

111TH CONGRESS
2^D 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

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.

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 referred to as the “FEHBP Pre-
5 scription Drug Integrity, Transparency, and Cost Savings
6 Act”.

1 **SEC. 2. IMPROVED PROGRAM INTEGRITY, TRANSPARENCY,**
2 **AND COST SAVINGS FOR PRESCRIPTION**
3 **DRUG BENEFITS IN THE FEDERAL EMPLOY-**
4 **EES HEALTH BENEFITS PROGRAM.**

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

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

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

18 **“§ 8915. Requirements for PBM arrangements**

19 “(a) LIMITATIONS ON CROSS-OWNERSHIP.—

20 “(1) IN GENERAL.—Under a PBM carrier ar-
21 rangement under this chapter—

22 “(A) no pharmaceutical drug manufacturer
23 or retail pharmacy may have a controlling inter-
24 est in the PBM; and

25 “(B) the PBM may not have a controlling
26 interest in a retail pharmacy.

1 “(2) COMPLIANCE.—Each carrier shall certify
2 annually to the Office of Personnel Management
3 that any PBM with which it has a PBM carrier ar-
4 rangement meets the requirements of paragraph (1).
5 The Office shall terminate any contract with a car-
6 rier with a PBM carrier arrangement that does not
7 comply with such requirements.

8 “(3) PROFIT RESTRICTION ON CARRIER CON-
9 TROLLED PBMS.—The Office may not permit a car-
10 rier that has a controlling interest in a PBM to earn
11 a profit from such interest with respect to a contract
12 under this chapter.

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

15 “(1) the PBM shall allow a drug substitution,
16 if it is not a generic drug substitution, only after the
17 prescriber (or another individual authorized to pre-
18 scribe drugs) provides the pharmacist with an ex-
19 press, verifiable authorization for such substitution;

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

23 “(3) the PBM may not propose that the pre-
24 scriber or pharmacist substitute a prescription drug

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

3 “(4) the PBM may not propose that the pre-
4 scriber or pharmacist substitute a prescription drug
5 that is a single source drug for a prescription drug
6 in the same class that is a multiple source drug;

7 “(5) the PBM may not require a drug substi-
8 tution if the prescriber determines that such substi-
9 tion will endanger the health of the enrollee for
10 whom the drug was prescribed;

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

14 “(A) the reason why the PBM is sug-
15 gesting a drug substitution for such drug; and

16 “(B) the financial impact of the drug sub-
17 stitution on the PBM, the carrier, and the pa-
18 tient; and

19 “(7) if a PBM has a controlling interest in a
20 mail order pharmacy, such PBM shall ensure that
21 any drug which is dispensed by such pharmacy to an
22 enrollee as a result of a drug substitution shall be
23 dispensed with a written notice that such drug sub-
24 stitution occurred and that such substitution oc-
25 curred with the approval of the prescriber.

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

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

6 “(A) all compensation that the PBM re-
7 ceived during the previous quarter from a phar-
8 maceutical drug manufacturer under a PBM
9 manufacturer arrangement (to the extent such
10 arrangement relates to the PBM carrier ar-
11 rangement) including compensation that the Of-
12 fice categorizes (regardless of how such com-
13 pensation is categorized by the PBM) as mar-
14 ket share incentives, drug-switch programs,
15 educational support, commissions, mail service
16 purchase discounts, administrative or manage-
17 ment fees, and all other forms of compensation
18 (excluding rebates);

19 “(B) all compensation received by the
20 PBM during the previous quarter for sales of
21 utilization or claims data that the PBM pos-
22 sesses as a result of the PBM carrier arrange-
23 ment; and

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

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

4 “(2) the PBM shall disclose to the carrier and
5 the Office, in a form and manner specified by the
6 Office—

7 “(A) the compensation described in para-
8 graph (1)(A), reported by the amount of com-
9 pensation for each category recognized by the
10 Office;

11 “(B) the compensation described in para-
12 graph (1)(B); and

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

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

19 “(1) the PBM shall notify the Office before sell-
20 ing such data and shall provide the Office with the
21 name of the potential purchaser of such data and
22 the expected use of any utilization or claims data by
23 such purchaser; and

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

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

3 “(e) PRICING.—

4 “(1) SPREAD PRICING.—

5 “(A) LIMITATION ON CHARGES TO CAR-
6 RIER.—The PBM shall not charge the carrier
7 more for a drug that is covered under the PBM
8 carrier arrangement than the amount that the
9 PBM reimburses a pharmacy which dispensed
10 such drug for the drug.

11 “(B) DISCLOSURES.—

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

16 “(I) the reimbursement basis
17 that the PBM uses (including the type
18 of benchmark price and the source of
19 the data for determining such price)
20 for reimbursing retail and mail order
21 pharmacies; and

22 “(II) the methodology that the
23 PBM uses to compute reimburse-
24 ments to retail and mail order phar-
25 macies that dispense the drug.

1 “(ii) UPDATES.—Not later than 30
2 days after making a change to the reim-
3 bursement basis or methodology under
4 clause (i), the PBM shall disclose such
5 change to the carrier and the Office.

