112TH CONGRESS 1ST SESSION

H. R. 1971

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

IN THE HOUSE OF REPRESENTATIVES

May 24, 2011

Mrs. McMorris Rodgers (for herself and Mr. Weiner) 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 the Workforce, 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

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".

1	SEC. 2. PHARMACY BENEFITS MANAGER TRANSPARENCY
2	AND PROPER OPERATION REQUIREMENTS.
3	(a) Amendment to the Public Health Service
4	ACT RELATING TO THE GROUP MARKET.—
5	(1) In general.—Subpart 2 of part A of title
6	XXVII of the Public Health Service Act (42 U.S.C.
7	300gg-4 et seq.) is amended by adding at the end
8	the following:
9	"SEC. 2729. PHARMACY BENEFITS MANAGER TRANS-
10	PARENCY AND PROPER OPERATION RE-
11	QUIREMENTS.
12	"(a) In General.—Notwithstanding any other pro-
13	vision of law, a group health plan, and a health insurance
14	issuer providing health insurance coverage in connection
15	with a group health plan (collectively, a 'plan sponsor'),
16	shall not enter into a contract with any pharmacy benefits
17	manager (referred to in this section as a 'PBM') to man-
18	age the prescription drug coverage provided under such
19	plan or insurance coverage, or to control the costs of such
20	prescription drug coverage, unless the PBM satisfies the
21	following requirements:
22	"(1) Required disclosures to plan spon-
23	SOR IN ANNUAL REPORT.—The PBM shall provide
24	at least annually a report to each plan sponsor, in-
25	cluding, at a minimum—

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1	"(A) information on the number and total
2	cost of prescriptions under the contract filled at
3	mail order and at retail pharmacies;
4	"(B) an estimate of aggregate average
5	payments under the contract, per prescription
5	(weighted by prescription volume), made to mail
7	order and retail pharmacies, and the average

order and retail pharmacies;

"(C) an estimate of 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 such payments that were shared with the plan, and the percentage of prescriptions for which the PBM received such payments;

amount per prescription that the PBM was

paid by the plan for prescriptions filled at mail

"(D) information on the overall percentage of generic drugs dispensed under the contract separately at retail and mail order pharmacies,

1	and the percentage of cases in which a generic
2	drug is dispensed when available; and
3	"(E) information on the percentage and
4	number of cases under the contract in which in-
5	dividuals who had been receiving a prescribed
6	drug that had a lower cost for the plan were
7	later given a drug with a higher cost for the
8	plan, because of PBM policies or at the direct
9	or indirect control of the PBM, and the ration-
10	ale for such changes and a description of the
11	applicable PBM policies.
12	"(2) PBM requirements with respect to
13	PHARMACIES.—With respect to contracts between a
14	PBM and a pharmacy, the PBM shall—
14 15	PBM and a pharmacy, the PBM shall— "(A) include in such contracts, the meth-
15	"(A) include in such contracts, the meth-
15 16	"(A) include in such contracts, the methodology and resources utilized for the Maximum
15 16 17	"(A) include in such contracts, the methodology and resources utilized for the Maximum Allowable Cost (referred to in this section as
15 16 17 18	"(A) include in such contracts, the methodology and resources utilized for the Maximum Allowable Cost (referred to in this section as 'MAC') pricing of the PBM, update pricing in-
15 16 17 18 19	"(A) include in such contracts, the methodology and resources utilized for the Maximum Allowable Cost (referred to in this section as 'MAC') pricing of the PBM, update pricing information on such list at least weekly, and es-
15 16 17 18 19 20	"(A) include in such contracts, the methodology and resources utilized for the Maximum Allowable Cost (referred to in this section as 'MAC') pricing of the PBM, update pricing information on such list at least weekly, and establish a process for the prompt notification of
15 16 17 18 19 20 21	"(A) include in such contracts, the methodology and resources utilized for the Maximum Allowable Cost (referred to in this section as 'MAC') pricing of the PBM, update pricing information on such list at least weekly, and establish a process for the prompt notification of such pricing updates to network pharmacies;

