112TH CONGRESS 1ST SESSION

H. R. 979

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

March 9, 2011

Mr. Lynch (for himself, Mr. Cummings, Mr. Clay, Ms. Norton, Mr. Connolly of Virginia, and Mr. Moran) 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 cited as the "FEHBP Prescription
- 5 Drug Integrity, Transparency, and Cost Savings 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 such
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 a PBM may not be under common cor-
22	porate control with—
23	"(A) a prescription drug manufacturer; or
24	"(B) a retail pharmacy.
25	"(2) Profit restriction on corporately
26	AFFILIATED CARRIERS AND PBMS.—With respect to

1	a PBM carrier arrangement related to a contract
2	under this chapter, the Office may not permit a car-
3	rier under common corporate control with a PBM to
4	earn a profit resulting from such control.
5	"(3) Certification.—Each carrier shall cer-
6	tify annually to the Office of Personnel Management
7	that any PBM with which it has a PBM carrier ar-
8	rangement meets the requirements of this sub-
9	section.
10	"(4) Definitions.—For purposes of this sub-
11	section—
12	"(A) COMMON CORPORATE CONTROL.—
13	The term 'common corporate control' means
14	that 2 entities are part of a controlled group of
15	corporations (as such term is defined in section
16	1563 of the Internal Revenue Code of 1986).
17	"(B) Retail Pharmacy.—The term 're-
18	tail pharmacy' excludes any mail order phar-
19	macy.
20	"(b) Restrictions on Brand Name Prescription
21	Drug Substitutions.—
22	"(1) In general.—Under a PBM carrier ar-
23	rangement, and with respect to a prescription drug
24	prescribed to an enrollee covered under such ar-

rangement, a PBM may not request payment from

- a carrier for a brand name prescription drug that was dispensed to the enrollee, at the request of the PBM, in substitution for the drug that was originally prescribed to such enrollee, unless each of the following requirements is met:
 - "(A) LOWER NET COST.—The substitute drug has a lower net cost than the drug originally prescribed to such enrollee.
 - "(B) AUTHORIZATION BY PRESCRIBER.—
 The prescriber of the originally prescribed drug submits an express, verifiable authorization of the substitution to the pharmacist and such authorization includes a determination by the prescriber that the drug substitution will not endanger the health of the enrollee for whom the drug is prescribed.
 - "(C) Additional requirements.—Each of the requirements described in paragraph (2) are met.
 - "(2) ADDITIONAL REQUIREMENTS.—The requirements described in this paragraph are, with respect to a brand name prescription drug that was dispensed to an enrollee, at the request of the PBM, in substitution for the drug that was originally prescribed to such enrollee, the following:

1	"(A) To the extent appropriate, the PBM
2	consults the enrollee concerning such drug sub-
3	stitution.
4	"(B) The PBM discloses to the prescriber
5	of the originally prescribed drug, the carrier,
6	and the enrollee for whom such drug was pre-
7	scribed—
8	"(i) the reason why the PBM pro-
9	posed a drug substitution for such drug;
10	and
11	"(ii) the financial impact of the drug
12	substitution on the PBM, the carrier, and
13	the enrollee.
14	"(C) In the case of a mail order pharmacy,
15	the PBM ensures that, at the time the drug is
16	dispensed, the enrollee receives a written notice
17	that such drug substitution occurred and that
18	such substitution occurred with the approval of
19	the prescriber.
20	"(3) Definitions.—For purposes of this sub-
21	section—
22	"(A) Brand Name Prescription
23	DRUG.—The term 'brand name prescription
24	drug' means a drug approved pursuant to an
25	application submitted under section 505(b) of

1	the Federal Food, Drug, and Cosmetic Act (21
2	U.S.C. 355(b)).
3	"(B) Net cost.—The term 'net cost'
4	means, with respect to a drug, a carrier, and an
5	enrollee, the sum of—
6	"(i) the final cost of the drug to the
7	carrier after all adjustments (including dis-
8	counts, rebates, associated dispensing fees
9	and administrative fees, and enrollee cost
10	sharing); and
11	"(ii) the final cost of the drug to the
12	enrollee (including cost-sharing).
13	"(C) Prescriber.—The term 'prescriber'
14	means an individual who is authorized under
15	State and Federal law to prescribe drugs and
16	who prescribes a drug to an enrollee of a health
17	benefits plan under this chapter.
18	"(c) Reimbursement of Carriers.—Under a
19	PBM carrier arrangement, not later than the last day of
20	each quarter of the contract year—
21	"(1) the PBM shall pay to a carrier an amount
22	that is at least 99 percent of the sum of—
23	"(A) all compensation that the PBM re-
24	ceived during the previous quarter from a pre-
25	scription drug manufacturer under a PBM

