

109TH CONGRESS
2D SESSION

S. 2238

To amend titles XVIII and XIX of the Social Security Act to assure uninterrupted access to necessary medicines under the Medicare prescription drug program.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 1, 2006

Mr. BAYH (for himself and Mr. BINGAMAN) introduced the following bill;
which was read twice and referred to the Committee on Finance

A BILL

To amend titles XVIII and XIX of the Social Security Act to assure uninterrupted access to necessary medicines under the Medicare 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; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Medicare Prescription Drug Emergency Guarantee Act
6 of 2006”.

7 (b) TABLE OF CONTENTS.—The table of contents of
8 this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Protections to provide for uninterrupted access to medicines.

- Sec. 3. Required application of intermediate sanctions to protect against fraud and abuse.
- Sec. 4. Changes of enrollment in prescription drug plans and MA–PD plans allowed twice during year.
- Sec. 5. Prohibiting additional restrictions or limitations on coverage during year.
- Sec. 6. MedPAC study on appropriate enrollment of dual eligible individuals.
- Sec. 7. Prohibition on conditioning Medicaid eligibility on enrollment in Medicare part D coverage or other creditable coverage.
- Sec. 8. Reimbursement of third parties for 2006 transition costs.

1 SEC. 2. PROTECTIONS TO PROVIDE FOR UNINTERRUPTED
2 ACCESS TO MEDICINES.

3 (a) MINIMUM STANDARD TRANSITION COVERAGE.—

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

8 “(4) UNINTERRUPTED ACCESS TO MEDI-
9 CINES.—

10 “(A) MINIMUM STANDARD TRANSITION
11 COVERAGE.—A PDP sponsor offering a pre-
12 scription drug plan under this part or an MA–
13 PD plan under part C shall provide minimum
14 standard transition coverage in accordance with
15 subparagraph (B).

16 “(B) REQUIREMENTS.—The minimum
17 standard transition coverage under this sub-
18 paragraph, with respect to a part D eligible in-
19 dividual who is enrolled in a prescription drug
20 plan (or an individual who is presumed to be

such an individual pursuant to subparagraph (F)) who presents a prescription for a drug at a pharmacy, is the following:

“(i) GUARANTEED INITIAL SUPPLY, REGARDLESS OF COVERAGE LIMITATIONS OR RESTRICTIONS.—In the case that the PDP sponsor of such plan uses a formulary that does not cover the drug or otherwise imposes a restriction on the coverage of the drug (such as through the application of a preferred status, usage restriction, step therapy, prior authorization or a quantity limits) and during the period in which such individual has been enrolled in such plan the individual has not previously sought coverage under the plan for such drug the plan shall provide for the following:

“(I) MINIMUM SUPPLY OF PRESCRIPTION DRUG.—The plan must provide for coverage for at least a 60-day supply (or a 90-day supply in the case of an individual who is a resident of a long-term care facility) of the drug, or, if less, a supply of the drug

1 that is the full amount of the pre-
2 scription.

3 “(II) INFORMATION ON FOR-
4 MULARY, PRESCRIPTION DRUG PLANS,
5 AND APPEAL RIGHTS.—The plan must
6 provide the individual with a standard
7 notice developed by the Secretary that
8 informs the individual about the limi-
9 tations and restrictions of the cov-
10 erage of the drug, that describes the
11 rights of the individual with respect to
12 requesting a determination under sub-
13 section (g)(2) or an appeal of such a
14 determination under subsection (h),
15 that describes any ability of the indi-
16 vidual to change the election of such
17 plan under section 1860D–1(b)(1)(B),
18 and that informs the individual about
19 sources of information on prescription
20 drug plans to make such a change in
21 plans.

22 “(III) REFILLS DURING PENDING
23 APPEAL.—In the case of such an indi-
24 vidual who brings an appeal under
25 subsection (h), with respect to the

1 prescription drug involved, an addi-
2 tional supply of the drug (for the
3 amount of days provided to the indi-
4 vidual under subclause (I)) during the
5 period ending on the date on which a
6 final determination is made on the ap-
7 peal.