6 “(iii) TRANSITION RULE.—Under a
7 PBM carrier arrangement under this chap-
8 ter that is in effect on the effective date of
9 the FEHBP Prescription Drug Integrity,
10 Transparency, and Cost Savings Act, the
11 PBM shall disclose the information under
12 clause (i) not later than 1 year after such
13 date.

14 “(2) MAXIMUM PRICE FOR PRESCRIPTION
15 DRUGS.—

16 “(A) IN GENERAL.—Subject to subpara-
17 graph (B), a carrier under a PBM carrier ar-
18 rangement under this chapter may not pay a
19 PBM an amount for a prescription drug that is
20 more than an amount that is equal to the aver-
21 age manufacturer price for the drug minus any
22 cost-sharing for such drug that is the responsi-
23 bility of an enrollee.

1 “(B) RULE OF CONSTRUCTION.—Subpara-
2 graph (A) shall not be construed to affect the
3 payment—

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

6 “(ii) subject to paragraph (3), the
7 payment of any dispensing fee to a phar-
8 macy by a PBM.

9 “(3) MAXIMUM DISPENSING FEE.—

10 “(A) IN GENERAL.—Under a PBM carrier
11 arrangement, a PBM may not pay to a phar-
12 macy a dispensing fee that exceeds the max-
13 imum dispensing fee determined under subpara-
14 graph (B).

15 “(B) DETERMINATION OF MAXIMUM DIS-
16 PENSING FEE.—The Office shall, with respect
17 to each drug covered by a health benefits plan
18 under this chapter, determine the maximum
19 dispensing fee.

20 “(f) RIGHT TO EXPLANATION OF BENEFITS.—Under
21 a PBM carrier arrangement under this chapter, not later
22 than 90 days after the date on which a pharmacy dis-
23 penses a prescription drug covered under the arrange-
24 ment, the PBM shall provide (by mail or electronically)
25 to the enrollee to whom such drug was dispensed an expla-

1 nation of benefits statement that contains the following
2 information:

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

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

7 “(3) The amount paid by the enrollee for the
8 prescription drug.

9 “(4) The amount paid to the pharmacy by the
10 PBM to reimburse such pharmacy for the prescrip-
11 tion drug and the provision of any covered service
12 related to dispensing such drug.

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

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

20 “(h) ACCESS TO PBM CONTRACT INFORMATION.—

21 “(1) IN GENERAL.—Under a PBM carrier ar-
22 rangement under this chapter, on the request of the
23 Office of Personnel Management, a PBM shall pro-
24 vide to the Office and to the Office of Inspector
25 General of the Office of Personnel Management full

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

5 “(A) corporate-wide rebate receipt aging
6 reports that cover all of the PBM’s lines of
7 business;

8 “(B) information and methodology used to
9 calculate and allocate rebates between the
10 PBM’s lines of business;

11 “(C) information on average wholesale
12 prices, wholesale acquisition costs, and max-
13 imum allowable costs;

14 “(D) information on dispensing fees paid;
15 and

16 “(E) information and methodologies used
17 to calculate additional administrative and serv-
18 ice fees charged to the carrier.

19 “(2) CONFIDENTIALITY.—Information disclosed
20 by a health benefits plan or PBM under this sub-
21 section is confidential and shall not be disclosed by
22 the Office or by a plan receiving the information, ex-
23 cept that nothing in this paragraph shall prevent—

24 “(A) a disclosure required under the Inspec-
25 tor General Act of 1978; or

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

7 “(3) EXEMPTION FROM FOIA.—Any information
8 obtained under this subsection shall be exempt from
9 disclosure under section 552 (commonly referred to
10 as the ‘Freedom of Information Act’).

11 “(i) CIVIL MONETARY PENALTIES.—

12 “(1) IN GENERAL.—A PBM or a carrier that
13 makes a false statement or false claim to the Gov-
14 ernment of the United States with respect to the
15 disclosure of information required under this section
16 shall be considered in violation of section 3729 of
17 title 31.

18 “(2) USE OF COLLECTIONS.—Any monetary
19 penalty collected under paragraph (1) shall be de-
20 posited into the Employees Health Benefits Fund
21 under section 8909.

22 “(j) COLLECTION OF DATA ON AVERAGE MANUFAC-
23 TURER PRICE.—

24 “(1) MASTER AGREEMENT.—For quarters be-
25 ginning on or after January 1, 2011—

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

8 “(B) unless the manufacturer meets the
9 requirement of subparagraph (A) for a quarter,
10 the manufacturer may not receive payment
11 from a carrier under this chapter or from a
12 PBM under a PBM carrier arrangement under
13 this chapter for the purchase of such drugs dis-
14 pensed during the period—

15 “(i) beginning with the second subse-
16 quent quarter; and

17 “(ii) ending with the second quarter
18 after the next quarter for which such re-
19 quirement is met).