1	manufacturer contract (to the extent such ar-
2	rangement relates to the PBM carrier arrange-
3	ment) including compensation (but excluding
4	rebates) that the Office of Personnel Manage-
5	ment categorizes (regardless of how such com-
6	pensation is categorized by the PBM) as—
7	"(i) market share incentives;
8	"(ii) prescription drug substitution
9	programs;
10	"(iii) educational support;
11	"(iv) commissions;
12	"(v) mail service purchase discounts;
13	"(vi) administrative or management
14	fees; or
15	"(vii) any other form of compensation;
16	"(B) all compensation received by the
17	PBM during the previous quarter for sales of
18	utilization or claims data that the PBM pos-
19	sesses as a result of the PBM carrier arrange-
20	ment; and
21	"(C) all rebates paid to the PBM during
22	the previous quarter by a prescription drug
23	manufacturer to the extent that such rebates
24	are based on prescription drugs dispensed
25	under the PBM carrier arrangement; and

1	"(2) the PBM shall disclose to the carrier and
2	the Office, in a form and manner specified by the
3	Office—
4	"(A) the compensation described in para-
5	graph (1)(A), by the amount of compensation
6	for each category under such paragraph;
7	"(B) the compensation described in para-
8	graph $(1)(B)$; and
9	"(C) the rebates described in paragraph
10	(1)(C), on a drug-by-drug basis.
11	"(d) Sale of Utilization and Claims Data.—
12	Under a PBM carrier arrangement, if the PBM intends
13	to sell utilization or claims data that the PBM possesses
14	as a result of such arrangement—
15	"(1) the PBM shall notify the Office of Per-
16	sonnel Management before selling such data and
17	shall provide the Office with the name of the poten-
18	tial purchaser of such data and the expected use of
19	such data by such purchaser; and
20	"(2) the PBM may not sell such data unless the
21	sale complies with all Federal and State laws and
22	the PBM has received approval for such sale from
23	the Office.
24	"(e) Pricing.—
25	"(1) Spread pricing.—

1 "(A) Limitation on charges to a car2 Rier.—A PBM under a PBM carrier arrange3 ment shall not charge a carrier an amount for
4 a prescription drug that is covered under such
5 arrangement (and is dispensed by a pharmacy)
6 that is more than the amount (including the in7 gredient cost and the dispensing fee) that the
8 PBM reimburses the pharmacy for the drug.

"(B) Disclosures.—

"(i) Initial disclosure.—Before entering into a PBM carrier arrangement, the PBM shall disclose to the carrier and the Office of Personnel Management the reimbursement basis (including the type of benchmark price and the source of the data for determining such price) and methodology that the PBM uses to compute reimbursement amounts for retail and mail order pharmacies.

"(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.

1	"(iii) Transition rule.—In the case
2	of a PBM carrier arrangement that is in
3	effect on the effective date of the FEHBP
4	Prescription Drug Integrity, Transparency,
5	and Cost Savings Act, the PBM shall dis-
6	close the information under clause (i) not
7	later than 1 year after such date.
8	"(2) MAXIMUM FOR MAIL ORDER PRESCRIPTION
9	DRUGS PRICES AND DISPENSING FEES.—
10	"(A) IN GENERAL.—If a prescription drug
11	is supplied by a mail order pharmacy to an en-
12	rollee, under a PBM carrier arrangement, a
13	PBM may not charge a carrier an amount for
14	the ingredient cost for such prescription drug
15	that is greater than an amount that is equal to
16	the actual acquisition cost for the drug minus
17	any cost sharing for such drug that is the re-
18	sponsibility of the enrollee.
19	"(B) DISPENSING FEE.—Under a PBM
20	carrier arrangement, a PBM may not charge a
21	carrier an amount for a dispensing fee related
22	to a prescription drug dispensed by a mail order
23	pharmacy to an enrollee that is greater than