8 “(ii) GUARANTEED SUPPLY WHEN UN-
9 ABLE TO VERIFY PLAN ENROLLMENT.—In
10 the case that the pharmacy is unable to lo-
11 cate or verify the individual’s enrollment in
12 such plan through a reasonable effort:

13 “(I) MINIMUM SUPPLY OF PRE-
14SCRIPTION DRUG.—The plan must
15 provide for coverage for at least a 60-
16 day supply (or a 90-day supply in the
17 case of an individual who is a resident
18 of a long-term care facility) of the
19 drug, or, if less, a supply of the drug
20 that is the full amount of the pre-
21 scription.

22 “(II) REFILLS.—The plan must
23 provide an additional 60-day supply
24 (or a 90-day supply in the case of an
25 individual who is a resident of a long-

term care facility) of the drug, or if less, a supply of the drug that is the full amount of the prescription, if the pharmacy continues to be unable to locate the individual's enrollment through such reasonable efforts when a prescription is presented on or after the date that a prescription refill is appropriate.

“(C) REIMBURSEMENTS.—

“(i) REIMBURSEMENTS TO PHARMACIES.—

“(I) IN GENERAL.—If a pharmacy provides prescription drugs for which the minimum standard transition coverage is required under subparagraph (B), the Secretary shall reimburse the pharmacy for the costs incurred in providing the prescription drugs, including acquisition costs, dispensing costs, and other overhead costs. The Secretary shall provide prompt payment (consistent with the provisions of section 1842(c)(2)) of such reimbursements from the Medi-

care Prescription Drug Account under section 1860D–16 of the Social Security Act (42 U.S.C. 1395w–116). Such reimbursements shall be deemed to be payments from such Account under subsection (b) of such section.

“(II) SANCTIONS FOR FRAUDULENT CLAIMS.—In the case of a pharmacy that knowingly provides to the Secretary false information in connection with a claim for reimbursement under subclause (I), the Secretary may impose a civil money penalty in an amount not to exceed \$10,000 for each such claim. The provisions of section 1128A (other than subsections (a) and (b) and the second sentence of subsection (f)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

“(ii) RECOVERY FROM PLANS OF PHARMACY REIMBURSEMENTS.—The Secretary shall establish a process for recov-

1 ering the reimbursements made to phar-
 2 macies under clause (i) from prescription
 3 drug plans and MA–PD plans if the Sec-
 4 retary determines that such plans should
 5 have incurred such costs. Amounts recov-
 6 ered pursuant to the preceding sentence
 7 shall be deposited in the Medicare Pre-
 8 scription Drug Account.

9 “(iii) APPLICATION OF INTERMEDIATE
 10 SANCTIONS.—In the case of a failure of a
 11 prescription drug plan under this part or
 12 an MA–PD plan under part C to provide
 13 for the minimum coverage required under
 14 subparagraph (B), the failure shall be
 15 treated as a failure to provide medically
 16 necessary items and services under section
 17 1857(g)(1)(A), as applied by section
 18 1860D–12(b)(3)(E), and the Secretary
 19 shall impose intermediate sanctions under
 20 such section 1857(g).

21 “(D) COST-SHARING.—The cost-sharing
 22 for a prescription filled pursuant to subpara-
 23 graph (B) for an individual shall be in accord-
 24 ance with the prescription drug plan in which
 25 the individual attests to be enrolled and the

1 class of individual (such as subsidy-eligible indi-
 2 viduals) to which the individual so attests.