1	scription prices that will be used to reimburse
2	pharmacies;
3	"(C) agree to pay pharmacies promptly for
4	clean claims under section 1860D-12(b)(4) of
5	the Social Security Act (42 U.S.C. 1395w-
6	112(b)(4));
7	"(D) not require that a pharmacist or
8	pharmacy participate in a pharmacy network
9	managed by such PBM as a condition for the
10	pharmacy to participate in another network
11	managed by such PBM, and shall not exclude
12	an otherwise qualified pharmacist or pharmacy
13	from participation in a particular network pro-
14	vided that the pharmacist or pharmacy—
15	"(i) accepts the terms, conditions and
16	reimbursement rates of the PBM;
17	"(ii) meets all applicable Federal and
18	State licensure and permit requirements;
19	and
20	"(iii) has not been excluded from par-
21	ticipation in any Federal or State program;
22	"(E) not automatically enroll a pharmacy
23	in a contract or modify an existing contract
24	without written agreement from the pharmacy
25	or pharmacist; and

1	"(F) require each pharmacy to sign a con-
2	tract before assuming responsibility to fill pre-
3	scriptions for the PBM.
4	"(3) PBM ownership interests and con-
5	FLICTS OF INTEREST; PHARMACY CHOICE.—A PBM
6	shall not—
7	"(A) mandate that a covered individual use
8	a specific retail pharmacy, mail order phar-
9	macy, specialty pharmacy, or other pharmacy
10	practice site or entity if the PBM has an own-
11	ership interest in such pharmacy, practice site,
12	or entity or the pharmacy, practice site, or enti-
13	ty has an ownership interest in the PBM; or
14	"(B) provide incentives to covered plan
15	beneficiaries, in the form of variations in pre-
16	miums, deductibles, co-payments, or co-insur-
17	ance rates, to encourage plan beneficiaries to
18	use a specific pharmacy if such incentives are
19	only applicable to a pharmacy, practice site, or
20	entity that the PBM has an ownership interest
21	in, unless such incentives are applicable to all
22	network pharmacies.
23	"(4) PBM audit of pharmacy providers.—
24	The following shall apply to audits of pharmacy pro-
25	viders by a PBM:

"(A) The period covered by an audit may 1 2 not exceed 2 years from the date the claim was submitted to or adjusted by the PBM. 3 "(B) An audit that involves clinical or professional judgment shall be conducted by, or in 6 consultation with, a pharmacist licensed in the 7 State of the audit or the State board of phar-8 macy. "(C) The PBM may not require more 9 10 stringent recordkeeping than that required by 11 State or Federal law. "(D) The PBM or the entity conducting 12 13 an audit for the PBM shall establish a written 14 appeals process that shall include procedures 15 for appeals for preliminary reports and final re-16 ports. 17 "(E) The pharmacy, practice site, or other 18 entity may use the records of a hospital, physi-19 cian, or other authorized practitioner to validate 20 the pharmacy records and any legal prescription 21 (one that complies with State Board of Phar-

macy requirements) may be used to validate

claims in connection with prescriptions, refills,

or changes in prescriptions.

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1	"(F) Any clerical or recordkeeping error,
2	such as a typographical error, scrivener's error,
3	or computer error, regarding a required docu-
4	ment or record shall not be subject to
5	recoupment unless proof of intent to commit
6	fraud or unless such discrepancy results in ac-
7	tual financial harm to an interested party.
8	"(G) The entity conducting the audit shall
9	not use extrapolation or other statistical expan-
10	sion techniques in calculating the recoupment
11	or penalties for audits.
12	"(H) The PBM shall disclose any audit
13	recoupment to the group health plan or health
14	insurance issuer with a copy to the pharmacy.
15	"(5) PBM conduct regarding covered in-
16	DIVIDUALS.—A PBM shall—
17	"(A) notify a plan sponsor if such PBM in-
18	tends to sell utilization or claims data that the
19	PBM possesses as a result of an arrangement
20	described in this section;
21	"(B) notify the plan sponsor in writing at
22	least 30 days before selling, leasing, or renting
23	such data and shall provide the plan sponsor
24	with the name of the potential purchaser of

