110TH CONGRESS 1ST SESSION S. 1954

To amend title XVIII of the Social Security Act to improve access to pharmacies under part D.

IN THE SENATE OF THE UNITED STATES

August 2, 2007

Mr. BAUCUS (for himself, Mr. GRASSLEY, Mrs. LINCOLN, Mr. ROBERTS, Mr. CONRAD, Mr. ENZI, Mr. SCHUMER, Mr. COCHRAN, Mr. SALAZAR, Mr. SMITH, Mr. BINGAMAN, and Ms. SNOWE) introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

To amend title XVIII of the Social Security Act to improve access to pharmacies under part D.

- 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 Access Im-
- 5 provement (PhAIm) Act of 2007".

1SEC. 2. STRENGTHENING STANDARDS FOR ACCESS TO2PHARMACIES.

3 (a) IN GENERAL.—Section 1860D-4(b)(1)(C) of the
4 Social Security Act (42 U.S.C. 1395w-104(b)(1)(C)) is
5 amended—

6 (1) in clause (i)—

7 (A) by inserting "that are accessible to the 8 general public (not including closed pharmacies, 9 such as pharmacies that dispense drugs by mail 10 order only or are located in a hospital or nurs-11 ing home, except that a closed pharmacy shall 12 be included if the pharmacy is operated by the 13 Indian Health Service, an Indian tribe or tribal 14 organization, or an urban Indian organization 15 (as defined in section 4 of the Indian Health Care Improvement Act))" after "sufficient 16 17 number of pharmacies"; and

18 (B) by striking "(other than by mail19 order)"; and

(2) in clause (ii), by adding at the end the following new sentence: "If the PDP sponsor of a prescription drug plan designates in-network pharmacies as either preferred or non-preferred pharmacies (or any designation other than preferred or
any other distinction between or among pharmacies
with respect to participation status), only in-network

1	preferred pharmacies shall be counted in deter-
2	mining if the requirements of such rules are met.".
3	(b) EXPANDING PARTICIPATION BY ANY WILLING
4	PHARMACY.—Section 1860D–4(b)(1)(A) of the Social Se-
5	curity Act (42 U.S.C. 1395w–104(b)(1)(A)) is amended—
6	(1) by striking "PHARMACY.—A prescription
7	drug plan" and inserting "PHARMACY.—
8	"(i) IN GENERAL.—Subject to clause
9	(ii), a prescription drug plan";
10	(2) in clause (i), as added by paragraph (1), by
11	adding at the end the following new sentence: "A
12	previous refusal by a pharmacy of an offer to par-
13	ticipate, or the expiration of such an offer, shall not
14	be grounds to exclude a pharmacy from participation
15	under this subparagraph."; and
16	(3) by adding at the end the following new
17	clause:
18	"(ii) Participation of 340b enti-
19	TIES.—
20	"(I) IN GENERAL.—A prescrip-
21	tion drug plan shall not exclude a
22	pharmacy from participation solely on
23	the basis that such pharmacy is a cov-
24	ered entity under section 340B of the
25	Public Health Service Act.

1	"(II) REASONABLE TERMS AND
2	CONDITIONS FOR 340B ENTITIES.—In
3	the case of a pharmacy that is a cov-
4	ered entity under such section 340B,
5	if such an entity requests that the
6	terms and conditions of the appro-
7	priate version (as determined by the
8	Secretary) of the Model Safety Net
9	Pharmacy Addendum to Pharmacy
10	Contract apply to a contract to dis-
11	pense covered part D drugs under
12	such plan, subject to subclause (III),
13	the terms and conditions of such con-
14	tract shall be the terms and condi-
15	tions for participation of such phar-
16	macy under clause (i).
17	"(III) PERMITTING WAIVER OF
18	COST-SHARING.—In the case of a
19	pharmacy that is a covered entity
20	under such section 340B, if such an
21	entity requests that the terms and
22	conditions of a contract to dispense
23	covered part D drugs under such plan
24	permit the pharmacy to waive or re-
25	duce cost-sharing under this part,

