

109<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

# H. R. 4395

To amend titles XVIII and XIX of the Social Security Act to provide for an improved voluntary Medicare prescription drug benefit, to provide greater access to affordable pharmaceuticals, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 18, 2005

Mr. CONYERS introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on 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

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## A BILL

To amend titles XVIII and XIX of the Social Security Act to provide for an improved voluntary Medicare prescription drug benefit, to provide greater access to affordable pharmaceuticals, and for other purposes.

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; REFERENCES IN ACT; TABLE OF**  
4 **CONTENTS.**

5 (a) SHORT TITLE.—This Act may be cited as the  
6 “Medicare Prescription Drug Affordability Act of 2005”.

1 (b) AMENDMENTS TO SOCIAL SECURITY ACT.—Ex-  
 2 cept as otherwise specifically provided, whenever in this  
 3 Act an amendment is expressed in terms of an amendment  
 4 to or repeal of a section or other provision, the reference  
 5 shall be considered to be made to that section or other  
 6 provision of the Social Security Act.

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

Sec. 1. Short title; references in act; table of contents.

#### TITLE I—MEDICARE PRESCRIPTION DRUG BENEFIT

Sec. 101. Substitution of voluntary Medicare outpatient prescription drug program.

##### “PART D—VOLUNTARY PRESCRIPTION DRUG BENEFIT FOR THE AGED AND DISABLED

“Sec. 1860D–1. Medicare outpatient prescription drug benefit.

“Sec. 1860D–2. Negotiating fair prices with pharmaceutical manufacturers.

“Sec. 1860D–3. Contract authority.

“Sec. 1860D–4. Eligibility; voluntary enrollment; coverage.

“Sec. 1860D–5. Provision of, and entitlement to, benefits; reduction in co-insurance for lower income beneficiaries.

“Sec. 1860D–6. Administration; quality assurance.

“Sec. 1860D–7. Federal Medicare Prescription Drug Trust Fund.

“Sec. 1860D–8. Compensation for employers covering retiree drug costs.

“Sec. 1860D–9. Medicare Prescription Drug Advisory Committee.

Sec. 102. Provision of Medicare outpatient prescription drug coverage under the Medicare Advantage program.

Sec. 103. Medigap revisions.

Sec. 104. Assistance for low income beneficiaries.

Sec. 105. Expansion of membership and duties of Medicare Payment Advisory Commission (MEDPAC).

#### TITLE II—AFFORDABLE PHARMACEUTICALS

##### Subtitle A—Importation of Prescription Drugs

Sec. 201. Short title.

Sec. 202. Findings.

Sec. 203. Purposes.

Sec. 204. Importation of prescription drugs.

Sec. 205. Use of counterfeit-resistant technologies to prevent counterfeiting.

“Sec. 505C. Counterfeit-resistant technologies.

Subtitle B—Quality Control and Cost Containment Blue Ribbon Task Force

Sec. 211. Task Force.

TITLE III—DEFENSE OF MEDICARE

Sec. 301. Elimination of privatization of Medicare.

Sec. 302. Repeal of MA regional plan stabilization fund.

Sec. 303. Repeal of health savings accounts.

Sec. 304. Application of risk adjustment reflecting characteristics for the entire Medicare population.

Sec. 305. Phase-in to payment at 100 percent of fee-for-service rate.

Sec. 306. Repeal of Medicare expenditure cap.

Sec. 307. Continuous open enrollment in Medicare Advantage plans.

Sec. 308. Effective date.

1                                   **TITLE I—MEDICARE**  
 2                                   **PRESCRIPTION DRUG BENEFIT**  
 3   **SEC. 101. SUBSTITUTION OF VOLUNTARY MEDICARE OUT-**  
 4                                   **PATIENT PRESCRIPTION DRUG PROGRAM.**

5           (a) IN GENERAL.—Subject to subsection (b), part D  
 6 of title XVIII, as inserted by section 101(a)(2) of the  
 7 Medicare Prescription Drug, Improvement, and Mod-  
 8 ernization Act of 2003 (Public Law 108–173), is amended  
 9 to read as follows:

10   “PART D—VOLUNTARY PRESCRIPTION DRUG BENEFIT  
 11                                   FOR THE AGED AND DISABLED

12   “MEDICARE OUTPATIENT PRESCRIPTION DRUG BENEFIT  
 13       “SEC. 1860D–1.

14       Subject to the succeeding provisions of this part, the  
 15 voluntary prescription drug benefit program under this  
 16 part provides the following:

17               “(1) NO PREMIUM.—There is no monthly pre-  
 18       mium.



1 part, the Secretary shall take into account the goal of pro-  
2 moting the development of breakthrough drugs (as defined  
3 in section 1860D–9(b)).

4 “CONTRACT AUTHORITY

5 “SEC. 1860D–3. (a) CONTRACT AUTHORITY.—

6 “(1) IN GENERAL.—The Secretary is respon-  
7 sible for the administration of this part and shall  
8 enter into contracts with appropriate pharmacy con-  
9 tractors on a national or regional basis to administer  
10 the benefits under this part.

11 “(2) PROCEDURES.—The Secretary shall estab-  
12 lish procedures under which the Secretary—

13 “(A) accepts bids submitted by entities to  
14 serve as pharmacy contractors under this part  
15 in a region or on a national basis;

16 “(B) awards contracts to such contractors  
17 to administer benefits under this part to eligible  
18 beneficiaries in the region or on a national  
19 basis; and

20 “(C) provides for the termination (and  
21 nonrenewal) of a contract in the case of a con-  
22 tractor’s failure to meet the requirements of the  
23 contract and this part.

24 “(3) COMPETITIVE PROCEDURES.—Competitive  
25 procedures (as defined in section 4(5) of the Office  
26 of Federal Procurement Policy Act (41 U.S.C.

1 403(5))) shall be used to enter into contracts under  
2 this part.

3 “(4) TERMS AND CONDITIONS.—Such contracts  
4 shall have such terms and conditions as the Sec-  
5 retary shall specify and shall be for such terms (of  
6 at least 2 years, but not to exceed 5 years) as the  
7 Secretary shall specify consistent with this part.

8 “(5) USE OF PHARMACY CONTRACTORS IN  
9 PRICE NEGOTIATIONS.—Such contracts shall require  
10 the contractor involved to negotiate contracts with  
11 manufacturers that provide for maximum prices for  
12 covered outpatient prescription drugs that are lower  
13 than the maximum prices negotiated under section  
14 1860D–2(a), if applicable. The price reductions shall  
15 be passed on to eligible beneficiaries and the Sec-  
16 retary shall hold the contractor accountable for  
17 meeting performance requirements with respect to  
18 price reductions and limiting price increases.

19 “(6) AREA FOR CONTRACTS.—

20 “(A) REGIONAL BASIS.—

21 “(i) IN GENERAL.—Except as pro-  
22 vided in clause (ii) and subject to subpara-  
23 graph (B), the contract entered into be-  
24 tween the Secretary and a pharmacy con-  
25 tractor shall require the contractor to ad-

1 minister the benefits under this part in a  
2 region determined by the Secretary under  
3 subparagraph (B) or on a national basis.

4 “(ii) PARTIAL REGIONAL BASIS.—

5 “(I) IN GENERAL.—If deter-  
6 mined appropriate by the Secretary,  
7 the Secretary may permit the benefits  
8 to be administered in a partial region  
9 determined appropriate by the Sec-  
10 retary.

11 “(II) REQUIREMENTS.—If the  
12 Secretary permits administration pur-  
13 suant to subclause (I), the Secretary  
14 shall ensure that the partial region in  
15 which administration is effected is no  
16 smaller than a State and is at least  
17 the size of the commercial service area  
18 of the contractor for that area.

19 “(B) DETERMINATION.—

20 “(i) IN GENERAL.—In determining re-  
21 gions for contracts under this part, the  
22 Secretary shall—

23 “(I) take into account the num-  
24 ber of individuals enrolled under this  
25 part in an area in order to encourage

1 participation by pharmacy contrac-  
2 tors; and

3 “(II) ensure that there are at  
4 least 10 different regions in the  
5 United States.

6 “(ii) NO ADMINISTRATIVE OR JUDI-  
7 CIAL REVIEW.—The determination of ad-  
8 ministrative areas under this paragraph  
9 shall not be subject to administrative or ju-  
10 dicial review.

11 “(7) SUBMISSION OF BIDS.—

12 “ (A) SUBMISSION.—

13 “(i) IN GENERAL.—Subject to sub-  
14 paragraph (B), each entity desiring to  
15 serve as a pharmacy contractor under this  
16 part in an area shall submit a bid with re-  
17 spect to such area to the Secretary at such  
18 time, in such manner, and accompanied by  
19 such information as the Secretary may rea-  
20 sonably require.

21 “(ii) BID THAT COVERS MULTIPLE  
22 AREAS.—The Secretary shall permit an en-  
23 tity to submit a single bid for multiple  
24 areas if the bid is applicable to all such  
25 areas.

1           “(B) REQUIRED INFORMATION.—The bids  
2 described in subparagraph (A) shall include—

3           “(i) a proposal for the estimated  
4 prices of covered outpatient prescription  
5 drugs and the projected annual increases  
6 in such prices, including the additional re-  
7 duction in price negotiated below the Sec-  
8 retary’s maximum price and differentials  
9 between preferred and nonpreferred prices,  
10 if applicable;

11           “(ii) a statement regarding the  
12 amount that the entity will charge the Sec-  
13 retary for administering the benefits under  
14 the contract;

15           “(iii) a statement regarding whether  
16 the entity will reduce the applicable coin-  
17 surance percentage pursuant to section  
18 1860D–6(a)(1)(A)(ii) and if so, the  
19 amount of such reduction and how such re-  
20 duction is tied to the performance require-  
21 ments described in subsection (c)(4)(A)(ii);

22           “(iv) a detailed description of the per-  
23 formance requirements for which the ad-  
24 ministrative fee of the entity will be subject  
25 to risk pursuant to subsection (c)(4)(A)(ii);

1           “(v) a detailed description of access to  
2 pharmacy services provided by the entity,  
3 including information regarding whether  
4 the pharmacy contractor will use a pre-  
5 ferred pharmacy network, and, if so, how  
6 the pharmacy contractor will ensure access  
7 to pharmacies that choose to be outside of  
8 that network, and whether there will be in-  
9 creased cost-sharing for beneficiaries if  
10 they obtain drugs at such pharmacies;

11           “(vi) a detailed description of the pro-  
12 cedures and standards the entity will use  
13 for—

14                   “(I) selecting preferred prescrip-  
15 tion drugs; and

16                   “(II) determining when and how  
17 often the list of preferred prescription  
18 drugs should be modified;

19           “(vii) a detailed description of any  
20 ownership or shared financial interests  
21 with pharmaceutical manufacturers, phar-  
22 macies, and other entities involved in the  
23 administration or delivery of benefits under  
24 this part as proposed in the bid;

1           “(viii) a detailed description of the en-  
2           tity’s estimated marketing and advertising  
3           expenditures related to enrolling and re-  
4           taining eligible beneficiaries; and

5           “(ix) such other information that the  
6           Secretary determines is necessary in order  
7           to carry out this part, including informa-  
8           tion relating to the bidding process under  
9           this part.