1	such data and the expected use of any utiliza-
2	tion or claims data by such purchaser;
3	"(C) not sell such data unless the sale
4	complies with all Federal and State laws and
5	the PBM has received written approval for such
6	sale from the plan sponsor;
7	"(D) not directly contact a covered indi-
8	vidual by any means (including via electronic
9	delivery, telephonic, SMS text or direct mail)
10	without the express written permission of the
11	plan sponsor and the covered individual;
12	"(E) not transmit any personally identifi-
13	able utilization or claims data to a pharmacy
14	owned by the PBM if the patient has not volun-
15	tarily elected in writing to fill that particular
16	prescription at the PBM-owned pharmacy; and
17	"(F) provide each covered individual with
18	an opportunity to affirmatively opt out of the
19	sale of his or her data prior to entering into
20	any arrangement for the lease, rental, or sale of
21	such information.
22	"(b) Definition.—For purposes of this section, the
23	term 'fraud' has the meaning given the term 'health care
24	fraud' in section 1347 of title 18, United States Code.".

1	(2) Effective date.—The amendment made
2	by this subsection shall apply to plan sponsors for
3	plan years beginning on or after the date of enact-
4	ment of this Act.
5	(b) Amendments to the Public Health Service
6	ACT RELATING TO THE INDIVIDUAL MARKET.—
7	(1) In general.—Subpart 2 of part B of title
8	XXVII of the Public Health Service Act (42 U.S.C.
9	300gg-51 et seq.) is amended by adding at the end
10	the following:
11	"SEC. 2754. PHARMACY BENEFITS MANAGER TRANS-
12	PARENCY AND PROPER OPERATION RE-
1 2	The Thomas The Thomas of Electron 101
13	QUIREMENTS.
13	QUIREMENTS.
13 14	QUIREMENTS. "The provisions of section 2729 of the Public Health
13 14 15	QUIREMENTS. "The provisions of section 2729 of the Public Health Service Act shall apply to health insurance coverage of-
13 14 15 16	QUIREMENTS. "The provisions of section 2729 of the Public Health Service Act shall apply to health insurance coverage of- fered by a health insurance issuer in the individual market
13 14 15 16	QUIREMENTS. "The provisions of section 2729 of the Public Health Service Act shall apply to health insurance coverage offered by a health insurance issuer in the individual market in the same manner as they apply to a group health plan
113 114 115 116 117	QUIREMENTS. "The provisions of section 2729 of the Public Health Service Act shall apply to health insurance coverage offered by a health insurance issuer in the individual market in the same manner as they apply to a group health plan and a health insurance issuer providing health insurance
13 14 15 16 17 18	QUIREMENTS. "The provisions of section 2729 of the Public Health Service Act shall apply to health insurance coverage offered by a health insurance issuer in the individual market in the same manner as they apply to a group health plan and a health insurance issuer providing health insurance coverage under that section.".
13 14 15 16 17 18 19 20	QUIREMENTS. "The provisions of section 2729 of the Public Health Service Act shall apply to health insurance coverage offered by a health insurance issuer in the individual market in the same manner as they apply to a group health plan and a health insurance issuer providing health insurance coverage under that section.". (2) Conforming amendments.—
13 14 15 16 17 18 19 20 21	QUIREMENTS. "The provisions of section 2729 of the Public Health Service Act shall apply to health insurance coverage offered by a health insurance issuer in the individual market in the same manner as they apply to a group health plan and a health insurance issuer providing health insurance coverage under that section.". (2) Conforming amendments.— (A) ERISA amendment.—

1	(29 U.S.C. 1185 et seq.) is amended by
2	adding at the end the following:
3	"SEC. 716. 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 a group health plan, and a
8	health insurance issuer providing health insurance cov-
9	erage in connection with a group health plan, in the same
10	manner as such provisions apply to a group health plan
11	and a health insurance issuer providing health insurance
12	coverage under that section.".
13	(ii) Clerical amendment.—The
14	table of contents in section 1 of the Em-
15	ployee Retirement Income Security Act of
16	1974 is amended by inserting after the
17	item relating to section 714 the following:
	"Sec. 715. Additional market reforms. "Sec. 716. Pharmacy benefits manager transparency and proper operation requirements.".
18	(B) IRC AMENDMENT.—
19	(i) In general.—Subpart B of chap-
20	ter 100 of the Internal Revenue Code of
21	1986 (26 U.S.C. 9811 et seq.) is amended
22	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 requirements.".
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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