3 “(E) REFUNDS TO INDIVIDUALS WITH IN-
 4 APPROPRIATE CHARGES.—If the Secretary de-
 5 termines, in accordance with a method deter-
 6 mined by the Secretary, that an individual was
 7 inappropriately charged for a prescription drug
 8 dispensed to such individual under this part or
 9 part C, the Secretary shall—

10 “(i) reduce payments to the sponsor
 11 of the prescription drug plan under section
 12 1860D–15 or to the organization offering
 13 the MA–PD plan under section 1853 that
 14 inappropriately charged the individual by
 15 an amount equal to the amount the indi-
 16 vidual was inappropriately charged; and

17 “(ii) refund such amount to the indi-
 18 vidual within 30 days of the date of the de-
 19 termination that the individual was inap-
 20 propriately charged.

21 “(F) PRESUMPTIVE ELIGIBILITY.—

22 “(i) SUBSIDY-ELIGIBLE INDIVID-
 23 UALS.—For purposes of this paragraph, an
 24 individual shall be presumed to be a dual
 25 eligible individual or subsidy-eligible indi-

vidual if the individual self attests to being
such an individual, respectively.

“(ii) PLAN ENROLLMENT.—For purposes of this paragraph, an individual shall be presumed to be enrolled in a prescription drug plan under this part or an MA-PD plan under part C if the individual self attests to being enrolled under such plan.

“(iii) INDIVIDUAL LIABLE FOR COSTS OF FALSE ATTESTATION.—

“(I) IN GENERAL.—If the Secretary, as the result of verification activities conducted by the Secretary, determines after a fair hearing that an individual has knowingly made a false self-attestation described in clause (i) or (ii) or in subparagraph (D), the Secretary may, subject to subclause (II), seek recovery from the individual for the full amount of the cost of benefits provided to the individual under this paragraph as a result of such self attestation.

“(II) EXCEPTION.—The Secretary shall at its discretion not seek

1 recovery under subclause (I) if the
2 Secretary determines that it would not
3 be cost-effective to do so.

4 “(III) REIMBURSEMENTS TO
5 FEDERAL GOVERNMENT.—Any
6 amounts recovered by the Secretary in
7 accordance with this clause shall be
8 returned to the prescription drug plan
9 or MA–PD plan if the Secretary has
10 previously recovered payment from
11 such plan.

12 “(iv) REQUIREMENTS FOR SELF AT-
13 TESTATION.—The Secretary shall promul-
14 gate requirements for self attestations
15 under this subparagraph, but the failure of
16 the Secretary to promulgate such require-
17 ments shall not preclude the applications
18 of the previous provisions of this subpara-
19 graph.”.

20 (2) EFFECTIVE DATE.—The amendment made
21 by paragraph (1) shall take effect on the date of the
22 enactment of this Act, but shall apply to prescription
23 drugs dispensed on and after January 1, 2006.

24 (b) NOTICE FOR CHANGE IN FORMULARY AND
25 OTHER RESTRICTIONS OR LIMITATIONS ON COVERAGE.—

1 (1) IN GENERAL.—Section 1860D–4(a) of such
 2 Act (42 U.S.C. 1395w–104(a)) is amended by add-
 3 ing at the end the following new paragraph:

4 “(5) ANNUAL NOTICE OF CHANGES IN FOR-
 5 MULARY AND OTHER RESTRICTIONS OR LIMITATIONS
 6 ON COVERAGE.—Each PDP sponsor offering a pre-
 7 scription drug plan (and each MA organization of-
 8 fering an MA–PD plan) shall furnish to each en-
 9 rollee at the time of each annual coordinated election
 10 period (referred to in section 1860D–1(b)(1)(B)(iii))
 11 for a plan year a notice of any changes in the for-
 12 mulary or other restrictions or limitations on cov-
 13 erage of a covered part D drug under the plan that
 14 will take effect for the plan year.”.

15 (2) EFFECTIVE DATE.—The amendment made
 16 by paragraph (1) shall apply to annual coordinated
 17 election periods beginning after the date of the en-
 18 actment of this Act.