10           The procedures under clause (vi) shall include  
11           the use of a pharmaceutical and therapeutics  
12           committee the members of which include prac-  
13           ticing pharmacists.

14           “(8) AWARDING OF CONTRACTS.—

15           “(A) NUMBER OF CONTRACTS.—The Sec-  
16           retary shall, consistent with the requirements of  
17           this part and the goals of providing quality care  
18           and of containing costs under this part, award  
19           in a competitive manner at least 2 contracts to  
20           administer benefits under this part in each area  
21           specified under paragraph (6), unless only 1  
22           pharmacy contractor submitting a bid meets the  
23           minimum standards specified under this part  
24           and by the Secretary.

1           “(B) DETERMINATION.—In determining  
2           which of the pharmacy contractors that sub-  
3           mitted bids that meet the minimum standards  
4           specified under this part and by the Secretary  
5           to award a contract, the Secretary shall con-  
6           sider the comparative merits of each bid, as de-  
7           termined on the basis of relevant factors, with  
8           respect to—

9                   “(i) how well the contractor meets  
10                   such minimum standards;

11                   “(ii) the amount that the contractor  
12                   will charge the Secretary for administering  
13                   the benefits under the contract;

14                   “(iii) the performance standards es-  
15                   tablished under subsection (c)(2) and per-  
16                   formance requirements for which the ad-  
17                   ministrative fee of the entity will be subject  
18                   to risk pursuant to subsection (c)(4)(A)(ii);

19                   “(iv) the proposed negotiated prices of  
20                   covered outpatient drugs and annual in-  
21                   creases in such prices;

22                   “(v) factors relating to benefits, qual-  
23                   ity and performance, beneficiary cost-shar-  
24                   ing, and consumer satisfaction;

1           “(vi) past performance and prior ex-  
2           perience of the contractor in administering  
3           a prescription drug benefit program;

4           “(vii) effectiveness of the contractor  
5           in containing costs through pricing incen-  
6           tives and utilization management; and

7           “(viii) such other factors as the Sec-  
8           retary deems necessary to evaluate the  
9           merits of each bid.

10           “(C) EXCEPTION TO CONFLICT OF INTER-  
11           EST RULES.—In awarding contracts with phar-  
12           macy contractors under this part, the Secretary  
13           may waive conflict of interest laws generally ap-  
14           plicable to Federal acquisitions (subject to such  
15           safeguards as the Secretary may find necessary  
16           to impose) in circumstances where the Sec-  
17           retary finds that such waiver—

18           “(i) is not inconsistent with the—

19           “(I) purposes of the programs  
20           under this part; or

21           “(II) best interests of bene-  
22           ficiaries enrolled under this part; and

23           “(ii) permits a sufficient level of com-  
24           petition for such contracts, promotes effi-  
25           ciency of benefits administration, or other-

1 wise serves the objectives of the program  
2 under this part.

3 “(D) NO ADMINISTRATIVE OR JUDICIAL  
4 REVIEW.—The determination of the Secretary  
5 to award or not award a contract to a phar-  
6 macy contractor under this part shall not be  
7 subject to administrative or judicial review.

8 “(9) ACCESS TO BENEFITS IN CERTAIN  
9 AREAS.—

10 “(A) AREAS NOT COVERED BY CON-  
11 TRACTS.—The Secretary shall develop proce-  
12 dures for the provision of covered outpatient  
13 prescription drugs under this part to each eligi-  
14 ble beneficiary enrolled under this part that re-  
15 sides in an area that is not covered by any con-  
16 tract under this part.

17 “(B) BENEFICIARIES RESIDING IN DIF-  
18 FERENT LOCATIONS.—The Secretary shall de-  
19 velop procedures to ensure that each eligible  
20 beneficiary enrolled under this part that resides  
21 in different areas in a year is provided the ben-  
22 efits under this part throughout the entire year.

23 “(b) QUALITY, FINANCIAL, AND OTHER STANDARDS  
24 AND PROGRAMS.—In consultation with appropriate phar-  
25 macy contractors, pharmacists, and health care profes-

1 sionals with expertise in prescribing, dispensing, and the  
2 appropriate use of prescription drugs, the Secretary shall  
3 establish standards and programs for the administration  
4 of this part to ensure appropriate prescribing, dispensing,  
5 and utilization of outpatient drugs under this part, to  
6 avoid adverse drug reactions, and to continually reduce er-  
7 rors in the delivery of medically appropriate covered bene-  
8 fits. The Secretary shall not award a contract to a phar-  
9 macy contractor under this part unless the Secretary finds  
10 that the contractor agrees to comply with such standards  
11 and programs and other terms and conditions as the Sec-  
12 retary shall specify. The standards and programs under  
13 this subsection shall be applied to any administrative  
14 agreements described in subsection (a) the Secretary en-  
15 ters into. Such standards and programs shall include the  
16 following:

17           “(1) ACCESS.—

18                   “(A) IN GENERAL.—The pharmacy con-  
19 tractor shall ensure that covered outpatient pre-  
20 scription drugs are accessible and convenient to  
21 eligible beneficiaries enrolled under this part for  
22 whom benefits are administered by the phar-  
23 macy contractor, including by offering the serv-  
24 ices 24 hours a day and 7 days a week for  
25 emergencies.

1           “(B) ON-LINE REVIEW.—The pharmacy  
2 contractor shall provide for on-line prospective  
3 review available 24 hours a day and 7 days a  
4 week in order to evaluate each prescription for  
5 drug therapy problems due to duplication, inter-  
6 action, or incorrect dosage or duration of ther-  
7 apy.

8           “(C) GUARANTEED ACCESS TO DRUGS IN  
9 RURAL AND HARD-TO-SERVE AREAS.—The Sec-  
10 retary shall ensure that all beneficiaries have  
11 guaranteed access to the full range of pharma-  
12 ceuticals under this part, and shall give special  
13 attention to access, pharmacist counseling, and  
14 delivery in rural and hard-to-serve areas, in-  
15 cluding through the use of incentives such as  
16 bonus payments to retail pharmacists in rural  
17 areas and extra payments to the pharmacy con-  
18 tractor for the cost of rapid delivery of pharma-  
19 ceuticals and any other actions necessary.

20           “(D) PREFERRED PHARMACY NET-  
21 WORKS.—

22           “(i) IN GENERAL.—If a pharmacy  
23 contractor uses a preferred pharmacy net-  
24 work to deliver benefits under this part,

1 such network shall meet minimum access  
2 standards established by the Secretary.

3 “(ii) STANDARDS.—In establishing  
4 standards under clause (i), the Secretary  
5 shall take into account reasonable dis-  
6 tances to pharmacy services in both urban  
7 and rural areas.

8 “(E) ADHERENCE TO NEGOTIATED  
9 PRICES.—The pharmacy contractor shall have  
10 in place procedures to assure compliance of  
11 pharmacies with the requirements of subsection  
12 (d)(3)(C) (relating to adherence to negotiated  
13 prices).

14 “(F) CONTINUITY OF CARE.—

15 “(i) IN GENERAL.—The pharmacy  
16 contractor shall ensure that, in the case of  
17 an eligible beneficiary who loses coverage  
18 under this part with such entity under cir-  
19 cumstances that would permit a special  
20 election period (as established by the Sec-  
21 retary under section 1860D–4(b)(3)), the  
22 contractor will continue to provide cov-  
23 erage under this part to such beneficiary  
24 until the beneficiary enrolls and receives  
25 such coverage with another pharmacy con-

1 tractor under this part or, if eligible, with  
2 a MedicareAdvantage organization.

3 “(ii) LIMITED PERIOD.—In no event  
4 shall a pharmacy contractor be required to  
5 provide the extended coverage required  
6 under clause (i) beyond the date which is  
7 30 days after the coverage with such con-  
8 tractor would have terminated but for this  
9 subparagraph.

10 “(2) ENROLLEE GUIDELINES.—The pharmacy  
11 contractor shall, consistent with State law, apply  
12 guidelines for counseling enrollees regarding—

13 “(A) the proper use of covered outpatient  
14 prescription drugs; and

15 “(B) interactions and contra-indications.

16 “(3) EDUCATION.—The pharmacy contractor  
17 shall apply methods to identify and educate pro-  
18 viders, pharmacists, and enrollees regarding—

19 “(A) instances or patterns concerning the  
20 unnecessary or inappropriate prescribing or dis-  
21 pensing of covered outpatient prescription  
22 drugs;

23 “(B) instances or patterns of substandard  
24 care;

1           “(C) potential adverse reactions to covered  
2           outpatient prescription drugs;

3           “(D) inappropriate use of antibiotics;

4           “(E) appropriate use of generic products;

5           and

6           “(F) the importance of using covered out-  
7           patient prescription drugs in accordance with  
8           the instruction of prescribing providers.

9           “(4) COORDINATION.—The pharmacy con-  
10          tractor shall coordinate with State prescription drug  
11          programs, other pharmacy contractors, pharmacies,  
12          and other relevant entities as necessary to ensure  
13          appropriate coordination of benefits with respect to  
14          enrolled individuals when such individual is traveling  
15          outside the home service area, and under such other  
16          circumstances as the Secretary may specify.

17          “(5) COST DATA.—

18                 “(A) The pharmacy contractor shall make  
19                 data on prescription drug negotiated prices (in-  
20                 cluding data on discounts) available to the Sec-  
21                 retary.

22                 “(B) The Secretary shall require, either di-  
23                 rectly or through a pharmacy contractor, that  
24                 participating pharmacists, physicians, and man-  
25                 ufacturers—

1           “(i) maintain their prescription drug  
2           cost data (including data on discounts) in  
3           a form and manner specified by the Sec-  
4           retary;

5           “(ii) make such prescription drug cost  
6           data available for review and audit by the  
7           Secretary; and

8           “(iii) certify that the prescription  
9           drug cost data are current, accurate, and  
10          complete, and reflect all discounts obtained  
11          by the pharmacist or physician in the pur-  
12          chasing of covered outpatient prescription  
13          drugs.

14          Discounts referred to in subparagraphs (A) and (B)  
15          shall include all volume discounts, manufacturer re-  
16          bates, prompt payment discounts, free goods, in-kind  
17          services, or any other thing of financial value pro-  
18          vided explicitly or implicitly in exchange for the pur-  
19          chase of a covered outpatient prescription drug.

20          “(6) REPORTING.—The pharmacy contractor  
21          shall provide the Secretary with periodic reports  
22          on—

23                  “(A) the contractor’s costs of admin-  
24                  istering this part;

25                  “(B) utilization of benefits under this part;

1           “(C) marketing and advertising expendi-  
2           tures related to enrolling and retaining individ-  
3           uals under this part; and

4           “(D) grievances and appeals.

5           “(7) RECORDS AND AUDITS.—The pharmacy  
6           contractor shall maintain adequate records related to  
7           the administration of benefits under this part and  
8           afford the Secretary access to such records for au-  
9           diting purposes.

10          “(8) APPROVAL OF MARKETING MATERIAL AND  
11          APPLICATION FORMS.—The pharmacy contractor  
12          shall comply with requirements of section 1851(h)  
13          (relating to marketing material and application  
14          forms) with respect to this part in the same manner  
15          as such requirements apply under part C, except  
16          that the provisions of paragraph (4)(A) of such sec-  
17          tion shall not apply with respect to discounts or re-  
18          bates provided in accordance with this part.