1	consistent with the requirements of
2	section 1128B(b)(3)(G), such permis-
3	sion shall be included in the terms
4	and conditions for participation of
5	such pharmacy under clause (i).".
6	(c) Strengthening Convenient Access Stand-
7	ARDS.—
8	(1) Access in long-term care facilities
9	AND TO PHARMACIES SERVING INDIANS.—Section
10	1860D-4(b)(1)(C) of the Social Security Act (42)
11	U.S.C. $1395w-104(b)(1)(C)$) is amended by striking
12	clause (iv) and inserting the following new clauses:
13	"(iv) Convenient access in long-
14	TERM CARE FACILITIES.—Such rules shall
15	include standards with respect to access
16	for enrollees who are residing in long-term
17	care facilities to ensure that such enrollees
18	have access to a long-term care network
19	pharmacy.
20	"(v) Convenient access to phar-
21	MACIES SERVING INDIANS.—Such rules
22	may include standards with respect to ac-
23	cess for enrollees to pharmacies operated
24	by the Indian Health Service, Indian tribes
25	and tribal organizations, and urban Indian

organizations (as defined in section 4 of
the Indian Health Care Improvement
Act.".
(2) Convenient access to extended sup-
PLIES AT RETAIL PHARMACIES.—Section 1860D-
4(b)(1)(C) of the Social Security Act (42 U.S.C.
1395w–104(b)(1)(C)), as amended by paragraph

8 (1), is amended—

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(A) in clause (ii), by striking "The Sec-9 retary" and inserting "Subject to clause (vi), 10 11 the Secretary"; and

12 (B) by adding at the end the following new 13 clause:

14 "(vi) The Secretary shall establish 15 rules for convenient access to in-network 16 pharmacies under this subparagraph that 17 dispense extended supplies of covered part 18 D drugs that are modeled after the rules 19 for convenient access to pharmacies in-20 cluded in the statement of work described 21 in clause (ii).".

22 (d) DISCLOSURE OF MAXIMUM ALLOWABLE COST 23 PRICING.—Section 1860D–4(b)(1) of the Social Security 24 Act (42 U.S.C. 1395w-104(b)(1)) is amended by adding at the end the following new subparagraph: 25

1	"(F) DISCLOSURE OF MAXIMUM ALLOW-
2	ABLE COST PRICING.—If a contract for a phar-
3	macy to dispense covered part D drugs under a
4	prescription drug plan references maximum al-
5	lowable cost lists or pricing, the PDP sponsor
6	of such plan shall disclose, through (at a min-
7	imum) an Internet website and a toll-free tele-
8	phone number—
9	"(i) any such lists or pricing to the
10	pharmacy at the time of offering such con-
11	tract; and
12	"(ii) information updated not less fre-
13	quently than every 7 days on such lists or
14	pricing to pharmacies that have entered
15	into such a contract.".
16	(e) EFFECTIVE DATE.—The amendments made by
17	this section shall take effect on the date that is 180 days
18	after the date of enactment of this Act.
19	SEC. 3. PROMPT PAYMENT BY PRESCRIPTION DRUG PLANS
20	AND MA-PD PLANS UNDER PART D.
21	(a) PROMPT PAYMENT BY PRESCRIPTION DRUG
22	PLANS.—Section 1860D–12(b) of the Social Security Act
23	(42 U.S.C. 1395w–112(b)) is amended by adding at the
24	end the following new paragraph:
25	"(4) PROMPT PAYMENT OF CLEAN CLAIMS.—

"(A) PROMPT PAYMENT.—

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2 "(i) IN GENERAL.—Each contract entered into with a PDP sponsor under this 3 4 part with respect to a prescription drug 5 plan offered by such sponsor shall provide 6 that payment shall be issued, mailed, or 7 otherwise transmitted with respect to all 8 clean claims submitted by pharmacies 9 (other than pharmacies that dispense 10 drugs by mail order only or are located in, 11 or contract with, a long-term care facility) 12 under this part within the applicable num-13 ber of calendar days after the date on 14 which the claim is received.