19 (c) STANDARDIZED FORMS AND PROCEDURES FOR
 20 RECONSIDERATIONS AND APPEALS.—

21 (1) IN GENERAL.—Section 1860D–4 of such
 22 Act (42 U.S.C. 1395w–104) is amended by adding
 23 at the end the following new subsection:

24 “(l) STANDARDIZED FORMS AND PROCEDURES FOR
 25 RECONSIDERATIONS AND APPEALS.—

1 “(1) STANDARD ENROLLEE NOTICE.—The Sec-
2 retary shall develop a standard notice to be distrib-
3 uted by a prescription drug plan (or an MA–PD
4 plan) to an enrollee when a covered part D drug pre-
5 scribed for the enrollee is not covered, or the cov-
6 erage of such drug is otherwise restricted, by the
7 plan.

8 “(2) STANDARDIZED PROCESS FOR RECONSID-
9 ERATIONS AND APPEALS.—The Secretary shall re-
10 quire prescription drug plans and MA–PD plans to
11 follow the same standardized process for reconsider-
12 ations and redeterminations under subsections (g)
13 and (h). Such process shall require that determina-
14 tions regarding medical necessity are based on pro-
15 fessional medical judgement, the medical condition
16 of the enrollee, the treating physician’s recommenda-
17 tion, and other medical evidence.”.

18 (2) EFFECTIVE DATE.—The Secretary of
19 Health and Human Services shall provide for the
20 standard notice and the standardized process, and
21 the application of such notice and process, under the
22 amendment made by paragraph (1) by not later
23 than January 1, 2007.

1 **SEC. 3. REQUIRED APPLICATION OF INTERMEDIATE SANC-**
 2 **TIONS TO PROTECT AGAINST FRAUD AND**
 3 **ABUSE.**

4 (a) IN GENERAL.—Section 1860D–12(b)(3)(E) of
 5 the Social Security Act (42 U.S.C. 1395w–112(b)(3)(E))
 6 is amended by inserting “and the reference to ‘may pro-
 7 vide’ in section 1857(g)(1) is deemed a reference to ‘shall
 8 provide’ ” after “this part”.

9 (b) APPLICATION TO MA–PD PLANS.—Section
 10 1857(g)(1) of such Act (42 U.S.C. 1395w–27(g)(1)) is
 11 amended by inserting “(or in the case of an MA–PD plan
 12 or a prescription drug plan under part D, the Secretary
 13 shall provide)” after “may provide”.

14 **SEC. 4. CHANGES OF ENROLLMENT IN PRESCRIPTION**
 15 **DRUG PLANS AND MA–PD PLANS ALLOWED**
 16 **TWICE DURING YEAR.**

17 (a) ADDITIONAL ELECTION PERMITTED ONCE EACH
 18 YEAR OUTSIDE OF ANNUAL COORDINATED ELECTION
 19 PERIOD.—Section 1851(e)(4) of the Social Security Act
 20 (42 U.S.C. 1395w–21(e)(4)) is amended by inserting
 21 “once every year, and in addition,” after “make a new
 22 election under this section”.

23 (b) EFFECTIVE DATE.—The amendment made by
 24 subsection (a) shall take effect as of the date of the enact-
 25 ment of this Act.

1 **SEC. 5. PROHIBITING ADDITIONAL RESTRICTIONS OR LIM-**
2 **TATIONS ON COVERAGE DURING YEAR.**

3 (a) IN GENERAL.—Section 1860D–4(b)(4) of the So-
4 cial Security Act (42 U.S.C. 1395w–104(b)(4)) is amend-
5 ed by inserting after subparagraph (F) the following new
6 subparagraph:

7 “(G) PROHIBITING ADDITIONAL RESTRIC-
8 TIONS OR LIMITATIONS ON COVERAGE DURING
9 YEAR.—A prescription drug plan and an MA-
10 PD plan may only impose a restriction or limi-
11 tation on the coverage of a covered part D drug
12 (such as through the application of a formulary,
13 preferred status, usage restriction, step therapy,
14 prior authorization, or a quantity limitation)
15 only at the beginning of a plan year, except in
16 the case that the Commissioner of Food and
17 Drugs issues a clinical warning during a year
18 that imposes such a restriction or limitation on
19 the drug.”.