19          “(c) INCENTIVES FOR COST AND UTILIZATION MAN-  
20          AGEMENT AND QUALITY IMPROVEMENT.—

21          “(1) IN GENERAL.—The Secretary shall include  
22          in a contract awarded under subsection (b) with a  
23          pharmacy contractor such incentives for cost and  
24          utilization management and quality improvement as  
25          the Secretary may deem appropriate. The contract

1 may provide financial or other incentives to encour-  
2 age greater savings to the program under this part.

3 “(2) PERFORMANCE STANDARDS.—The Sec-  
4 retary shall provide for performance standards  
5 (which may include monetary bonuses if the stand-  
6 ards are met and penalties if the standards are not  
7 met), including standards relating to the time taken  
8 to answer member and pharmacy inquiries (written  
9 or by telephone), the accuracy of responses, claims  
10 processing accuracy, online system availability, ap-  
11 peal procedure turnaround time, system availability,  
12 the accuracy and timeliness of reports, and level of  
13 beneficiary satisfaction.

14 “(3) OTHER INCENTIVES.—Such incentives  
15 under this subsection may also include—

16 “(A) financial incentives under which sav-  
17 ings derived from the substitution of generic  
18 and other preferred multi-source drugs in lieu  
19 of nongeneric and nonpreferred drugs are made  
20 available to pharmacy contractors, pharmacies,  
21 beneficiaries, and the Federal Medicare Pre-  
22 scription Drug Trust Fund; and

23 “(B) any other incentive that the Secretary  
24 deems appropriate and likely to be effective in  
25 managing costs or utilization or improving qual-

1           ity that does not reduce the access of bene-  
2           ficiaries to medically necessary covered out-  
3           patient drugs.

4           “(4) REQUIREMENTS FOR PROCEDURES.—

5                 “(A) IN GENERAL.—The Secretary shall  
6           establish procedures for making payments to  
7           each pharmacy contractor with a contract under  
8           this part for the administration of the benefits  
9           under this part. The procedures shall provide  
10          for the following:

11                         “(i) ADMINISTRATIVE PAYMENT.—

12           Payment of administrative fees for such  
13           administration.

14                         “(ii) RISK REQUIREMENT.—An ad-

15           justment of a percentage (determined  
16           under subparagraph (B)) of the adminis-  
17           trative fee payments made to a pharmacy  
18           contractor to ensure that the contractor, in  
19           administering the benefits under this part,  
20           pursues performance requirements estab-  
21           lished by the Secretary, including the fol-  
22           lowing:

23                                 “(I) QUALITY SERVICE.—The

24           contractor provides eligible bene-  
25           ficiaries for whom it administers bene-

1 fits with quality services, as measured  
2 by such factors as sustained pharmacy  
3 network access, timeliness and accu-  
4 racy of service delivery in claims proc-  
5 essing and card production, pharmacy  
6 and member service support access,  
7 and timely action with regard to ap-  
8 peals and current beneficiary service  
9 surveys.

10 “(II) QUALITY CLINICAL CARE.—

11 The contractor provides such bene-  
12 ficiaries with quality clinical care, as  
13 measured by such factors as providing  
14 notification to such beneficiaries and  
15 to providers in order to prevent ad-  
16 verse drug reactions and reduce medi-  
17 cation errors and specific clinical sug-  
18 gestions to improve health and patient  
19 and prescriber education as appro-  
20 priate.

21 “(III) CONTROL OF MEDICARE

22 COSTS.—The contractor contains costs  
23 under this part to the Federal Medi-  
24 care Prescription Drug Trust Fund  
25 and enrollees, as measured by generic

1 substitution rates, price discounts,  
2 and other factors determined appro-  
3 priate by the Secretary that do not re-  
4 duce the access of beneficiaries to  
5 medically necessary covered outpatient  
6 prescription drugs.

7 “(B) PERCENTAGE OF PAYMENT TIED TO  
8 RISK.—

9 “(i) IN GENERAL.—Subject to clause  
10 (ii), the Secretary shall determine the per-  
11 centage of the administrative payments to  
12 a pharmacy contractor that will be tied to  
13 the performance requirements described in  
14 subparagraph (A)(ii).

15 “(ii) LIMITATION ON RISK TO ENSURE  
16 PROGRAM STABILITY.—In order to provide  
17 for program stability, the Secretary may  
18 not establish a percentage to be adjusted  
19 under this paragraph at a level that jeop-  
20 ardizes the ability of a pharmacy con-  
21 tractor to administer the benefits under  
22 this part or administer such benefits in a  
23 quality manner.

24 “(C) RISK ADJUSTMENT OF PAYMENTS  
25 BASED ON ENROLLEES IN PLAN.—To the extent

1           that a pharmacy contractor is at risk under this  
2           paragraph, the procedures established under  
3           this paragraph may include a methodology for  
4           risk adjusting the payments made to such con-  
5           tractor based on the differences in actuarial  
6           risk of different enrollees being served if the  
7           Secretary determines such adjustments to be  
8           necessary and appropriate.

9           “(d) AUTHORITY RELATING TO PHARMACY PARTICI-  
10          PATION.—

11           “(1) IN GENERAL.—Subject to the succeeding  
12           provisions of this subsection, a pharmacy contractor  
13           may establish consistent with this part conditions for  
14           the participation of pharmacies, including conditions  
15           relating to quality (including reduction of medical  
16           errors) and technology.

17           “(2) AGREEMENTS WITH PHARMACIES.—Each  
18           pharmacy contractor shall enter into a participation  
19           agreement with any pharmacy that meets the re-  
20           quirements of this subsection and section 1860D–6  
21           to furnish covered outpatient prescription drugs to  
22           individuals enrolled under this part.

23           “(3) TERMS OF AGREEMENT.—An agreement  
24           under this subsection shall include the following  
25           terms and conditions:

1           “(A) APPLICABLE REQUIREMENTS.—The  
2 pharmacy shall meet (and throughout the con-  
3 tract period continue to meet) all applicable  
4 Federal requirements and State and local li-  
5 censing requirements.

6           “(B) ACCESS AND QUALITY STANDARDS.—  
7 The pharmacy shall comply with such standards  
8 as the Secretary (and such a pharmacy con-  
9 tractor) shall establish concerning the quality  
10 of, and enrolled individuals’ access to, phar-  
11 macy services under this part. Such standards  
12 shall require the pharmacy—

13           “(i) not to refuse to dispense covered  
14 outpatient prescription drugs to any indi-  
15 vidual enrolled under this part;

16           “(ii) to keep patient records (includ-  
17 ing records on expenses) for all covered  
18 outpatient prescription drugs dispensed to  
19 such enrolled individuals;

20           “(iii) to submit information (in a  
21 manner specified by the Secretary to be  
22 necessary to administer this part) on all  
23 purchases of such drugs dispensed to such  
24 enrolled individuals; and

1                   “(iv) to comply with periodic audits to  
2                   assure compliance with the requirements of  
3                   this part and the accuracy of information  
4                   submitted.

5                   “(C) ADHERENCE TO NEGOTIATED  
6                   PRICES.—(i) The total charge for each prescrip-  
7                   tion drug dispensed by the pharmacy to an en-  
8                   rolled individual under this part, without regard  
9                   to whether the individual is financially respon-  
10                  sible for any or all of such charge, shall not ex-  
11                  ceed the price negotiated under section 1860D-  
12                  2(a) or, if lower, negotiated under subsection  
13                  (a)(5) (or, if less, the retail price for the drug  
14                  involved) with respect to such drug plus a rea-  
15                  sonable dispensing fee determined contractually  
16                  with the pharmacy contractor.

17                  “(ii) The pharmacy does not charge (or  
18                  collect from) an enrolled individual an amount  
19                  that exceeds the individual’s obligation (as de-  
20                  termined in accordance with the provisions of  
21                  this part) of the applicable price described in  
22                  clause (i).

23                  “(D) ELECTRONIC TRANSMITTAL OF PAY-  
24                  MENT.—At the option of a participating phar-  
25                  macy, the pharmacy shall be promptly provided

1 in an electronic manner reimbursement for pre-  
2 scription drugs dispensed under this part.

3 “(E) ADDITIONAL REQUIREMENTS.—The  
4 pharmacy shall meet such additional contract  
5 requirements as the applicable pharmacy con-  
6 tractor specifies under this section.

7 “(4) APPLICABILITY OF FRAUD AND ABUSE  
8 PROVISIONS.—The provisions of section 1128  
9 through 1128C (relating to fraud and abuse) apply  
10 to pharmacies participating in the program under  
11 this part.

12 “ELIGIBILITY; VOLUNTARY ENROLLMENT; COVERAGE

13 “SEC. 1860D–4. (a) ELIGIBILITY.—

14 “(1) IN GENERAL.—Each individual who is en-  
15 titled to hospital insurance benefits under part A or  
16 is eligible to be enrolled in the medical insurance  
17 program under part B shall, subject to subsection  
18 (b)(3), be enrolled in accordance with this section  
19 for outpatient prescription drug benefits under this  
20 part.

21 “(2) PUBLICITY.—The Secretary shall widely  
22 disseminate, through public service announcements  
23 and other means, the benefits availability through  
24 enrollment under this part. The Secretary shall  
25 enter into arrangements with hospitals and senior

1 centers for educating medicare beneficiaries con-  
2 cerning enrollment and the benefits under this part.

3 “(3) AUTHORIZATION OF APPROPRIATIONS.—

4 There are authorized to be appropriated  
5 \$10,000,000 to carry out paragraph (2) and the  
6 issuance of the pamphlet described in subsection  
7 (b)(2)(B).

8 “(b) AUTOMATIC ENROLLMENT WITHOUT NEED FOR  
9 SEPARATE APPLICATION.—

10 “(1) IN GENERAL.—The Secretary shall auto-  
11 matically enroll under this part each eligible indi-  
12 vidual described in subsection (a) without the need  
13 for any separate application.

14 “(2) ISSUANCE OF MEDICARE PRESCRIPTION  
15 DRUG CARD; INFORMATION PAMPHLET.—

16 “(A) IN GENERAL.—The Secretary shall  
17 provide for the issuance, through the mail to  
18 each individual enrolled under this section, of a  
19 medicare prescription drug card evidencing such  
20 enrollment. Such card shall be designed to indi-  
21 cate whether or not the individual is eligible for  
22 lowered cost-sharing under section 1860D-  
23 5(e)(2).

24 “(B) INFORMATION PAMPHLET.— The  
25 issuance of such card shall be accompanied by

1 a brief pamphlet that describes the benefits  
2 available under this part and how to use them.

3 “(3) VOLUNTARY PROGRAM.—Nothing in this  
4 section shall prevent an individual from voluntarily  
5 electing not to be enrolled under this part. No pen-  
6 alty shall be imposed under this part at any time for  
7 an individual who voluntarily decides to enroll or not  
8 enroll in the program under this part.

9 “(4) INFORMATION.—

10 “(A) IN GENERAL.—The Secretary shall  
11 broadly distribute information to individuals  
12 who satisfy subsection (a) on the benefits pro-  
13 vided under this part. The Secretary shall peri-  
14 odically make available information on the cost  
15 differentials to enrollees for the use of generic  
16 drugs and other drugs.

