)(7) of the Social Security Act.

''(8) NET COST.—The term 'net cost' means the final cost of the drug to the carrier (or an enrollee) after all adjustments (including discounts, rebates, associated dispensing fees and administrative fees, and enrollee cost sharing).

''(9) PBM.—The term 'PBM' means a pharmacy benefit manager.

''(10) PBM CARRIER ARRANGEMENT.—The term 'PBM carrier arrangement' means a contract between a PBM and a carrier for the provision or administration of a program of prescription drug coverage under a health benefits plan under this chapter. Such a contract may provide, among other duties, for the PBM to—

''(A) process and pay prescription drug claims;

''(B) provide programs and services designed to—

''(i) maximize the effectiveness of drugs dispensed under such plan; or

''(ii) contain drug expenditures under such plan; and

''(C) engage in other activities related to the administration of such prescription drug coverage.

''(11) PBM MANUFACTURER ARRANGEMENT.—The term 'PBM manufacturer arrangement' means a contract between a PBM and a drug manufacturer for the provision of prescription drugs to enrollees of

health benefits plans with prescription drug coverage that is administered or provided by the PBM.

''(12) PHARMACY BENEFIT MANAGER.—The term 'pharmacy benefit manager' means an entity that contracts with a carrier to provide or administer prescription drug coverage under a health benefits plan under this chapter.

''(13) PRESCRIBER.—The term 'prescriber' means an individual who is authorized under State and Federal law to prescribe drugs and who prescribes a drug to an enrollee of a health benefits plan under this chapter.

''(14) RETAIL PHARMACY.—The term 'retail pharmacy' excludes any mail order pharmacy.

''(15) SINGLE SOURCE DRUG.—The term 'single source drug' has the meaning given such term in section 1927(k)(7) of the Social Security Act.

''(16) WHOLESALE ACQUISITION COST.—The term 'wholesale acquisition cost' means a publicly available list price for sales of a drug by a manufacturer to a wholesaler.''.

(c) CLERICAL AMENDMENT.—The table of sections for chapter 89 of title 5, United States Code, is amended by adding at the end the following:

''8915. Requirements for PBM arrangements.''.

(d) EFFECTIVE DATE; WAIVER; REGULATIONS.—

(1) EFFECTIVE DATE.—The amendments made by this section shall apply to contract years beginning on or after January 1, 2011.

(2) WAIVER.—The Office of Personnel Management may waive the application of 1 or more of the requirements of section 8915 of title 5, United States Code, but only for contract year 2011.

(3) EXPEDITING IMPLEMENTATION OF REGULATIONS.—Not later than 6 months after the date of the enactment of this Act, the Office of Personnel Management shall issue interim final regulations to carry out this section which may be effective and final immediately on an interim basis as of the date of publication of such regulations. If the Office of Personnel Management provides for an interim final regulation, the Office of Personnel Management shall provide for a period of public comment on such regulation after the date of publication. The Office of Personnel Management may change or revise such regulation after completion of the period of public comment.

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