20 (b) EFFECTIVE DATE.—The amendment made by
21 subsection (a) shall take effect on the date of the enact-
22 ment of this Act and shall apply to the removal of a drug
23 or a change in the status of such drug on and after such
24 date.

1 **SEC. 6. MEDPAC STUDY ON APPROPRIATE ENROLLMENT**
 2 **OF DUAL ELIGIBLE INDIVIDUALS.**

3 (a) STUDY.—The Medicare Payment Advisory Com-
 4 mission shall conduct a study to determine the extent to
 5 which full-benefit dual eligible individuals (as defined in
 6 section 1935(c)(6) of the Social Security Act (42 U.S.C.
 7 1396u5(c)(6)) were enrolled (by assignment or otherwise)
 8 in the most appropriate prescription drug plans under
 9 part D of title XVIII of such Act for such individuals.

10 (b) REPORT.—The Commission shall submit a report
 11 to Congress on the study under subsection (a) not later
 12 than February 1, 2007.

13 **SEC. 7. PROHIBITION ON CONDITIONING MEDICAID ELI-**
 14 **BILITY ON ENROLLMENT IN MEDICARE PART**
 15 **D COVERAGE OR OTHER CREDITABLE COV-**
 16 **ERAGE.**

17 (a) IN GENERAL.—Section 1935 of the Social Secu-
 18 rity Act (42 U.S.C. 1396v) is amended by adding at the
 19 end the following new subsection:

20 “(f) PROHIBITION ON CONDITIONING MEDICAID ELI-
 21 GIBILITY ON ENROLLMENT IN MEDICARE PART D COV-
 22 ERAGE OR OTHER CREDITABLE COVERAGE.—

23 “(1) IN GENERAL.—A State shall not condition
 24 eligibility for medical assistance under the State
 25 plan for a part D eligible individual (as defined in
 26 section 1860D–1(a)(3)(A)) who is enrolled in cred-

1 itable prescription drug coverage described in any of
 2 subparagraphs (C) through (H) of section 1860D–
 3 13(b)(4) on the individual’s enrollment in a prescrip-
 4 tion drug plan under part D of title XVIII or an
 5 MA–PD plan under part C of such title.

6 “(2) COORDINATION OF BENEFITS WITH PART
 7 D FOR OTHER INDIVIDUALS.—Nothing in this sub-
 8 section shall be construed as prohibiting a State
 9 from coordinating medical assistance under the
 10 State plan with benefits under part D of title XVIII
 11 for individuals not described in paragraph (1).”.

12 (b) TREATMENT OF STATE PLAN AMENDMENTS, RE-
 13 DETERMINATION OF ELIGIBILITY.—In the case of a State
 14 that, as of the date of the enactment of this Act, has an
 15 approved amendment to its State plan under title XIX of
 16 the Social Security Act with a provision that conflicts with
 17 section 1935(f) of such Act (as added by subsection (a)),
 18 such provision is, as of such date of enactment, null and
 19 void. The State shall redetermine any applications for
 20 medical assistance that have been denied solely on the
 21 basis of such a State plan amendment not later than De-
 22 cember 31, 2006. Such redetermination shall be effective
 23 as of the date of the individual’s application for medical
 24 assistance.