"(ii) CLEAN CLAIM DEFINED.—In this 15 16 paragraph, the term 'clean claim' means a 17 claim that has no defect or impropriety 18 (including any lack of any required sub-19 stantiating documentation) or particular 20 circumstance requiring special treatment that prevents timely payment from being 21 22 made on the claim under this part.

23 "(B) APPLICABLE NUMBER OF CALENDAR
24 DAYS DEFINED.—In this paragraph, the term
25 'applicable number of calendar days' means—

1	"(i) with respect to claims submitted
2	electronically, 14 days; and
3	"(ii) with respect to claims submitted
4	otherwise, 30 days.
5	"(C) INTEREST PAYMENT.—If payment is
6	not issued, mailed, or otherwise transmitted
7	within the applicable number of calendar days
8	(as defined in subparagraph (B)) after a clean
9	claim is received, the PDP sponsor shall pay in-
10	terest to the pharmacy that submitted the claim
11	at a rate equal to the weighted average of inter-
12	est on 3-month marketable Treasury securities
13	determined for such period, increased by 0.1
14	percentage point for the period beginning on
15	the day after the required payment date and
16	ending on the date on which payment is made
17	(as determined under subparagraph $(D)(iv)$).
18	Interest amounts paid under this subparagraph
19	shall not be counted against the administrative
20	costs of a prescription drug plan or treated as
21	allowable risk corridor costs under section
22	1860D–15(e).
23	"(D) PROCEDURES INVOLVING CLAIMS.—
24	"(i) CLAIM DEEMED TO BE CLEAN.—
25	A claim is deemed to be a clean claim if

1 the PDP sponsor involved does not provide 2 notice to the claimant of any deficiency in the claim within 10 days of the date on 3 4 which the claim is submitted. 5 "(ii) Claim determined to not be 6 A CLEAN CLAIM.— 7 "(I) IN GENERAL.—If a PDP 8 sponsor determines that a submitted 9 claim is not a clean claim, the PDP 10 sponsor shall, not later than the end 11 of the period described in clause (i), notify the claimant of such determina-12 13 tion. Such notification shall specify all 14 defects or improprieties in the claim 15 and shall list all additional informa-16 tion or documents necessary for the 17 proper processing and payment of the 18 claim. 19 "(II) DETERMINATION AFTER 20 SUBMISSION OF ADDITIONAL INFOR-

MATION.—A claim is deemed to be a

clean claim under this paragraph if

the PDP sponsor involved does not

provide notice to the claimant of any

defect or impropriety in the claim

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1	within 10 days of the date on which
2	additional information is received
3	under subclause (I).
4	"(III) PAYMENT OF CLEAN POR-
5	TION OF A CLAIM.—A PDP sponsor
6	shall, as appropriate, pay any portion
7	of a claim that would be a clean claim
8	but for a defect or impropriety in a
9	separate portion of the claim in ac-
10	cordance with subparagraph (A).
11	"(iii) Obligation to pay.—A claim
12	submitted to a PDP sponsor that is not
13	paid or contested by the sponsor within the
14	applicable number of days (as defined in
15	subparagraph (B)) shall be deemed to be a
16	clean claim and shall be paid by the PDP
17	sponsor in accordance with subparagraph
18	(A).
19	"(iv) Date of payment of claim
20	Payment of a clean claim under such sub-
21	paragraph is considered to have been made
22	on the date on which—
23	"(I) with respect to claims paid
24	electronically, the payment is trans-
25	ferred; and

"(II) with respect to claims paid
 otherwise, the payment is submitted
 to the United States Postal Service or
 common carrier for delivery.

5 "(E) ELECTRONIC TRANSFER OF FUNDS.—A PDP sponsor shall pay all clean 6 7 claims submitted electronically by electronic 8 transfer of funds if the pharmacy so requests or 9 has so requested previously. In the case where 10 such payment is made electronically, remittance 11 may be made by the PDP sponsor electronically 12 as well.

