## 108TH CONGRESS 2D SESSION

## H. R. 5278

To ensure and foster continued patient safety and quality of care by making the antitrust laws apply to negotiations between groups of independent pharmacies and health plans and health insurance issuers in the same manner as such laws apply to collective bargaining by labor organizations under the National Labor Relations Act, to ensure integrity in the operation of pharmacy benefit managers, and to preserve access standards to community pharmacies under the Medicare outpatient prescription drug program.

## IN THE HOUSE OF REPRESENTATIVES

OCTOBER 7, 2004

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 the Judiciary and Ways and Means, 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 ensure and foster continued patient safety and quality of care by making the antitrust laws apply to negotiations between groups of independent pharmacies and health plans and health insurance issuers in the same manner as such laws apply to collective bargaining by labor organizations under the National Labor Relations Act, to ensure integrity in the operation of pharmacy benefit managers, and to preserve access standards to

community pharmacies under the Medicare outpatient prescription drug 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 "Community Pharmacy
- 5 Preservation Act of 2004".
- 6 SEC. 2. APPLICATION OF THE ANTITRUST LAWS TO INDE-
- 7 PENDENT PHARMACIES NEGOTIATING WITH
- 8 HEALTH PLANS.
- 9 (a) IN GENERAL.—Any independent pharmacies who
- 10 are engaged in negotiations with a health plan regarding
- 11 the terms of any contract under which the pharmacies pro-
- 12 vide health care items or services for which benefits are
- 13 provided under such plan shall, in connection with such
- 14 negotiations, be entitled to the same treatment under the
- 15 antitrust laws as the treatment to which bargaining units
- 16 which are recognized under the National Labor Relations
- 17 Act are entitled in connection with such collective bar-
- 18 gaining. Such a pharmacy shall, only in connection with
- 19 such negotiations, be treated as an employee engaged in
- 20 concerted activities and shall not be regarded as having
- 21 the status of an employer, independent contractor, mana-
- 22 gerial employee, or supervisor.
- 23 (b) Protection for Good Faith Actions.—Ac-
- 24 tions taken in good faith reliance on subsection (a) shall

- 1 not be the subject under the antitrust laws of criminal
- 2 sanctions nor of any civil damages, fees, or penalties be-
- 3 yound actual damages incurred.
- 4 (c) Limitation.—
- 5 (1) No New RIGHT FOR COLLECTIVE CES-6 SATION OF SERVICE.—The exemption provided in 7 subsection (a) shall not confer any new right to par-8 ticipate in any collective cessation of service to pa-9 tients not already permitted by existing law.
- 10 (2) NO CHANGE IN NATIONAL LABOR RELA11 TIONS ACT.—This section applies only to inde12 pendent pharmacies excluded from the National
  13 Labor Relations Act. Nothing in this section shall be
  14 construed as changing or amending any provision of
  15 the National Labor Relations Act, or as affecting
  16 the status of any group of persons under that Act.
- 17 (d) Effective Date.—The exemption provided in 18 subsection (a) shall apply to conduct occurring beginning 19 on the date of the enactment of this Act.
- 20 (e) Limitation on Exemption.—Nothing in this 21 section shall exempt from the application of the antitrust 22 laws any agreement or otherwise unlawful conspiracy that 23 excludes, limits the participation or reimbursement of, or 24 otherwise limits the scope of services to be provided by

- 1 macies with respect to the performance of services that
- 2 are within their scope of practice as defined or permitted
- 3 by relevant law or regulation.
- 4 (f) No Effect on Title VI of Civil Rights Act
- 5 OF 1964.—Nothing in this section shall be construed to
- 6 affect the application of title VI of the Civil Rights Act
- 7 of 1964.
- 8 (g) No Application to Federal Programs.—
- 9 Nothing in this section shall apply to negotiations between
- 10 independent pharmacies and health plans pertaining to
- 11 benefits provided under any of the following:
- 12 (1) The Medicaid Program under title XIX of
- the Social Security Act (42 U.S.C. 1396 et seq.).
- 14 (2) The SCHIP program under title XXI of the
- 15 Social Security Act (42 U.S.C. 1397aa et seq.).
- 16 (3) Chapter 55 of title 10, United States Code
- 17 (relating to medical and dental care for members of
- the uniformed services).
- 19 (4) Chapter 17 of title 38, United States Code
- 20 (relating to Veterans' medical care).
- 21 (5) Chapter 89 of title 5, United States Code
- (relating to the Federal employees' health benefits
- program).
- 24 (6) The Indian Health Care Improvement Act
- 25 (25 U.S.C. 1601 et seq.).