the amount that the PBM charges health plans

1	for similar services that are not covered under
2	a PBM carrier arrangement.
3	"(C) Transparency.—Under a PBM car-
4	rier arrangement, a PBM shall provide the car-
5	rier and the Office of Personnel Management,
6	at the request of such carrier or Office, infor-
7	mation on the method used to determine the
8	amount of—
9	"(i) the ingredient cost under sub-
10	paragraph (A); and
11	"(ii) the dispensing fee under sub-
12	paragraph (B).
13	"(D) ACTUAL ACQUISITION COST DE-
14	FINED.—For purposes of this paragraph, the
15	term 'actual acquisition cost' means the amount
16	a pharmacy pays for a prescription drug, net of
17	discounts, rebates, charge backs, and other ad-
18	justments to the price of the drug.
19	"(f) RIGHT TO EXPLANATION OF BENEFITS.—Under
20	a PBM carrier arrangement, not later than 90 days after
21	the date on which a pharmacy dispenses a prescription
22	drug covered under the arrangement, the PBM shall pro-
23	vide (by mail or electronically) to the enrollee to whom
24	such drug was dispensed an explanation of benefits state-
25	ment that contains the following information:

1 "(1) The date the claim for such drug was 2 made by the pharmacy. 3 "(2) The name of such drug and the strength 4 and quantity dispensed to the enrollee. 5 "(3) The amount paid by the enrollee for such 6 drug. 7 "(4) The total amount paid to the pharmacy by 8 the PBM for such drug. Such amount shall include 9 all amounts paid to the pharmacy with respect to 10 dispensing such drug, including fees. 11 "(5) The amount paid by the carrier to the 12 PBM for such drug. "(g) Nondiscriminatory Contract.— 13 14 "(1) In general.—Under a PBM carrier ar-15 rangement, a PBM may not require that a phar-16 macy participate in a pharmacy network managed 17 by such PBM as a condition of the pharmacy par-18 ticipating in another network managed by such 19 PBM. 20 "(2)PHARMACY NETWORK DEFINED.—For 21 purposes of this subsection, the term 'pharmacy net-22 work' means a group of pharmacies that have 23 agreed, through a contract with a PBM or carrier,

to provide prescription medications to enrollees at

1	rates and with discounts that are specified in such
2	contract.
3	"(h) Access to PBM Contract Information.—
4	"(1) In general.—Under a PBM carrier ar-
5	rangement, at the request of the Office of Personne
6	Management, a PBM shall provide to the Office and
7	to the Inspector General of the Office of Personnel
8	Management full access to information relating to
9	contracts entered into by such PBM under such ar-
10	rangement (such as PBM manufacturer contracts
11	and PBM contracts with pharmacies). Such informa-
12	tion shall include—
13	"(A) companywide rebate receipt aging re-
14	ports that cover all of the PBM's lines of busi-
15	ness;
16	"(B) information and methodology used to
17	calculate and allocate rebates between the
18	PBM's lines of business;
19	"(C) information on average wholesale
20	prices, wholesale acquisition costs, and max-
21	imum allowable costs;
22	"(D) information on dispensing fees paid
23	and

1	"(E) information and methodologies used
2	to calculate additional administrative and serv-
3	ice fees charged to the carrier.
4	"(2) Confidentiality.—Information provided
5	by a PBM under this subsection is confidential and
6	shall not be disclosed by the Office, except that
7	nothing in this paragraph shall prevent—
8	"(A) a disclosure required under the In-
9	spector General Act of 1978; or
10	"(B) any disclosure which the Office, in its
11	sole discretion, considers necessary in order to
12	carry out this section, if such disclosure is made
13	in a form which does not disclose the identity
14	of a specific PBM or carrier or the price
15	charged for a particular prescription drug.
16	"(3) Exemption from foia.—Any information
17	obtained under this subsection shall be exempt from
18	disclosure under section 552.
19	"(4) Definitions.—For purposes of this sub-
20	section—
21	"(A) GENERIC DRUG.—The term 'generic
22	drug' means a drug approved pursuant to an
23	abbreviated application submitted under section
24	505(j) of the Federal Food, Drug, and Cos-
25	metic Act (21 U.S.C. 355(j)).