13 "(F) PROTECTING THE RIGHTS OF CLAIM14 ANTS.—

15 "(i) IN GENERAL.—Nothing in this
16 paragraph shall be construed to prohibit or
17 limit a claim or action not covered by the
18 subject matter of this section that any in19 dividual or organization has against a pro20 vider or a PDP sponsor.

21 "(ii) ANTI-RETALIATION.—Consistent
22 with applicable Federal or State law, a
23 PDP sponsor shall not retaliate against an
24 individual or provider for exercising a right
25 of action under this subparagraph.

1 "(G) RULE OF CONSTRUCTION.—A deter-2 mination under this paragraph that a claim 3 submitted by a pharmacy is a clean claim shall 4 not be construed as a positive determination re-5 garding eligibility for payment under this title, 6 nor is it an indication of government approval 7 of, or acquiescence regarding, the claim sub-8 mitted. The determination shall not relieve any 9 party of civil or criminal liability with respect to 10 the claim, nor does it offer a defense to any ad-11 ministrative, civil, or criminal action with re-12 spect to the claim.". 13 (b) PROMPT PAYMENT BY MA-PD PLANS.—Section

14 1857(f) of the Social Security Act (42 U.S.C. 1395w-27)
15 is amended by adding at the end the following new para16 graph:

17 "(3) INCORPORATION OF CERTAIN PRESCRIP18 TION DRUG PLAN CONTRACT REQUIREMENTS.—The
19 following provisions shall apply to contracts with a
20 Medicare Advantage organization in the same man21 ner as they apply to contracts with a PDP sponsor
22 offering a prescription drug plan under part D:
23 "(A) PROMPT PAYMENT.—Section 1860D–

24 12(b)(4).".

(c) EFFECTIVE DATE.—The amendments made by
 this section shall take effect on the date that is 1 year
 after the date of enactment of this Act.

4 SEC. 4. MEDICARE PART D INFORMATIONAL RESOURCES 5 AND CUSTOMER SERVICE.

6 (a) HEALTH AND HUMAN SERVICES PHARMACY
7 HOTLINE.—The Secretary of Health and Human Services
8 shall—

9 (1) establish a toll-free telephone number that 10 is dedicated to providing information regarding the 11 Medicare prescription drug benefit under part D of 12 title XVIII of the Social Security Act to pharmacists 13 and pharmacy staff; and

14 (2) staff such telephone number in order to en15 sure that the toll-free number is available to answer
16 calls 24-hours each day.

17 (b) CUSTOMER SERVICE PROVIDED BY PRESCRIP-18 TION DRUG PLANS AND MA-PD PLANS.—

(1) IN GENERAL.—Section 1860D-4 of the Social Security Act (42 U.S.C. 1395w-104) is amended by adding at the end the following new subsection:

23 "(1) CUSTOMER SERVICE.—

24 "(1) PHARMACY HOTLINE.—A PDP sponsor of25 a prescription drug plan shall—

1	"(A) establish a toll-free telephone number
2	that is dedicated to providing information re-
3	garding the plan to pharmacists and pharmacy
4	staff; and
5	"(B) staff such telephone number in order
6	to ensure compliance with customer service
7	standards (as established by the Secretary).
8	"(2) Physician and provider hotline.—A
9	PDP sponsor of a prescription drug plan shall—
10	"(A) establish a toll-free telephone number
11	that is dedicated to providing information re-
12	garding the plan to physicians and providers;
13	and
14	"(B) staff such telephone number in order
15	to ensure compliance with customer service
16	standards (as established by the Secretary).".
17	(2) EFFECTIVE DATE.—The amendments made
18	by this subsection shall apply to plan years begin-
19	ning on or after January 1, 2008.
20	SEC. 5. RESTRICTIONS ON PHARMACY CO-BRANDING BY
21	PRESCRIPTION DRUG PLANS AND MA-PD
22	PLANS.
23	(a) IN GENERAL.—Section 1860D–4 of the Social
24	Security Act (42 U.S.C. 1395w–104), as amended by sec-

1 tion 4(b), is amended by adding at the end the following2 new subsection:

3 "(m) CO-BRANDING.—

4 "(1) PROHIBITION OF CO-BRANDING ON PRE5 SCRIPTION DRUG CARD.—A card that is issued
6 under subsection (b)(2)(A) for use under a prescrip7 tion drug plan offered by a PDP sponsor shall not
8 display the name, brand, logo, or trademark of any
9 pharmacy.