17 “(B) TOLL-FREE HOTLINE.—The Sec-  
18 retary shall maintain a toll-free telephone hot-  
19 line (which may be a hotline already used by  
20 the Secretary under this title) for purposes of  
21 providing assistance to beneficiaries in the pro-  
22 gram under this part, including responding to  
23 questions concerning coverage, enrollment, ben-  
24 efits, grievances and appeals procedures, and  
25 other aspects of such program.

1           “(5) ENROLLEE DEFINED.—For purposes of  
2 this part, the term ‘enrollee’ means an individual en-  
3 rolled for benefits under this part.

4           “(c) COVERAGE PERIOD.—

5           “(1) IN GENERAL.—The period during which  
6 an individual is entitled to benefits under this part  
7 (in this subsection referred to as the individual’s  
8 ‘coverage period’) shall begin on such a date as the  
9 Secretary shall establish consistent with the type of  
10 coverage rules described in subsections (a) and (e)  
11 of section 1838, except that in no case shall a cov-  
12 erage period begin before July 1, 2006. No pay-  
13 ments may be made under this part with respect to  
14 the expenses of an individual unless such expenses  
15 were incurred by such individual during a period  
16 which, with respect to the individual, is a coverage  
17 period.

18           “(2) TERMINATION.—The Secretary shall pro-  
19 vide for the application of provisions under this sub-  
20 section similar to the provisions in section 1838(b).

21           “(d) PROVISION OF BENEFITS TO  
22 MEDICAREADVANTAGE ENROLLEES.—In the case of an  
23 individual who is enrolled under this part and is enrolled  
24 in an MA plan under part C, the individual shall be pro-

1 vided the benefits under this part through such plan and  
 2 not through payment under this part.

3 “(e) ELECTION OF PHARMACY CONTRACTOR TO AD-  
 4 MINISTER BENEFITS.—The Secretary shall establish a  
 5 process whereby each individual enrolled under this part  
 6 and residing in a region may elect the pharmacy con-  
 7 tractor that will administer the benefits under this part  
 8 with respect to the individual. Such process shall permit  
 9 the individual to make an initial election and to change  
 10 such an election on at least an annual basis and under  
 11 such other circumstances as the Secretary shall specify.

12 “PROVISION OF, AND ENTITLEMENT TO, BENEFITS; RE-  
 13 DUCATION IN COINSURANCE FOR LOWER INCOME  
 14 BENEFICIARIES

15 “SEC. 1860D–5. (a) BENEFITS.—Subject to the suc-  
 16 ceeding provisions of this section, the benefits provided to  
 17 an enrollee by the program under this part shall consist  
 18 of the following:

19 “(1) COVERED OUTPATIENT PRESCRIPTION  
 20 DRUG BENEFITS.—Entitlement to have payment  
 21 made on the individual’s behalf for covered out-  
 22 patient prescription drugs.

23 “(2) LIMITATION ON COST-SHARING FOR PART  
 24 B OUTPATIENT PRESCRIPTION DRUGS.—

25 “(A) IN GENERAL.—Once an enrollee has  
 26 incurred aggregate countable cost-sharing (as

1 defined in subparagraph (B)) equal to the stop-  
2 loss limit specified in subsection (c)(4) for ex-  
3 penses in a year, entitlement to the elimination  
4 of cost-sharing otherwise applicable under part  
5 B for additional expenses incurred in the year  
6 for outpatient prescription drugs or biologicals  
7 for which payment is made under part B.

8 “(B) COUNTABLE COST-SHARING DE-  
9 FINED.—For purposes of this part, the term  
10 ‘countable cost-sharing’ means—

11 “(i) out-of-pocket expenses for out-  
12 patient prescription drugs with respect to  
13 which benefits are payable under part B,  
14 and

15 “(ii) cost-sharing under subsections  
16 (c)(3)(B) and (c)(3)(C)(i).

17 “(b) COVERED OUTPATIENT PRESCRIPTION DRUG  
18 DEFINED.—

19 “(1) IN GENERAL.—Except as provided in para-  
20 graph (2), for purposes of this part the term ‘cov-  
21 ered outpatient prescription drug’ means any of the  
22 following products:

23 “(A) A drug which may be dispensed only  
24 upon prescription, and—

1           “(i) which is approved for safety and  
2           effectiveness as a prescription drug under  
3           section 505 of the Federal Food, Drug,  
4           and Cosmetic Act;

5           “(ii)(I) which was commercially used  
6           or sold in the United States before the  
7           date of enactment of the Drug Amend-  
8           ments of 1962 or which is identical, simi-  
9           lar, or related (within the meaning of sec-  
10          tion 310.6(b)(1) of title 21 of the Code of  
11          Federal Regulations) to such a drug,  
12          and—

13          “(II) which has not been the subject  
14          of a final determination by the Secretary  
15          that it is a ‘new drug’ (within the meaning  
16          of section 201(p) of the Federal Food,  
17          Drug, and Cosmetic Act) or an action  
18          brought by the Secretary under section  
19          301, 302(a), or 304(a) of such Act to en-  
20          force section 502(f) or 505(a) of such Act;  
21          or

22          “(iii)(I) which is described in section  
23          107(e)(3) of the Drug Amendments of  
24          1962 and for which the Secretary has de-  
25          termined there is a compelling justification

1 for its medical need, or is identical, simi-  
2 lar, or related (within the meaning of sec-  
3 tion 310.6(b)(1) of title 21 of the Code of  
4 Federal Regulations) to such a drug,  
5 and—

6 “(II) for which the Secretary has not  
7 issued a notice of an opportunity for a  
8 hearing under section 505(e) of the Fed-  
9 eral Food, Drug, and Cosmetic Act on a  
10 proposed order of the Secretary to with-  
11 draw approval of an application for such  
12 drug under such section because the Sec-  
13 retary has determined that the drug is less  
14 than effective for all conditions of use pre-  
15 scribed, recommended, or suggested in its  
16 labeling.

17 “(B) A biological product which—

18 “(i) may only be dispensed upon pre-  
19 scription;

20 “(ii) is licensed under section 351 of  
21 the Public Health Service Act; and

22 “(iii) is produced at an establishment  
23 licensed under such section to produce  
24 such product.

1           “(C) Insulin approved under appropriate  
2 Federal law, and needles, syringes, and dispos-  
3 able pumps for the administration of such insu-  
4 lin.

5           “(D) A prescribed drug or biological prod-  
6 uct that would meet the requirements of sub-  
7 paragraph (A) or (B) but that is available over-  
8 the-counter in addition to being available upon  
9 prescription, but only if the particular dosage  
10 form or strength prescribed and required for  
11 the individual is not available over-the-counter.

12           “(E) Smoking cessation agents (as speci-  
13 fied by the Secretary).

14           “(2) EXCLUSION.—The term ‘covered out-  
15 patient prescription drug’ does not include—

16           “(A) drugs or classes of drugs, or their  
17 medical uses, which may be excluded from cov-  
18 erage or otherwise restricted under section  
19 1927(d)(2), other than subparagraph (E) there-  
20 of (relating to smoking cessation agents), as the  
21 Secretary may specify and does not include  
22 such other drugs, classes, and uses as the Sec-  
23 retary may specify consistent with the goals of  
24 providing quality care and containing costs  
25 under this part;

1           “(B) except as provided in paragraphs  
2           (1)(D) and (1)(E), any product which may be  
3           distributed to individuals without a prescrip-  
4           tion;

5           “(C) any product when furnished as part  
6           of, or as incident to, a diagnostic service or any  
7           other item or service for which payment may be  
8           made under this title; or

9           “(D) any product that is covered under  
10          part B of this title.

11         “(c) PAYMENT OF BENEFITS.—

12           “(1) COVERED OUTPATIENT PRESCRIPTION  
13         DRUGS.—There shall be paid from the Federal Medi-  
14         care Prescription Drug Trust Fund, in the case of  
15         each enrollee who incurs expenses for prescription  
16         drugs with respect to which benefits are payable  
17         under this part under subsection (a)(1), amounts  
18         equal to the sum of—

19           “(A) the price for which the drug is made  
20           available under this part (consistent with sec-  
21           tions 1860D–2 and 1860D–3), reduced by any  
22           applicable cost-sharing under paragraphs (2)  
23           and (3); and

24           “(B) a reasonable dispensing fee.

1 The price under subparagraph (A) shall in no case  
2 exceed the retail price for the prescription drug in-  
3 volved.

4 “(2) NO DEDUCTIBLE.—There is no deductible  
5 applicable to payment of benefits under this part.

6 “(3) COINSURANCE.—

7 “(A) IN GENERAL.—The amount of pay-  
8 ment under paragraph (1) for expenses in-  
9 curred in a year shall be further reduced (sub-  
10 ject to the stop-loss limit under paragraph (4))  
11 by coinsurance as provided under this para-  
12 graph.

13 “(B) PREFERRED DRUGS.—Subject to sub-  
14 section (e), the coinsurance under this para-  
15 graph in the case of a preferred drug (including  
16 a drug treated as a preferred drug under para-  
17 graph (5)), is equal to 10 percent of the price  
18 applicable under paragraph (1)(A) (or such  
19 lower percentage as may be provided for under  
20 section 1860D–6(a)(1)(A)(ii)). In this part, the  
21 term ‘preferred drug’ means, with respect to  
22 drugs classified within a therapeutic class, those  
23 drugs which have been designated as a pre-  
24 ferred drug by the Secretary or the pharmacy  
25 contractor involved with respect to that class

1 and (in the case of a nongeneric drug) with re-  
2 spect to which a contract has been negotiated  
3 under this part.

4 “(C) NONPREFERRED DRUGS.—Subject to  
5 subsection (e), the coinsurance under this para-  
6 graph in the case of a nonpreferred drug that  
7 is not treated as a preferred drug under para-  
8 graph (5) is equal to the sum of—

9 “(i) 10 percent of the price for lowest  
10 price preferred drug that is within the  
11 same therapeutic class; and

12 “(ii) the amount by which—

13 “(I) the price at which the non-  
14 preferred drug is made available to  
15 the enrollee; exceeds

16 “(II) the price of such lowest  
17 price preferred drug.

18 “(4) NO COINSURANCE ONCE OUT-OF-POCKET  
19 EXPENDITURES EQUAL STOP-LOSS LIMIT.—Once an  
20 enrollee has incurred aggregate countable cost-shar-  
21 ing under paragraph (3) (including cost-sharing  
22 under part B attributable to outpatient prescription  
23 drugs or biologicals) equal to the amount specified  
24 in section 1860D–1(4) (subject to adjustment under  
25 paragraph (8)) for expenses in a year—

1           “(A) there shall be no coinsurance under  
2 paragraph (3) for additional expenses incurred  
3 in the year involved; and

4           “(B) there shall be no coinsurance under  
5 part B for additional expenses incurred in the  
6 year involved for outpatient prescription drugs  
7 and biologicals.

8           “(5) APPEALS RIGHTS RELATING TO COVERAGE  
9 OF NONPREFERRED DRUGS.—

10           “(A) PROCEDURES REGARDING THE DE-  
11 TERMINATION OF DRUGS THAT ARE MEDICALLY  
12 NECESSARY.—Each pharmacy contractor shall  
13 have in place procedures on a case-by-case basis  
14 to treat a nonpreferred drug as a preferred  
15 drug under this part if the preferred drug is de-  
16 termined to be not as effective for the enrollee  
17 or to have significant adverse effect on the en-  
18 rollee. Such procedures shall require that such  
19 determinations are based on professional med-  
20 ical judgment, the medical condition of the en-  
21 rollee, and other medical evidence.

