

109<sup>TH</sup> CONGRESS  
2<sup>D</sup> 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

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

4 “(i) GUARANTEED INITIAL SUPPLY,  
5 REGARDLESS OF COVERAGE LIMITATIONS  
6 OR RESTRICTIONS.—In the case that the  
7 PDP sponsor of such plan uses a for-  
8 mulary that does not cover the drug or  
9 otherwise imposes a restriction on the cov-  
10 erage of the drug (such as through the ap-  
11 plication of a preferred status, usage re-  
12 striction, step therapy, prior authorization  
13 or a quantity limits) and during the period  
14 in which such individual has been enrolled  
15 in such plan the individual has not pre-  
16 viously sought coverage under the plan for  
17 such drug the plan shall provide for the  
18 following:

19 “(I) MINIMUM SUPPLY OF PRE-  
20 SCRIPTION DRUG.—The plan must  
21 provide for coverage for at least a 60-  
22 day supply (or a 90-day supply in the  
23 case of an individual who is a resident  
24 of a long-term care facility) of the  
25 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-  
14 SCRIPTION 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-

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

10 “(C) REIMBURSEMENTS.—

11 “(i) REIMBURSEMENTS TO PHAR-  
12 MACIES.—

13 “(I) IN GENERAL.—If a phar-  
14 macy provides prescription drugs for  
15 which the minimum standard transi-  
16 tion coverage is required under sub-  
17 paragraph (B), the Secretary shall re-  
18 imburse the pharmacy for the costs  
19 incurred in providing the prescription  
20 drugs, including acquisition costs, dis-  
21 pensing costs, and other overhead  
22 costs. The Secretary shall provide  
23 prompt payment (consistent with the  
24 provisions of section 1842(c)(2)) of  
25 such reimbursements from the Medi-

1 care Prescription Drug Account under  
2 section 1860D–16 of the Social Secu-  
3 rity Act (42 U.S.C. 1395w–116).  
4 Such reimbursements shall be deemed  
5 to be payments from such Account  
6 under subsection (b) of such section.

7 “(II) SANCTIONS FOR FRAUDU-  
8 LENT CLAIMS.—In the case of a phar-  
9 macy that knowingly provides to the  
10 Secretary false information in connec-  
11 tion with a claim for reimbursement  
12 under subclause (I), the Secretary  
13 may impose a civil money penalty in  
14 an amount not to exceed \$10,000 for  
15 each such claim. The provisions of  
16 section 1128A (other than subsections  
17 (a) and (b) and the second sentence of  
18 subsection (f)) shall apply to a civil  
19 money penalty under the previous sen-  
20 tence in the same manner as such  
21 provisions apply to a penalty or pro-  
22 ceeding under section 1128A(a).

23 “(ii) RECOVERY FROM PLANS OF  
24 PHARMACY REIMBURSEMENTS.—The Sec-  
25 retary 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-

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

3           “(ii) PLAN ENROLLMENT.—For pur-  
4           poses of this paragraph, an individual shall  
5           be presumed to be enrolled in a prescrip-  
6           tion drug plan under this part or an MA-  
7           PD plan under part C if the individual self  
8           attests to being enrolled under such plan.

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

11           “(I) IN GENERAL.—If the Sec-  
12          retary, as the result of verification ac-  
13          tivities conducted by the Secretary,  
14          determines after a fair hearing that  
15          an individual has knowingly made a  
16          false self-attestation described in  
17          clause (i) or (ii) or in subparagraph  
18          (D), the Secretary may, subject to  
19          subclause (II), seek recovery from the  
20          individual for the full amount of the  
21          cost of benefits provided to the indi-  
22          vidual under this paragraph as a re-  
23          sult of such self attestation.

24           “(II) EXCEPTION.—The Sec-  
25          retary 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.

○