1	(h) Definitions.—For purposes of this section:
2	(1) Antitrust laws.—The term "antitrust
3	laws''—
4	(A) has the meaning given it in subsection
5	(a) of the first section of the Clayton Act (15
6	U.S.C. 12(a)), except that such term includes
7	section 5 of the Federal Trade Commission Act
8	(15 U.S.C. 45) to the extent such section 5 ap-
9	plies to unfair methods of competition; and
10	(B) includes any State law similar to the
11	laws referred to in subparagraph (A).
12	(2) Health plan and related terms.—
13	(A) IN GENERAL.—The term "health plan"
14	means a group health plan or a health insur-
15	ance issuer that is offering health insurance
16	coverage.
17	(B) HEALTH INSURANCE COVERAGE
18	HEALTH INSURANCE ISSUER.—The terms
19	"health insurance coverage" and "health insur-
20	ance issuer" have the meanings given such
21	terms under paragraphs (1) and (2), respec-
22	tively, of section 733(b) of the Employee Retire-
23	ment Income Security Act of 1974 (29 U.S.C
24	1191b(b)).

1	(C) GROUP HEALTH PLAN.—The term
2	"group health plan" has the meaning given that
3	term in section 733(a)(1) of the Employee Re-
4	tirement Income Security Act of 1974 (29
5	U.S.C. $1191b(a)(1)$ ).
6	(3) Independent pharmacy.—The term
7	"independent pharmacy" means a pharmacy which
8	is not owned (or operated) by a publicly traded com-
9	pany. For purposes of the previous sentence, the
10	term "publicly traded company" means a company
11	that is an issuer within the meaning of section
12	2(a)(7) of the Sarbanes-Oxley Act of $2002$ (15)
	$H \otimes C = 7901(2)(7)$
13	U.S.C. $7201(a)(7)$ ).
13 14	SEC. 3. REQUIREMENTS RELATING TO PHARMACY BENEFIT
14	SEC. 3. REQUIREMENTS RELATING TO PHARMACY BENEFIT
14 15	SEC. 3. REQUIREMENTS RELATING TO PHARMACY BENEFIT MANAGERS.
14 15 16	SEC. 3. REQUIREMENTS RELATING TO PHARMACY BENEFIT MANAGERS.  (a) Prohibition on Cross Ownership.—
14 15 16 17	SEC. 3. REQUIREMENTS RELATING TO PHARMACY BENEFIT MANAGERS.  (a) PROHIBITION ON CROSS OWNERSHIP.—  (1) IN GENERAL.—No pharmaceutical drug
14 15 16 17	SEC. 3. REQUIREMENTS RELATING TO PHARMACY BENEFIT MANAGERS.  (a) PROHIBITION ON CROSS OWNERSHIP.—  (1) IN GENERAL.—No pharmaceutical drug manufacturer may have a controlling interest in an
14 15 16 17 18	SEC. 3. REQUIREMENTS RELATING TO PHARMACY BENEFIT MANAGERS.  (a) PROHIBITION ON CROSS OWNERSHIP.—  (1) IN GENERAL.—No pharmaceutical drug manufacturer may have a controlling interest in an entity that is a pharmacy benefit manager.
14 15 16 17 18 19 20	SEC. 3. REQUIREMENTS RELATING TO PHARMACY BENEFIT MANAGERS.  (a) PROHIBITION ON CROSS OWNERSHIP.—  (1) IN GENERAL.—No pharmaceutical drug manufacturer may have a controlling interest in an entity that is a pharmacy benefit manager.  (2) PENALTY.—The Secretary of Health and
14 15 16 17 18 19 20	SEC. 3. REQUIREMENTS RELATING TO PHARMACY BENEFIT MANAGERS.  (a) PROHIBITION ON CROSS OWNERSHIP.—  (1) IN GENERAL.—No pharmaceutical drug manufacturer may have a controlling interest in an entity that is a pharmacy benefit manager.  (2) Penalty.—The Secretary of Health and Human Services may issue such civil penalties for a
14 15 16 17 18 19 20 21	MANAGERS.  (a) Prohibition on Cross Ownership.—  (1) In General.—No pharmaceutical drug manufacturer may have a controlling interest in an entity that is a pharmacy benefit manager.  (2) Penalty.—The Secretary of Health and Human Services may issue such civil penalties for a violation of paragraph (1) as the Secretary of