22           “(B) PROCEDURES REGARDING DENIALS  
23 OF CARE.—Such contractor shall have in place  
24 procedures to ensure—

1           “(i) a timely internal review for reso-  
2           lution of denials of coverage (in whole or  
3           in part and including those regarding the  
4           coverage of nonpreferred drugs) in accord-  
5           ance with the medical exigencies of the  
6           case and a timely resolution of complaints,  
7           by enrollees in the plan, or by providers,  
8           pharmacists, and other individuals acting  
9           on behalf of each such enrollee (with the  
10          enrollee’s consent) in accordance with re-  
11          quirements (as established by the Sec-  
12          retary) that are comparable to such re-  
13          quirements for MA organizations under  
14          part C;

15          “(ii) that the entity complies in a  
16          timely manner with requirements estab-  
17          lished by the Secretary that (I) provide for  
18          an external review by an independent enti-  
19          ty selected by the Secretary of denials of  
20          coverage described in clause (i) not re-  
21          solved in the favor of the beneficiary (or  
22          other complainant) under the process de-  
23          scribed in such clause and (II) are com-  
24          parable to the external review requirements

1 established for MA organizations under  
2 part C; and

3 “(iii) that enrollees are provided with  
4 information regarding the appeals proce-  
5 dures under this part at the time of enroll-  
6 ment with a pharmacy contractor under  
7 this part and upon request thereafter.

8 “(6) TRANSFER OF FUNDS TO COVER COSTS OF  
9 PART B PRESCRIPTION DRUG CATASTROPHIC BEN-  
10 EFIT.—With respect to benefits described in sub-  
11 section (a)(2), there shall be transferred from the  
12 Federal Medicare Prescription Drug Trust Fund to  
13 the Federal Supplementary Medical Insurance Trust  
14 Fund amounts equivalent to the elimination of cost-  
15 sharing described in such subsection.

16 “(7) PERMITTING APPLICATION UNDER PART B  
17 OF NEGOTIATED PRICES.—For purposes of making  
18 payment under part B for drugs that would be cov-  
19 ered outpatient prescription drugs but for the exclu-  
20 sion under subparagraph (B) or (C) of subsection  
21 (b)(2), the Secretary may elect to apply the payment  
22 basis used for payment of covered outpatient pre-  
23 scription drugs under this part instead of the pay-  
24 ment basis otherwise used under such part, if it re-  
25 sults in a lower cost to the program.

1           “(8) INFLATION ADJUSTMENT.—

2                   “(A) IN GENERAL.—With respect to ex-  
3           penses incurred in a year after 2006, the stop-  
4           loss limit under paragraph (3) is equal to the  
5           stop-loss limit determined under such para-  
6           graph (or this subparagraph) for the previous  
7           year increased by such percentage increase. The  
8           Secretary shall adjust such percentage increase  
9           in subsequent years to take into account  
10          misestimations made of the per capita program  
11          expenditures under this subparagraph in pre-  
12          vious years. Any increase under this subpara-  
13          graph that is not a multiple of \$10 shall be  
14          rounded to the nearest multiple of \$10.

15                   “(B) ESTIMATION OF INCREASE IN PER  
16          CAPITA PROGRAM EXPENDITURES.—The Sec-  
17          retary shall before the beginning of each year  
18          (beginning with 2007) estimate the percentage  
19          increase in average per capita aggregate ex-  
20          penditures from the Federal Medicare Prescrip-  
21          tion Drug Trust Fund for the year involved  
22          compared to the previous year.

23                   “(C) RECONCILIATION.—The Secretary  
24          shall also compute (beginning with 2008) the  
25          actual percentage increase in such aggregate

1 expenditures in order to provide for reconcili-  
2 ation of deductibles, and stop-loss limits, under  
3 the second sentence of subparagraph (A) and  
4 under section 1860D–5(d)(2).

5 “(d) NO MONTHLY PREMIUMS.—In accordance with  
6 section 1860D–1(1) there is no monthly premium for pre-  
7 scription drug benefits under this part.

8 “(e) REDUCTIONS IN COINSURANCE FOR LOWER IN-  
9 COME BENEFICIARIES.—

10 “(1) INSTITUTIONALIZED INDIVIDUALS.—In the  
11 case of an individual who is a full-benefit dual eligi-  
12 ble individual (as defined in paragraph (4)(C)) and  
13 who is an institutionalized individual or couple (as  
14 defined in section 1902(q)(1)(B)), the coinsurance  
15 under subsection (c)(4) shall be eliminated.

16 “(2) INDIVIDUALS WITH INCOME BELOW 150  
17 PERCENT OF THE POVERTY LEVEL.—In the case of  
18 an individual who is not described in paragraph (1)  
19 and whose family income does not exceed 150 per-  
20 cent of the poverty level applicable to a family of the  
21 size involved, the coinsurance under subsection  
22 (c)(4) shall not exceed—

23 “(A) \$1 in the case of a preferred drug de-  
24 scribed in subsection (c)(3)(B); or

1           “(B) §3 in the case of a nonpreferred drug  
2 described in subsection (c)(3)(C).

3           “(3) PROCESS OF QUALIFICATION FOR RE-  
4 DUCED COINSURANCE.—

5           “(A) IN GENERAL.—The Secretary shall  
6 provide a process for the qualification of bene-  
7 ficiaries for reduced coinsurance under this sub-  
8 section. Such process shall be coordinated, to  
9 the maximum extent practicable, with State  
10 medicaid programs, but shall also permit indi-  
11 viduals to qualify on the basis of simple, 1-page  
12 applications made directly to the Secretary (or  
13 the Secretary’s designee, such as through a  
14 local pharmacy).

15           “(B) NO ASSETS TEST.—An individual’s  
16 eligibility for reduced coinsurance under this  
17 subsection shall be determined without regard  
18 to the amount of the assets of the individual or  
19 family members.

20           “(4) DEFINITIONS.—In this part:

21           “(A) FAMILY INCOME.—The Secretary  
22 shall define the term ‘family income’.

23           “(B) POVERTY LEVEL.—The term ‘poverty  
24 line’ has the meaning given the term ‘poverty  
25 line’ in section 673(2) of the Community Serv-

1           ices Block Grant Act (42 U.S.C. 9902(2)), in-  
2           cluding any revision required by such section.

3                   “(C) FULL-BENEFIT DUAL ELIGIBLE INDI-  
4           VIDUAL DEFINED.—

5                           “(i) IN GENERAL.—The term ‘full-  
6           benefit dual eligible individual’ means, with  
7           respect to a month, an individual residing  
8           in a State who—

9                                   “(I) has coverage for the month  
10           for covered part D drugs under this  
11           part (including under an MA plan  
12           under part C); and

13                                   “(II) is determined eligible by the  
14           State for medical assistance for full  
15           benefits under title XIX for such  
16           month under section 1902(a)(10)(A)  
17           or 1902(a)(10)(C), by reason of sec-  
18           tion 1902(f), or under any other cat-  
19           egory of eligibility for medical assist-  
20           ance for full benefits under such title,  
21           as determined by the Secretary.

22                                   “(ii) TREATMENT OF MEDICALLY  
23           NEEDY AND OTHER INDIVIDUALS RE-  
24           QUIRED TO SPEND DOWN.—In applying  
25           clause (i) in the case of an individual de-

1           terminated to be eligible by the State for  
2           medical assistance under section  
3           1902(a)(10)(C) or by reason of section  
4           1902(f), the individual shall be treated as  
5           meeting the requirement of clause (i)(II)  
6           for any month if such medical assistance is  
7           provided for in any part of the month.

8           “(5) TREATMENT OF RESIDENTS OF TERRI-  
9           TORIES.—The Secretary shall provide for such ad-  
10          justment in the application of this subsection to resi-  
11          dents of the territories as may be necessary to take  
12          into account differences in average family income for  
13          such residents compared to average family income  
14          for eligible individuals residing in the 50 States or  
15          the District of Columbia.

16          “ADMINISTRATION; QUALITY ASSURANCE

17          “SEC. 1860D–6. (a) RULES RELATING TO PROVI-  
18          SION OF BENEFITS.—

19                 “(1) PROVISION OF BENEFITS.—

20                         “(A) IN GENERAL.—In providing benefits  
21                         under this part, the Secretary (directly or  
22                         through the contracts with pharmacy contrac-  
23                         tors) shall employ mechanisms to provide bene-  
24                         fits appropriately and efficiently, and those  
25                         mechanisms may include—

26                                 “(i) the use of—

1                   “(I) price negotiations (con-  
2                   sistent with subsection (b));

3                   “(II) reduced coinsurance (below  
4                   20 percent) to encourage the utiliza-  
5                   tion of appropriate preferred prescrip-  
6                   tion drugs; and

7                   “(III) methods to reduce medica-  
8                   tion errors and encourage appropriate  
9                   use of medications; and

10                  “(ii) permitting pharmacy contractors,  
11                  as approved by the Secretary, to make ex-  
12                  ceptions to section 1860D–5(c)(3)(C) (re-  
13                  lating to cost-sharing for non-preferred  
14                  drugs) to secure best prices for enrollees so  
15                  long as the payment amount under section  
16                  1860D–5(c)(1) does not equal zero.

17                  “(B) CONSTRUCTION.—Nothing in this  
18                  subsection shall be construed to prevent the  
19                  Secretary (directly or through the contracts  
20                  with pharmacy contractors) from using incen-  
21                  tives to encourage enrollees to select generic or  
22                  other cost-effective drugs, so long as—

23                         “(i) such incentives are designed not  
24                         to result in any increase in the aggregate

1 expenditures under the Federal Medicare  
2 Prescription Drug Trust Fund; and

3 “(ii) a beneficiary’s coinsurance shall  
4 be no greater than 20 percent in the case  
5 of a preferred drug (including a nonpre-  
6 ferred drug treated as a preferred drug  
7 under section 1860D–5(c)(5)).

8 “(2) CONSTRUCTION.—Nothing in this part  
9 shall preclude the Secretary or a pharmacy con-  
10 tractor from—

11 “(A) educating prescribing providers, phar-  
12 macists, and enrollees about medical and cost  
13 benefits of preferred drugs;

14 “(B) requesting prescribing providers to  
15 consider a preferred drug prior to dispensing of  
16 a nonpreferred drug, as long as such request  
17 does not unduly delay the provision of the drug;

18 “(C) using mechanisms to encourage en-  
19 rollees under this part to select cost-effective  
20 drugs or less costly means of receiving or ad-  
21 ministering drugs, including the use of thera-  
22 peutic interchange programs, disease manage-  
23 ment programs, and notification to the bene-  
24 ficiary that a more affordable generic drug  
25 equivalent was not selected by the prescribing

1 provider and a statement of the lost cost sav-  
2 ings to the beneficiary;

3 “(D) using price negotiations to achieve re-  
4 duced prices on covered outpatient prescription  
5 drugs, including new drugs, drugs for which  
6 there are few therapeutic alternatives, and  
7 drugs of particular clinical importance to indi-  
8 viduals enrolled under this part; and

9 “(E) utilizing information on drug prices  
10 of OECD countries and of other payors in the  
11 United States in the negotiation of prices under  
12 this part.