1	"(B) MAXIMUM ALLOWABLE COST.—The
2	term 'maximum allowable cost' means a cost
3	that is set by a PBM as the upper payment
4	limit on the ingredient costs for a generic drug.
5	"(C) Wholesale acquisition cost.—
6	The term 'wholesale acquisition cost' means a
7	publicly available list price for sales of a drug
8	by a manufacturer to a wholesaler.
9	"(i) Treatment of Non-Compliance.—
10	"(1) In general.—Under a PBM carrier ar-
11	rangement, a PBM that knowingly provides false in-
12	formation to a carrier related to a claim made to
13	such carrier by the PBM under such arrangement
14	shall be treated, for purposes of chapter 37 of title
15	31, in the same manner as a person that makes a
16	false claim to the United States Government under
17	section 3729 of such chapter.
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	"(3) Additional penalties.—Any penalties
23	resulting from the application of paragraph (1) shall

be in addition to any other penalties available to the

- 1 Office of Personnel Management under law or regu-
- 2 lation.
- 3 "(j) No Application to Community Rated Car-
- 4 RIERS.—The provisions of this section and section
- 5 8902(p) of this title—
- 6 "(1) shall apply to experience-rated carriers;
- 7 and
- 8 "(2) shall not apply to carriers that use rates
- 9 based on a per member per month capitation
- amount.
- 11 "(k) Limitation of Application to Prescription
- 12 Drugs.—The provisions of this section and section
- 13 8902(p) of this title shall not be construed to apply to
- 14 drugs that are not prescription drugs.
- 15 "(l) General Definitions.—For purposes of this
- 16 section and section 8902(p) of this title:
- 17 "(1) DISPENSING FEE.—The term 'dispensing
- 18 fee' means a fee paid to a pharmacy for the service
- of filling or dispensing prescriptions and excludes
- any payment for the cost of the drug dispensed.
- 21 "(2) Drug substitution.—The term 'drug
- substitution' means any change from one prescrip-
- 23 tion drug to another prescription drug that is in-
- tended to address or treat the same illness or condi-
- 25 tion.

1	"(3) PBM CARRIER ARRANGEMENT.—The term
2	'PBM carrier arrangement' means a contract be-
3	tween a PBM and a carrier for the provision or ad-
4	ministration of a program of prescription drug cov-
5	erage under a health benefits plan under this chap-
6	ter. Such a contract may provide, among other du-
7	ties, for the PBM to—
8	"(A) process and pay prescription drug
9	claims;
10	"(B) provide programs and services de-
11	signed to—
12	"(i) maximize the effectiveness of pre-
13	scription drugs dispensed under such plan;
14	or
15	"(ii) contain prescription drug ex-
16	penditures under such plan; and
17	"(C) engage in other activities related to
18	the administration of such prescription drug
19	coverage.
20	"(4) PBM MANUFACTURER CONTRACT.—The
21	term 'PBM manufacturer contract' means a contract
22	between a PBM and a prescription drug manufac-
23	turer for the provision of prescription drugs to en-
24	rollees of health benefits plans with prescription

1	drug coverage that is administered or provided by
2	the PBM.
3	"(5) Pharmacy benefit manager; pbm.—
4	The terms 'pharmacy benefit manager' and 'PBM'
5	mean an entity that contracts with a carrier to pro-
6	vide or administer prescription drug coverage under
7	a health benefits plan under this chapter.".
8	(c) Clerical Amendment.—The table of sections
9	for chapter 89 of title 5, United States Code, is amended
10	by adding at the end the following:
	"8915. Requirements for PBM arrangements.".
11	(d) Effective Date; Waiver; Regulations.—
12	(1) Effective date.—The amendments made
13	by this section shall apply to contract years begin-
14	ning on or after January 1, 2012.
15	(2) Waiver.—The Office of Personnel Manage-
16	ment may waive the application of 1 or more of the
17	requirements of section 8915 of title 5, United
18	States Code, but only for contract year 2012.
19	(3) Expediting implementation of regula-
20	TIONS.—Not later than 6 months after the date of
21	the enactment of this Act, the Office of Personnel
22	Management shall issue interim final regulations to
23	carry out this section which may be effective and
24	final immediately on an interim basis as of the date

of publication of such regulations. If the Office pro-

vides for an interim final regulation, the Office shall provide for a period of public comment on such regulation after the date of publication. The Office may change or revise such regulation after completion of the period of public comment.

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