1 **SEC. 8. REIMBURSEMENT OF THIRD PARTIES FOR 2006**

2 **TRANSITION COSTS.**

3 (a) REIMBURSEMENT.—

4 (1) IN GENERAL.—Notwithstanding section
5 1935(d) of the Social Security Act (42 U.S.C.
6 1396u–5(d) or any other provision of law, the Sec-
7 retary of Health and Human Services shall reim-
8 burse covered third parties for 100 percent of the
9 costs incurred by the covered third party during
10 2006 for covered part D drugs for part D eligible in-
11 dividuals who are enrolled in a prescription drug
12 plan under part D of title XVIII of such Act (or an
13 MA–PD plan under part C of such title) which the
14 individual reasonably expected would have been cov-
15 ered under such part but were not because the indi-
16 vidual was unable to access on a timely basis pre-
17 scription drug benefits to which the individual was
18 entitled under such part. Such payments shall be
19 made from the Medicare Prescription Drug Account
20 under section 1860D–16 of the Social Security Act
21 (42 U.S.C. 1395w–116) and shall be deemed to be
22 payments from such Account under subsection (b) of
23 such section. The provisions of clauses (ii) through
24 (iv) of subparagraph (F) of paragraph (4) of section
25 1860D–4(b) of the Social Security Act, as added by
26 section 2(a), shall apply under this paragraph in the

1 same manner as they apply under such paragraph
2 (4).

3 (2) SANCTIONS FOR FRAUDULENT CLAIMS.—

4 The provisions of subclause (II) of section 1860D–
5 4(b)(4)(C)(i) of the Social Security Act, as added by
6 section 2(a), shall apply to a covered third party
7 with respect to a claim for reimbursement under
8 paragraph (1) in the same manner that such provi-
9 sions apply to a pharmacy in connection with a
10 claim for reimbursement under subclause (I) of such
11 section 1860D–4(b)(4)(C)(i).

12 (3) RETROACTIVE APPLICATION TO BEGINNING
13 OF 2006.—The costs incurred by a third party which
14 may be reimbursed under paragraph (1) shall in-
15 clude costs incurred during the period beginning on
16 January 1, 2006, and before the date of enactment
17 of this Act.

18 (b) RECOVERY OF COSTS FROM PLANS BY SEC-
19 RETARY.—The Secretary of Health and Human Services
20 shall establish a process for recovering the costs described
21 in subsection (a)(1) from prescription drug plans and
22 MA–PD plans if the Secretary determines that such plans
23 should have incurred such costs. Amounts recovered pur-
24 suant to the preceding sentence shall be deposited in the

1 Medicare Prescription Drug Account described in sub-
 2 section (a)(1).

3 (c) DEFINITIONS.—For purposes of this section:

4 (1) COVERED PART D DRUG.—The term “cov-
 5 ered part D drug” has the meaning given such term
 6 under section 1860D–2(e) of the Social Security Act
 7 (42 U.S.C. 1395w–102(e)).

8 (2) COVERED THIRD PARTY.—The term “cov-
 9 ered third party” means any individual or party
 10 (such as a State, charity, or family member of the
 11 part D eligible individual involved) other than a
 12 party that is obligated under part D of title XVIII
 13 of the Social Security Act to incur the costs in-
 14 volved. Such term shall not include a pharmaceutical
 15 company or an assistance program sponsored or as-
 16 sisted (in whole or in part) by such company.

17 (3) MA–PD PLAN.—The term “MA–PD plan”
 18 has the meaning given such term under section
 19 1860D–41(a)(14) of the Social Security Act (42
 20 U.S.C. 1395w–151(a)(14)).

21 (4) PART D ELIGIBLE INDIVIDUAL.—The term
 22 “part D eligible individual” has the meaning given
 23 such term under section 1860D–1(a)(3)(A) of the
 24 Social Security Act (42 U.S.C. 1394w–
 25 101(a)(3)(A)).

1 (5) PRESCRIPTION DRUG PLAN.—The term
2 “prescription drug plan” has the meaning given
3 such term under section 1860D–1(a)(3)(C) of the
4 Social Security Act (42 U.S.C. 1394w–
5 101(a)(3)(C)).

6 (6) STATE.—The term “State” includes the
7 District of Columbia.

○