13 “(b) PRICE NEGOTIATIONS PROCESS.—

14 “(1) REQUIREMENTS WITH RESPECT TO PRE-  
15 FERRED DRUGS.—Negotiations of contracts with  
16 manufacturers with respect to covered outpatient  
17 prescription drugs under this part shall be con-  
18 ducted in a manner so that—

19 “(A) there is at least a contract for a drug  
20 within each therapeutic class (as defined by the  
21 Secretary in consultation with such Medicare  
22 Prescription Drug Advisory Committee);

23 “(B) if there is more than 1 drug available  
24 in a therapeutic class, there are contracts for at  
25 least 2 drugs within such class unless deter-

1           mined clinically inappropriate in accordance  
2           with standards established by the Secretary;  
3           and

4                   “(C) if there are more than 2 drugs avail-  
5           able in a therapeutic class, there is a contract  
6           for at least 2 drugs within such class and a  
7           contract for generic drug substitute if available  
8           unless determined clinically inappropriate in ac-  
9           cordance with standards established by the Sec-  
10          retary.

11                   “(2) ESTABLISHMENT OF THERAPEUTIC CLASS-  
12          ES.—The Secretary, in consultation with the Medi-  
13          care Prescription Drug Advisory Committee (estab-  
14          lished under section 1860D–9), shall establish for  
15          purposes of this part therapeutic classes and assign  
16          to such classes covered outpatient prescription  
17          drugs.

18                   “(3) DISCLOSURE CONCERNING PREFERRED  
19          DRUGS.—The Secretary shall provide, through phar-  
20          macy contractors or otherwise, for—

21                           “(A) disclosure to current and prospective  
22                           enrollees and to participating providers and  
23                           pharmacies in each service area a list of the  
24                           preferred drugs and differences in applicable

1 cost-sharing between such drugs and nonpre-  
2 ferred drugs; and

3 “(B) advance disclosure to current enroll-  
4 ees and to participating providers and phar-  
5 macies in each service area of changes to any  
6 such list of preferred drugs and differences in  
7 applicable cost-sharing.

8 “(4) NO REVIEW.—The Secretary’s establish-  
9 ment of therapeutic classes and the assignment of  
10 drugs to such classes and the Secretary’s determina-  
11 tion of what is a breakthrough drug are not subject  
12 to administrative or judicial review.

13 “(c) CONFIDENTIALITY.—The Secretary shall ensure  
14 that the confidentiality of individually identifiable health  
15 information relating to the provision of benefits under this  
16 part is protected, consistent with the standards for the  
17 privacy of such information promulgated by the Secretary  
18 under the Health Insurance Portability and Accountability  
19 Act of 1996, or any subsequent comprehensive and more  
20 protective set of confidentiality standards enacted into law  
21 or promulgated by the Secretary. Nothing in this sub-  
22 section shall be construed as preventing the coordination  
23 of data with a State prescription drug program so long  
24 as such program has in place confidentiality standards

1 that are equal to or exceed the standards used by the Sec-  
2 retary.

3 “(d) FRAUD AND ABUSE SAFEGUARDS.—The Sec-  
4 retary, through the Office of the Inspector General, is au-  
5 thorized and directed to issue regulations establishing ap-  
6 propriate safeguards to prevent fraud and abuse under  
7 this part. Such safeguards, at a minimum, should include  
8 compliance programs, certification data, audits, and rec-  
9 ordkeeping practices. In developing such regulations, the  
10 Secretary shall consult with the Attorney General and  
11 other law enforcement and regulatory agencies.

12 “(e) USE OF 800 NUMBER.—Through the tollfree  
13 number provided under section 1804(b), the Secretary  
14 shall provide a means for beneficiaries to discuss problems  
15 and challenges with costs or access to prescription drugs  
16 under this part.

17 “(f) USE OF WEBSITE.—The Internet website main-  
18 tained by the Secretary for purposes of this title shall in-  
19 clude information on the price of, access to, and quality  
20 of prescription drugs provided under this part.

21 “FEDERAL MEDICARE PRESCRIPTION DRUG TRUST FUND

22 “SEC. 1860D–7. (a) ESTABLISHMENT.—There is  
23 hereby created on the books of the Treasury of the United  
24 States a trust fund to be known as the ‘Federal Medicare  
25 Prescription Drug Trust Fund’ (in this section referred  
26 to as the ‘Trust Fund’). The Trust Fund shall consist of

1 such gifts and bequests as may be made as provided in  
2 section 201(i)(1), and such amounts as may be deposited  
3 in, or appropriated to, such fund as provided in this part.

4 “(b) APPLICATION OF SMI TRUST FUND PROVI-  
5 SIONS.—The provisions of subsections (b) through (i) of  
6 section 1841 shall apply to this part and the Trust Fund  
7 in the same manner as they apply to part B and the Fed-  
8 eral Supplementary Medical Insurance Trust Fund, re-  
9 spectively.

10 “COMPENSATION FOR EMPLOYERS COVERING RETIREE

11 DRUG COSTS

12 “SEC. 1860D–8. (a) IN GENERAL.—In the case of  
13 an individual who is eligible to be enrolled under this part  
14 and is a participant or beneficiary under a group health  
15 plan that provides outpatient prescription drug coverage  
16 to retirees the actuarial value of which is not less than  
17 the actuarial value of the coverage provided under this  
18 part, the Secretary shall make payments to such plan sub-  
19 ject to the provisions of this section. Such payments shall  
20 be treated as payments under this part for purposes of  
21 sections 1860D–7 and 1860D–4(e)(2). In applying the  
22 previous sentence with respect to section 1860D–4(e)(2),  
23 the amount of the Government contribution referred to in  
24 section 1844(a)(1)(A) is deemed to be equal to the aggre-  
25 gate amount of the payments made under this section.

1       “(b) REQUIREMENTS.—To receive payment under  
2 this section, a group health plan shall comply with the fol-  
3 lowing requirements:

4           “(1) COMPLIANCE WITH REQUIREMENTS.—The  
5 group health plan shall comply with the require-  
6 ments of this Act and other reasonable, necessary,  
7 and related requirements that are needed to admin-  
8 ister this section, as determined by the Secretary.

9           “(2) ANNUAL ASSURANCES AND NOTICE BE-  
10 FORE TERMINATION.—The sponsor of the plan  
11 shall—

12           “(A) annually attest, and provide such as-  
13 surances as the Secretary may require, that the  
14 coverage offered under the group health plan  
15 meets the requirements of this section and will  
16 continue to meet such requirements for the du-  
17 ration of the sponsor’s participation in the pro-  
18 gram under this section; and

19           “(B) guarantee that it will give notice to  
20 the Secretary and covered enrollees—

21           “(i) at least 120 days before termi-  
22 nating its plan, and

23           “(ii) immediately upon determining  
24 that the actuarial value of the prescription  
25 drug benefit under the plan falls below the

1           actuarial value required under subsection  
2           (a).

3           “(3) BENEFICIARY INFORMATION.—The spon-  
4           sor of the plan shall report to the Secretary, for  
5           each calendar quarter for which it seeks a payment  
6           under this section, the names and social security  
7           numbers of all enrollees described in subsection (a)  
8           covered under such plan during such quarter and  
9           the dates (if less than the full quarter) during which  
10          each such individual was covered.

11          “(4) AUDITS.—The sponsor or plan seeking  
12          payment under this section shall agree to maintain,  
13          and to afford the Secretary access to, such records  
14          as the Secretary may require for purposes of audits  
15          and other oversight activities necessary to ensure the  
16          adequacy of prescription drug coverage, the accuracy  
17          of payments made, and such other matters as may  
18          be appropriate.

19          “(c) PAYMENT.—

20          “(1) IN GENERAL.—The sponsor of a group  
21          health plan that meets the requirements of sub-  
22          section (b) with respect to a quarter in a calendar  
23          year shall be entitled to have payment made on a  
24          quarterly basis of the amount specified in paragraph  
25          (2) for each individual described in subsection (a)

1 who during the quarter is covered under the plan  
2 and was not enrolled in the insurance program  
3 under this part.

4 “(2) AMOUNT OF PAYMENT.—

5 “(A) IN GENERAL.—The amount of the  
6 payment for a quarter shall approximate, for  
7 each such covered individual,  $\frac{2}{3}$  of the sum of  
8 the monthly Government contribution amounts  
9 (computed under subparagraph (B)) for each of  
10 the 3 months in the quarter.

11 “(B) COMPUTATION OF MONTHLY GOV-  
12 ERNMENT CONTRIBUTION AMOUNT.—For pur-  
13 poses of subparagraph (A), the monthly Gov-  
14 ernment contribution amount for a month in a  
15 year is equal to the amount by which—

16 “(i)  $\frac{1}{12}$  of the average per capita ag-  
17 gregate expenditures, as estimated under  
18 section 1860D–5(c)(8) for the year in-  
19 volved; exceeds

20 “(ii) the monthly premium rate under  
21 section 1860D–5(d) for the month in-  
22 volved.

23 “MEDICARE PRESCRIPTION DRUG ADVISORY COMMITTEE

24 “SEC. 1860D–9. (a) ESTABLISHMENT OF COM-  
25 MITTEE.—There is established a Medicare Prescription

1 Drug Advisory Committee (in this section referred to as  
2 the ‘Committee’).

3 “(b) FUNCTIONS OF COMMITTEE.—The Committee  
4 shall advise the Secretary on policies related to—

5 “(1) the development of guidelines for the im-  
6 plementation and administration of the outpatient  
7 prescription drug benefit program under this part;  
8 and

9 “(2) the development of—

10 “(A) standards required of pharmacy con-  
11 tractors under section 1860D–5(c)(5) for deter-  
12 mining if a drug is as effective for an enrollee  
13 or has a significant adverse effect on an en-  
14 rollee under this part;

15 “(B) standards for—

16 “(i) defining therapeutic classes;

17 “(ii) adding new therapeutic classes;

18 “(iii) assigning to such classes covered  
19 outpatient prescription drugs; and

20 “(iv) identifying breakthrough drugs;

21 “(C) procedures to evaluate the bids sub-  
22 mitted by pharmacy contractors under this  
23 part;

24 “(D) procedures for negotiations, and  
25 standards for entering into contracts, with

1 manufacturers, including identifying drugs or  
2 classes of drugs where Secretarial negotiation is  
3 most likely to yield savings under this part sig-  
4 nificantly above those that which could be  
5 achieved by a pharmacy contractor; and

6 “(E) procedures to ensure that pharmacy  
7 contractors with a contract under this part are  
8 in compliance with the requirements under this  
9 part.

10 For purposes of this part, a drug is a ‘breakthrough drug’  
11 if the Secretary, in consultation with the Committee, de-  
12 termines it is a new product that will make a significant  
13 and major improvement by reducing physical or mental  
14 illness, reducing mortality, or reducing disability, and that  
15 no other product is available to beneficiaries that achieves  
16 similar results for the same condition. The Committee  
17 may consider cost-effectiveness in establishing standards  
18 for defining therapeutic classes and assigning drugs to  
19 such classes under subparagraph (B).