- (A) Cost increase.—A pharmacy benefit manager shall not make any drug interchange proposal for an individual who is served by such manager where the net cost of the drug to which the prescription would be changed exceeds that of the drug from which the prescription would be changed.
  - (B) DISCLOSURE TO INDIVIDUAL.—A pharmacy benefit manager shall not make any drug interchange for an individual who is served by such manager unless the pharmacy benefit manager discloses to the individual, in a clear and conspicuous manner, the savings to the individual associated with such interchange.
  - (C) GENERICS.—A pharmacy benefit manager shall not make any drug interchange proposal for an individual who is served by such manager if the drug from which the prescription would be changed has generic equivalents and the drug to which the prescription would be changed has no generic equivalents, unless the drug to which the prescription would be changed has a lower net cost to the individual than does each of the generic equivalents of the

- drug from which the prescription would be changed.
- that violates subparagraph (A), (B), or (C) of paragraph (1) with respect to an individual and presents a claim for payment to the United States Government as reimbursement for services to such individual, shall be considered in violation of section 3729 of title 31, United States Code.
- 10 (c) Disclosure of Compensation From Drug 11 Manufacturers.—
- 12 (1) QUARTERLY AND ANNUAL DISCLOSURES.—
  13 At the end of each fiscal year quarter, each phar14 macy benefit manager shall disclose—
  - (A) to the client plans of such manager and to the Antitrust Division of the Department of Justice, all compensation and remuneration that the pharmacy benefit manager received during such fiscal year quarter from a pharmaceutical drug manufacturer, including, regardless of how categorized, market share incentives, commissions, mail service purchase discounts, and administrative or management fees; and

- 1 (B) to the client plans of such manager, 2 any fees received for sales of utilization data to 3 a pharmaceutical drug manufacturer.
  - (2) DISCLOSURE AT CONTRACTING STAGE.—
    Each pharmacy benefit manager shall disclose to each client plan and prospective client plan of such manager, in advance of executing an agreement with such plan, information relating to the pharmacy benefit manager's methodology of soliciting and receiving payments from pharmaceutical drug manufacturers.
    - (d) Definitions.—For purposes of this section:
    - (1) CLIENT PLAN.—The term "client plan" means a pharmaceutical plan in which the entity that offers such plan to its beneficiaries contracts directly with a pharmacy benefit manager to provide or administer such plan.
  - (2) Drug interchange.—The term "drug interchange" means any change from one prescription drug to another prescription drug that is intended to address or treat the same illness or condition.

1	SEC. 4. COMMUNITY PHARMACY ACCESS STANDARDS
2	UNDER THE MEDICARE OUTPATIENT PRE-
3	SCRIPTION DRUG PROGRAM.
4	In establishing rules under subparagraph (C) of sec-
5	tion 1860D-4(b)(1) of the Social Security Act, as added
6	by the Medicare Prescription Drug, Improvement, and
7	Modernization Act of 2003 (Public Law 108–173), for
8	convenient access to non-mail-order pharmacies consistent
9	with the application of standards under clause (ii) of such
10	subparagraph, the Secretary of Health and Human Serv-
11	ices shall provide for application of the following stand-
12	ards:
13	(1)(A) In each urban area, at least 90 percent
14	of Medicare beneficiaries in a plan's service area, or
15	average, live within 2 miles of a retail pharmacy par-
16	ticipation in the prescription drug plan's or MA-PD
17	plan's network.
18	(B) In each suburban area, at least 90 percent
19	of Medicare beneficiaries in a plan's service area, or
20	average, live within 5 miles of a retail pharmacy par-
21	ticipation in the prescription drug plan's or MA-PD
22	plan's network.
23	(C) In each rural area, at least 70 percent of
24	Medicare beneficiaries in a plan's service area, or
25	average, live within 15 miles of a retail pharmacy

- participation in the prescription drug plan's or MA–
   PD plan's network.
  - (D) There shall be no averaging of such distances across or among urban, suburban, and rural areas.
    - (2) The rules shall require plans to measure traveling distances from beneficiaries' homes to community pharmacies based on commonly traveled routes.

 $\bigcirc$