10 "(2) MARKETING MATERIALS.—Marketing ma11 terials distributed by a PDP sponsor that has a co12 branding relationship with a pharmacy with respect
13 to such a plan shall include a disclaimer in large,
14 off-set, bold-face type of the following: Other phar15 macies are also available in our network.".

(b) EFFECTIVE DATE.—The amendments made by
this section shall apply to cards and marketing materials
distributed on or after the date that is 60 days after the
date of enactment of this Act.

20 SEC. 6. SUBMISSION OF CLAIMS BY PHARMACIES LOCATED

21 IN OR CONTRACTING WITH LONG-TERM CARE 22 FACILITIES.

(a) SUBMISSION OF CLAIMS BY PHARMACIES LO24 CATED IN OR CONTRACTING WITH LONG-TERM CARE FA25 CILITIES.—

(1) SUBMISSION OF CLAIMS TO PRESCRIPTION
 DRUG PLANS.—Section 1860D-12(b) of the Social
 Security Act (42 U.S.C. 1395w-112(b)), as amend ed by section 3(a), is amended by adding at the end
 the following new paragraph:

6 "(5) SUBMISSION OF CLAIMS BY PHARMACIES 7 LOCATED IN OR CONTRACTING WITH LONG-TERM 8 CARE FACILITIES.—Each contract entered into with 9 a PDP sponsor under this part with respect to a 10 prescription drug plan offered by such sponsor shall 11 provide that a pharmacy located in, or having a con-12 tract with, a long-term care facility shall have not 13 less than 30 days (but not more than 90 days) to 14 submit claims to the sponsor for reimbursement 15 under the plan.".

16 (2) SUBMISSION OF CLAIMS TO MA-PD
17 PLANS.—Section 1857(f)(3) of the Social Security
18 Act, as added by section 3(b), is amended by adding
19 at the end the following new subparagraph:

20 "(B) SUBMISSION OF CLAIMS BY PHAR21 MACIES LOCATED IN OR CONTRACTING WITH
22 LONG-TERM CARE FACILITIES.—Section
23 1860D-12(b)(5).".

(b) EFFECTIVE DATE.—The amendments made by
 this section shall apply to plan years beginning on or after
 January 1, 2008.

4 SEC. 7. OIG STUDY AND REPORT ON DISPENSING FEES.

5 (a) STUDY.—The Inspector General of the Depart-6 ment of Health and Human Services shall conduct an 7 analysis of the cost of dispensing covered part D drugs 8 (as defined in section 1860D–2(e) of the Social Security 9 Act (42 U.S.C. 1395w–102(e)) under a prescription drug 10 plan under part D of title XVIII of such Act or an MA-PD plan under part C of such title that takes into consid-11 12 eration the following:

13 (1) Any reasonable costs associated with a
14 pharmacist's time in—

15 (A) checking for information about an in-16 dividual's coverage; and

17 (B) performing necessary clinical review 18 and quality assurance activities, such as activi-19 ties to identify and reduce the frequency of pat-20 terns of fraud, abuse, gross overuse, or inappro-21 priate or medically unnecessary care, among 22 physicians, pharmacists, and patients, or associ-23 ated with specific drugs or groups of drugs, as 24 well as potential and actual severe adverse reac-25 tions to drugs including education on thera-