20 “(c) STRUCTURE AND MEMBERSHIP OF THE COM-  
21 MITTEE.—

22 “(1) STRUCTURE.—The Committee shall be  
23 composed of 19 members who shall be appointed by  
24 the Secretary.

25 “(2) MEMBERSHIP.—

1           “(A) IN GENERAL.—The members of the  
2           Committee shall be chosen on the basis of their  
3           integrity, impartiality, and good judgment, and  
4           shall be individuals who are, by reason of their  
5           education, experience, and attainments, excep-  
6           tionally qualified to perform the duties of mem-  
7           bers of the Committee.

8           “(B) SPECIFIC MEMBERS.—Of the mem-  
9           bers appointed under paragraph (1)—

10           “(i) 5 shall be chosen to represent  
11           practicing physicians, 2 of whom shall be  
12           gerontologists;

13           “(ii) 2 shall be chosen to represent  
14           practicing nurse practitioners;

15           “(iii) 4 shall be chosen to represent  
16           practicing pharmacists;

17           “(iv) 1 shall be chosen to represent  
18           the Centers for Medicare & Medicaid Serv-  
19           ices;

20           “(v) 4 shall be chosen to represent ac-  
21           tuaries, pharmacoeconomists, researchers,  
22           and other appropriate experts;

23           “(vi) 1 shall be chosen to represent  
24           emerging medicine technologies;

1                   “(vii) 1 shall be chosen to represent  
2                   the Food and Drug Administration; and

3                   “(viii) 1 shall be chosen to represent  
4                   individuals enrolled under this part.

5           “(d) TERMS OF APPOINTMENT.—Each member of  
6 the Committee shall serve for a term determined appro-  
7 priate by the Secretary. The terms of service of the mem-  
8 bers initially appointed shall begin on January 1, 2006.

9           “(e) CHAIRPERSON.—The Secretary shall designate  
10 a member of the Committee as Chairperson. The term as  
11 Chairperson shall be for a 1-year period.

12           “(f) COMMITTEE PERSONNEL MATTERS.—

13                   “(1) MEMBERS.—

14                           “(A) COMPENSATION.—Each member of  
15 the Committee who is not an officer or em-  
16 ployee of the Federal Government shall be com-  
17 pensated at a rate equal to the daily equivalent  
18 of the annual rate of basic pay prescribed for  
19 level IV of the Executive Schedule under section  
20 5315 of title 5, United States Code, for each  
21 day (including travel time) during which such  
22 member is engaged in the performance of the  
23 duties of the Committee. All members of the  
24 Committee who are officers or employees of the  
25 United States shall serve without compensation

1           in addition to that received for their services as  
2           officers or employees of the United States.

3           “(B) TRAVEL EXPENSES.—The members  
4           of the Committee shall be allowed travel ex-  
5           penses, including per diem in lieu of subsist-  
6           ence, at rates authorized for employees of agen-  
7           cies under subchapter I of chapter 57 of title 5,  
8           United States Code, while away from their  
9           homes or regular places of business in the per-  
10          formance of services for the Committee.

11          “(2) STAFF.—The Committee may appoint  
12          such personnel as the Committee considers appro-  
13          priate.

14          “(g) OPERATION OF THE COMMITTEE.—

15          “(1) MEETINGS.—The Committee shall meet at  
16          the call of the Chairperson (after consultation with  
17          the other members of the Committee) not less often  
18          than quarterly to consider a specific agenda of  
19          issues, as determined by the Chairperson after such  
20          consultation.

21          “(2) QUORUM.—Ten members of the Com-  
22          mittee shall constitute a quorum for purposes of  
23          conducting business.

1       “(h) FEDERAL ADVISORY COMMITTEE ACT.—Section  
2 14 of the Federal Advisory Committee Act (5 U.S.C.  
3 App.) shall not apply to the Committee.

4       “(i) TRANSFER OF PERSONNEL, RESOURCES, AND  
5 ASSETS.—For purposes of carrying out its duties, the Sec-  
6 retary and the Committee may provide for the transfer  
7 to the Committee of such civil service personnel in the em-  
8 ploy of the Department of Health and Human Services  
9 (including the Centers for Medicare & Medicaid Services),  
10 and such resources and assets of the Department used in  
11 carrying out this title, as the Committee requires.

12       “(j) AUTHORIZATION OF APPROPRIATIONS.—There  
13 are authorized to be appropriated such sums as may be  
14 necessary to carry out the purposes of this section.”.

15       (b) RETENTION OF CERTAIN PROVISIONS.—

16           (1) TITLE I OF MPDIMA.—Except as provided  
17 in paragraph (2), the provisions of title I (other than  
18 sections 105 and 107(c)) of the Medicare Prescrip-  
19 tion Drug, Improvement, and Modernization Act of  
20 2003 (Public Law 108–173) are repealed and the  
21 laws affected by such title shall be in effect as if  
22 such title had not been enacted.

23           (2) PART D PROVISIONS.—The following provi-  
24 sions of part D of title XVIII of the Social Security  
25 Act, as inserted by section 101 of the Medicare Pre-

1       scription Drug, Improvement, and Modernization  
2       Act of 2003 (Public Law 108–173), shall remain in  
3       effect:

4               (A) Section 1860D–31 (relating to medi-  
5       care prescription drug discount card and transi-  
6       tional assistance program).

7               (B) Section 1860D–4(e) (relating to elec-  
8       tronic prescription program).

9       (c) APPLICATION OF GENERAL EXCLUSIONS FROM  
10      COVERAGE.—

11              (1) APPLICATION TO PART D.—Section 1862(a)  
12      (42 U.S.C. 1395y(a)) is amended in the matter pre-  
13      ceding paragraph (1) by striking “part A or part B”  
14      and inserting “part A, B, or D”.

15              (2) PRESCRIPTION DRUGS NOT EXCLUDED  
16      FROM COVERAGE IF APPROPRIATELY PRESCRIBED.—  
17      Section 1862(a)(1) (42 U.S.C. 1395y(a)(1)) is  
18      amended—

19              (A) in subparagraph (H), by striking  
20      “and” at the end;

21              (B) in subparagraph (I), by striking the  
22      semicolon at the end and inserting “, and”; and

23              (C) by adding at the end the following new  
24      subparagraph:

1           “(J) in the case of prescription drugs cov-  
2           ered under part D, which are not prescribed in  
3           accordance with such part;”.

4           (d)           CONFORMING           AMENDMENT.—Section  
5 1171(a)(5)(D) (42 U.S.C. 1320d(a)(5)(D)) is amended by  
6 striking “or (C)” and inserting “(C), or (D)”.

7 **SEC. 102. PROVISION OF MEDICARE OUTPATIENT PRE-**  
8                           **SCRIPTION DRUG COVERAGE UNDER THE**  
9                           **MEDICAREADVANTAGE PROGRAM.**

10          (a) REQUIRING AVAILABILITY OF AN ACTUARIALLY  
11 EQUIVALENT PRESCRIPTION DRUG BENEFIT.—Section  
12 1851 (42 U.S.C. 1395w–21) is amended by adding at the  
13 end the following new subsection:

14          “(j) AVAILABILITY OF PRESCRIPTION DRUG BENE-  
15 FITS.—

16               “(1) IN GENERAL.—Notwithstanding any other  
17 provision of this part, each MA organization that  
18 makes available an MA plan described in section  
19 1851(a)(2)(A) shall make available such a plan that  
20 offers coverage of covered outpatient prescription  
21 drugs that is at least actuarially equivalent to the  
22 benefits provided under part D. Information respect-  
23 ing such benefits shall be made available in the same  
24 manner as information on other benefits provided  
25 under this part is made available. Nothing in this

1 paragraph shall be construed as requiring the offer-  
2 ing of such coverage separate from coverage that in-  
3 cludes benefits under parts A and B.

4 “(2) TREATMENT OF PRESCRIPTION DRUG EN-  
5 ROLLEES.—In the case of an MA eligible individual  
6 who is enrolled under part D, the benefits described  
7 in paragraph (1) shall be treated in the same man-  
8 ner as benefits described in part B for purposes of  
9 coverage and payment and any reference in this part  
10 to the Federal Supplementary Medical Insurance  
11 Trust Fund shall be deemed, with respect to such  
12 benefits, to be a reference to the Federal Medicare  
13 Prescription Drug Trust Fund.”.

14 (b) APPLICATION OF QUALITY STANDARDS.—Section  
15 1852(e)(2)(A) (42 U.S.C. 1395w–22(e)(2)(A)) is amend-  
16 ed—

17 (1) by striking “and” at the end of clause (xi);

18 (2) by striking the period at the end of clause  
19 (xii) and inserting “, and”; and

20 (3) by adding at the end the following new  
21 clause:

22 “(xiii) comply with the standards, and  
23 apply the programs, under section 1860D–  
24 3(b) for covered outpatient prescription  
25 drugs under the plan.”.

1 (c) PAYMENT SEPARATE FROM PAYMENT FOR PART  
2 A AND B BENEFITS.—Section 1853 (42 U.S.C. 1395w-  
3 23) is amended—

4 (1) in subsection (a)(1)(A), by striking “and  
5 (i)” and inserting “(i), and (j)”; and

6 (2) by adding at the end the following new sub-  
7 section:

8 “(j) PAYMENT FOR PRESCRIPTION DRUG COVERAGE  
9 OPTION.—

10 “(1) IN GENERAL.—In the case of an MA plan  
11 that provides prescription drug benefits described in  
12 section 1851(j)(1), the amount of payment otherwise  
13 made to the MA organization offering the plan shall  
14 be increased by the amount described in paragraph  
15 (2). Such payments shall be made in the same man-  
16 ner and time as the amount otherwise paid, but such  
17 amount shall be payable from the Federal Medicare  
18 Prescription Drug Trust Fund.

19 “(2) AMOUNT.—The amount described in this  
20 paragraph is the monthly Government contribution  
21 amount computed under section 1860D-8(c)(2)(B),  
22 but subject to adjustment under paragraph (3).  
23 Such amount shall be uniform geographically and  
24 shall not vary based on the MA payment area in-  
25 volved.

1           “(3) RISK ADJUSTMENT.—The Secretary shall  
2           establish a methodology for the adjustment of the  
3           payment amount under this subsection in a manner  
4           that takes into account the relative risks for use of  
5           outpatient prescription drugs by MA enrollees. Such  
6           methodology shall be designed in a manner so that  
7           the total payments under this title (including part  
8           D) are not changed as a result of the application of  
9           such methodology.”.

10          (d) SEPARATE APPLICATION OF ADJUSTED COMMU-  
11          NITY RATE (ACR).—Section 1854 (42 U.S.C. 1395w–24)  
12          is amended by adding at the end the following:

13           “(i) APPLICATION TO PRESCRIPTION DRUG COV-  
14          ERAGE.—The Secretary shall apply the previous provisions  
15          of this section (as such provisions were in effect before  
16          the date of the enactment of the Medicare Prescription  
17          Drug, Improvement, and Modernization Act of 2003 (Pub-  
18          lic Law 108–173), including the computation of the ad-  
19          justed community rate) separately with respect to pre-  
20          scription drug benefits described in section 1851(j)(1).”.