20 “(2) APPLICATION OF PROVISIONS.—The provi-
21 sions of subparagraphs (B), (C), and (D) of section
22 1927(b)(3) of the Social Security Act shall apply to
23 covered drugs and the Office under this section with
24 respect to information required to be reported under
25 paragraph (1)(A) in the same manner as such provi-

1 sions apply to covered outpatient drugs and the Sec-
2 retary of Health and Human Services with respect
3 to information required to be reported under sub-
4 paragraph (A) of such section 1927(b)(3).

5 “(3) COVERED DRUG DEFINED.—For purposes
6 of this subsection, the term ‘covered drug’ means a
7 covered outpatient drug (as defined in section
8 1927(k) of the Social Security Act) for which bene-
9 fits are payable under a health benefits plan under
10 this chapter.

11 “(k) DEFINITIONS.—For purposes of this section and
12 section 8902(p):

13 “(1) AVERAGE MANUFACTURER PRICE.—The
14 term ‘average manufacturer price’ means the aver-
15 age price for a drug that is paid to a manufacturer
16 by wholesalers, retail pharmacies, and mail order
17 pharmacies that buy directly from the manufacturer.

18 “(2) AVERAGE WHOLESALE PRICE.—The term
19 ‘average wholesale price’ means a publicly available,
20 suggested list price for a prescription drug that is
21 provided by a wholesaler to a pharmacy or other en-
22 tity that provides prescription drugs directly to con-
23 sumers.

24 “(3) CONTROLLING INTEREST.—An entity that
25 has a ‘controlling interest’ in a second entity owns

1 or otherwise controls at least 20 percent of the sec-
2 ond entity.

3 “(4) DISPENSING FEE.—The term ‘dispensing
4 fee’ means a fee paid to a pharmacy for the service
5 of filling or dispensing prescriptions (excluding the
6 cost of the drug dispensed).

7 “(5) DRUG SUBSTITUTION.—The term ‘drug
8 substitution’ means any change from one prescrip-
9 tion drug to another prescription drug that is in-
10 tended to address or treat the same illness or condi-
11 tion.

12 “(6) MAXIMUM ALLOWABLE COST.—The term
13 ‘maximum allowable cost’ means a cost that is set
14 by a PBM as the upper payment limit on the ingre-
15 dient costs for a multiple source drug.

16 “(7) MULTIPLE SOURCE DRUG.—The term
17 ‘multiple source drug’ has the meaning given such
18 term in section 1927(k)(7) of the Social Security
19 Act.

20 “(8) NET COST.—The term ‘net cost’ means
21 the final cost of the drug to the carrier (or an en-
22 rollee) after all adjustments (including discounts, re-
23 bates, associated dispensing fees and administrative
24 fees, and enrollee cost sharing).

1 “(9) PBM.—The term ‘PBM’ means a phar-
2 macy benefit manager.

3 “(10) PBM CARRIER ARRANGEMENT.—The
4 term ‘PBM carrier arrangement’ means a contract
5 between a PBM and a carrier for the provision or
6 administration of a program of prescription drug
7 coverage under a health benefits plan under this
8 chapter. Such a contract may provide, among other
9 duties, for the PBM to—

10 “(A) process and pay prescription drug
11 claims;

12 “(B) provide programs and services de-
13 signed to—

14 “(i) maximize the effectiveness of
15 drugs dispensed under such plan; or

16 “(ii) contain drug expenditures under
17 such plan; and

18 “(C) engage in other activities related to
19 the administration of such prescription drug
20 coverage.

21 “(11) PBM MANUFACTURER ARRANGEMENT.—
22 The term ‘PBM manufacturer arrangement’ means
23 a contract between a PBM and a drug manufacturer
24 for the provision of prescription drugs to enrollees of

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

3 “(12) PHARMACY BENEFIT MANAGER.—The
4 term ‘pharmacy benefit manager’ means an entity
5 that contracts with a carrier to provide or admin-
6 ister prescription drug coverage under a health bene-
7 fits plan under this chapter.

8 “(13) PRESCRIBER.—The term ‘prescriber’
9 means an individual who is authorized under State
10 and Federal law to prescribe drugs and who pre-
11 scribes a drug to an enrollee of a health benefits
12 plan under this chapter.

13 “(14) RETAIL PHARMACY.—The term ‘retail
14 pharmacy’ excludes any mail order pharmacy.

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

18 “(16) WHOLESALE ACQUISITION COST.—The
19 term ‘wholesale acquisition cost’ means a publicly
20 available list price for sales of a drug by a manufac-
21 turer to a wholesaler.”.

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

“8915. Requirements for PBM arrangements.”.

25 (d) EFFECTIVE DATE; WAIVER; REGULATIONS.—

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

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

8 (3) EXPEDITING IMPLEMENTATION OF REGULA-
9 TIONS.—Not later than 6 months after the date of
10 the enactment of this Act, the Office of Personnel
11 Management shall issue interim final regulations to
12 carry out this section which may be effective and
13 final immediately on an interim basis as of the date
14 of publication of such regulations. If the Office of
15 Personnel Management provides for an interim final
16 regulation, the Office of Personnel Management
17 shall provide for a period of public comment on such
18 regulation after the date of publication. The Office
19 of Personnel Management may change or revise such
20 regulation after completion of the period of public
21 comment.

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