1	peutic appropriateness, overutilization and un-
2	derutilization, appropriate use of generic prod-
3	ucts, the rapeutic duplication, drug-disease con-
4	traindications, drug-drug interactions, incorrect
5	drug dosage or duration of drug treatment,
6	drug-allergy interactions, and clinical abuse/
7	misuse, and any other clinical review and qual-
8	ity assurance activities required under Federal
9	or State law.
10	(2) Costs incurred by the pharmacist that are
11	associated with—
12	(A) the measurement or mixing of a cov-
13	ered part D drug;
14	(B) filling the container for such a drug;
15	(C) physically providing the completed pre-
16	scription to an individual enrolled in such a
17	plan;
18	(D) delivery;
19	(E) special packaging;
20	(F) overhead related to the pharmacy, or
21	the section of the facility that is devoted to a
22	pharmacy, and its maintenance (including the
23	equipment necessary to operate such pharmacy
24	or such section and the salaries of pharmacists
25	and other pharmacy workers); and

1	(G) geographic factors that impact oper-
2	ational costs.
3	(3) The variation in costs described in para-
4	graph (2) based on—
5	(A) whether the pharmacist is dispensing a
6	standard or extended supply of a covered part
7	D drug;
8	(B) whether the pharmacy is an inde-
9	pendent or chain pharmacy;
10	(C) whether a product dispensed is a spe-
11	cialty pharmacy product; and
12	(D) whether the pharmacy is located in, or
13	contracts with, a long-term care facility.
14	(4) The increase in dispensing fees, taking into
15	consideration the costs described in paragraphs (1) ,
16	(2), and (3), that is sufficient to create an incentive
17	for a pharmacist to promote the substitution of cov-
18	ered general alternative therapies.
19	(b) REPORT.—Not later than December 1, 2008, the
20	Inspector General of the Department of Health and
21	Human Services shall submit a report to the Secretary
22	of Health and Human Services on the study conducted
23	under subsection (a). The report shall include the fol-
24	lowing:

1	(1) The average cost to dispense a prescription
2	drug under part D of title XVIII of the Social Secu-
3	rity Act determined with respect to the area in
4	which a prescription drug plan or an MA–PD plan
5	is offered, including with respect to each PDP re-
6	gion (as determined under section $1860D-11(a)(2)$
7	of such Act (42 U.S.C. 1395w–111(a)(2)) and each
8	MA region (as determined under section 1858(a) of
9	such Act (42 U.S.C. 1395w–27(a)).
10	(2) The findings of the study conducted under
11	subsection (a) with respect to—
12	(A) the variation in costs studied under
13	subparagraphs (A) through (D) of paragraph
14	(3) of such subsection; and
15	(B) the increase in dispensing fees studied
16	under paragraph (4) of such subsection.
17	SEC. 8. REGULAR UPDATE OF PRESCRIPTION DRUG PRIC-
18	ING STANDARD REQUIRED.
19	(a) Requirement for Prescription Drug
20	Plans.—Section 1860D–12(b) of the Social Security Act
21	(42 U.S.C. 1395 w- 112 (b)), as amended by section
22	6(a)(1), is amended by adding at the end the following
23	new paragraph:
24	"(6) Regular update of prescription
25	DRUG PRICING STANDARD.—If the PDP sponsor of

1 a prescription drug plan uses a standard for reim-2 bursement of pharmacies based on the cost of a 3 drug, each contract entered into with such sponsor 4 under this part with respect to the plan shall provide 5 that the sponsor shall update such standard not less 6 frequently than once every 7 days, beginning with an 7 initial update on January 1 of each year, to accu-8 rately reflect the market price of acquiring the 9 drug.".

(b) REQUIREMENT FOR MA-PD PLANS.—Section
11 1857(f)(3) of the Social Security Act, as amended by sec12 tion 6(a)(2), is amended by adding at the end the fol13 lowing new subparagraph:

14 "(C) REGULAR UPDATE OF PRESCRIPTION
15 DRUG PRICING STANDARD.—Section 1860D–
16 12(b)(6).".

17 (c) EFFECTIVE DATE.—The amendments made by18 this section shall apply to plan years beginning on or after19 January 1, 2008.