21          (e) CONFORMING AMENDMENTS.—

22           (1) Section 1851 (42 U.S.C. 1395w–21) is  
23          amended—

1 (A) in subsection (a)(1)(A), by striking  
2 “parts A and B” and inserting “parts A, B,  
3 and D”; and

4 (B) in subsection (i) by inserting “(and, if  
5 applicable, part D)” after “parts A and B”.

6 (2) Section 1852(a)(1)(A) (42 U.S.C. 1395w-  
7 22(a)(1)(A)) is amended by inserting “(and under  
8 part D to individuals also enrolled under such part)”  
9 after “parts A and B”.

10 (3) Section 1852(d)(1) (42 U.S.C. 1395w-  
11 22(d)(1)) is amended—

12 (A) by striking “and” at the end of sub-  
13 paragraph (D);

14 (B) by striking the period at the end of  
15 subparagraph (E) and inserting “; and”; and

16 (C) by adding at the end the following:

17 “(F) the plan for part D benefits guaran-  
18 tees coverage of any specifically named pre-  
19 scription drug for an enrollee to the extent that  
20 it would be required to be covered under part  
21 D.

22 In carrying out subparagraph (F), an MA organiza-  
23 tion has the same authority to enter into contracts  
24 with respect to coverage of preferred drugs as the  
25 Secretary has under part D, but subject to an inde-

1 pendent contractor appeal or other appeal process  
2 that would be applicable to determinations by such  
3 a pharmacy contractor consistent with section  
4 1860D–5(c)(5).”.

5 (f) LIMITATION ON COST-SHARING.—Section  
6 1854(e) (42 U.S.C. 1395w–24(e)) is amended by adding  
7 at the end the following new paragraph:

8 “(5) LIMITATION ON COST-SHARING.—In no  
9 event may a MA organization include a requirement  
10 that an enrollee pay cost-sharing in excess of the  
11 cost-sharing otherwise permitted under part D.”.

12 **SEC. 103. MEDIGAP REVISIONS.**

13 (a) REQUIRED COVERAGE OF COVERED OUTPATIENT  
14 PRESCRIPTION DRUGS.—Section 1882(p)(2)(B) (42  
15 U.S.C. 1395ss(p)(2)(B)) is amended by inserting before  
16 “and” at the end the following: “including a requirement  
17 that an appropriate number of policies provide coverage  
18 of drugs which complements but does not duplicate the  
19 drug benefits that beneficiaries are otherwise eligible for  
20 benefits under part D of this title (with the Secretary and  
21 the National Association of Insurance Commissioners de-  
22 termining the appropriate level of drug benefits that each  
23 benefit package must provide and ensuring that policies  
24 providing such coverage are affordable for beneficiaries;”.

1 (b) EFFECTIVE DATE.—The amendment made by  
2 subsection (a) shall take effect on January 1, 2006.

3 (c) TRANSITION PROVISIONS.—

4 (1) IN GENERAL.—If the Secretary of Health  
5 and Human Services identifies a State as requiring  
6 a change to its statutes or regulations to conform its  
7 regulatory program to the amendments made by this  
8 section, the State regulatory program shall not be  
9 considered to be out of compliance with the require-  
10 ments of section 1882 of the Social Security Act due  
11 solely to failure to make such change until the date  
12 specified in paragraph (4).

13 (2) NAIC STANDARDS.—If, within 9 months  
14 after the date of enactment of this Act, the National  
15 Association of Insurance Commissioners (in this  
16 subsection referred to as the “NAIC”) modifies its  
17 NAIC Model Regulation relating to section 1882 of  
18 the Social Security Act (referred to in such section  
19 as the 1991 NAIC Model Regulation, as subse-  
20 quently modified) to conform to the amendments  
21 made by this section, such revised regulation incor-  
22 porating the modifications shall be considered to be  
23 the applicable NAIC model regulation (including the  
24 revised NAIC model regulation and the 1991 NAIC  
25 Model Regulation) for the purposes of such section.

1           (3) SECRETARY STANDARDS.—If the NAIC  
2 does not make the modifications described in para-  
3 graph (2) within the period specified in such para-  
4 graph, the Secretary of Health and Human Services  
5 shall make the modifications described in such para-  
6 graph and such revised regulation incorporating the  
7 modifications shall be considered to be the appro-  
8 priate regulation for the purposes of such section.

9           (4) DATE SPECIFIED.—

10           (A) IN GENERAL.—Subject to subpara-  
11 graph (B), the date specified in this paragraph  
12 for a State is the earlier of—

13           (i) the date the State changes its stat-  
14 utes or regulations to conform its regu-  
15 latory program to the changes made by  
16 this section; or

17           (ii) 1 year after the date the NAIC or  
18 the Secretary first makes the modifications  
19 under paragraph (2) or (3), respectively.

20           (B) ADDITIONAL LEGISLATIVE ACTION RE-  
21 QUIRED.—In the case of a State which the Sec-  
22 retary identifies as—

23           (i) requiring State legislation (other  
24 than legislation appropriating funds) to

1 conform its regulatory program to the  
2 changes made in this section; but

3 (ii) having a legislature which is not  
4 scheduled to meet in 2006 in a legislative  
5 session in which such legislation may be  
6 considered;

7 the date specified in this paragraph is the first  
8 day of the first calendar quarter beginning after  
9 the close of the first legislative session of the  
10 State legislature that begins on or after Janu-  
11 ary 1, 2006. For purposes of the previous sen-  
12 tence, in the case of a State that has a 2-year  
13 legislative session, each year of such session  
14 shall be deemed to be a separate regular session  
15 of the State legislature.

16 **SEC. 104. ASSISTANCE FOR LOW INCOME BENEFICIARIES.**

17 (a) QMB COVERAGE OF COST-SHARING.—Section  
18 1905(p)(3) (42 U.S.C. 1396d(p)(3)) is amended—

19 (1) in subparagraph (A)—

20 (A) by striking “and” at the end of clause

21 (i),

22 (B) by adding “and” at the end of clause

23 (ii), and

24 (C) by adding at the end the following new

25 clause:

1 “(iii) premiums under section 1860D–5(d).”;

2 and

3 (2) in subparagraph (B), by inserting “(i)”  
4 after “(B)” and by adding at the end the following  
5 new clause:

6 “(ii) A reduction in coinsurance under sub-  
7 paragraphs (B) and (C)(i) of section 1860D–  
8 5(e)(3) to the amounts specified in section  
9 1860D–5(e)(1).”.

10 (b) REDUCTION IN COST SHARING FOR BENE-  
11 FICIARIES WITH INCOME BELOW 185 PERCENT OF THE  
12 POVERTY LEVEL.—Section 1902(a)(10)(E) (42 U.S.C.  
13 1396a(a)(10)(E)) is amended——

14 (1) by striking “and” at the end of clause (iii);

15 (2) by adding “and” at the end of clause (iv);

16 and

17 (3) by adding at the end the following new  
18 clause:

19 “(v)(I) for making medical assistance  
20 available, subject to section 1905(p)(4), for a  
21 reduction in medicare cost-sharing described in  
22 section 1860D–5(e)(1) for individuals (other  
23 than qualified medicare beneficiaries) who are  
24 enrolled under part D of title XVIII and are de-  
25 scribed in section 1905(p)(1)(B) or would be so

1 described but for the fact that their income ex-  
2 ceeds 100 percent, but does not exceed 135 per-  
3 cent, of the official poverty line (referred to in  
4 such section) for a family of the size involved;

5 “(II) for making medical assistance avail-  
6 able, subject to section 1905(p)(4), for a reduc-  
7 tion in medicare cost-sharing described in sec-  
8 tion 1860D–5(e)(2) for individuals (other than  
9 qualified medicare beneficiaries and individuals  
10 described in subclause (I)) who are enrolled  
11 under part D of title XVIII and are described  
12 in section 1905(p)(1)(B) or would be described  
13 under such section but for the fact that their  
14 income exceeds 135 percent, but does not ex-  
15 ceed 185 percent, of the official poverty line  
16 (referred to in such section) for a family of the  
17 size involved; and

18 “(III) for individuals (other than qualified  
19 medicare beneficiaries and individuals described  
20 in subclause (I) or (II)) who are enrolled under  
21 part D of title XVIII and would be described in  
22 section 1905(p)(1)(B) but for the fact that  
23 their income exceeds 200 percent, but does not  
24 exceed 300 percent, of the official poverty line  
25 (referred to in such section) for a family of the

1 size involved, for making medical assistance  
2 available for medicare cost-sharing described in  
3 section 1905(p)(3)(A)(iii);”.

4 (c) FEDERAL FINANCING OF ADDITIONAL LOW IN-  
5 COME ASSISTANCE.—The third sentence of section  
6 1905(b) (42 U.S.C. 1396d(b)) is amended by inserting be-  
7 fore the period at the end the following: “and with respect  
8 to amounts expended that are attributable to the amend-  
9 ments made by subsection (a) or (b) of section 104 of the  
10 Medicare Prescription Drug Affordability Act of 2005”.

11 (d) TREATMENT OF TERRITORIES.—

12 (1) IN GENERAL.—Section 1905(p) (42 U.S.C.  
13 1396d(p)) is amended—

14 (A) by redesignating paragraphs (5) and  
15 (6) as paragraphs (6) and (7), respectively; and

16 (B) by inserting after paragraph (4) the  
17 following new paragraph:

18 “(5)(A) In the case of a State, other than the 50  
19 States and the District of Columbia—

20 “(i) the provisions of paragraph (3) insofar as  
21 they relate to section 1860D–5 and the provisions of  
22 section 1902(a)(10)(E)(v) shall not apply to resi-  
23 dents of such State; and

24 “(ii) if the State establishes a plan described in  
25 subparagraph (B) (for providing medical assistance

1 with respect to the provision of prescription drugs to  
2 medicare beneficiaries), the amount otherwise deter-  
3 mined under section 1108(f) (as increased under  
4 section 1108(g)) for the State shall be increased by  
5 the amount specified in subparagraph (C).

6 “(B) The plan described in this subparagraph is a  
7 plan that—

8 “(i) provides medical assistance with respect to  
9 the provision of covered outpatient drugs (as defined  
10 in section 1860D–5(b)) to low-income medicare  
11 beneficiaries; and

12 “(ii) assures that additional amounts received  
13 by the State that are attributable to the operation  
14 of this paragraph are used only for such assistance.

15 “(C)(i) The amount specified in this subparagraph  
16 for a State for a year is equal to the product of—

17 “(I) the aggregate amount specified in clause  
18 (ii); and

19 “(II) the amount specified in section 1108(g)(1)  
20 for that State, divided by the sum of the amounts  
21 specified in such section for all such States.

22 “(ii) The aggregate amount specified in this clause  
23 for—

24 “(I) 2006, is equal to \$25,000,000; or

1           “(II) a subsequent year, is equal to the aggre-  
2           gate amount specified in this clause for the previous  
3           year increased by annual percentage increase speci-  
4           fied in section 1860D–5(e)(8)(B) for the year in-  
5           volved.

6           “(D) The Secretary shall submit to Congress a report  
7           on the application of this paragraph and may include in  
8           the report such recommendations as the Secretary deems  
9           appropriate.”.

10           (2)    CONFORMING    AMENDMENT.—Section  
11           1108(f) (42 U.S.C. 1308(f)) is amended by inserting  
12           “and section 1905(p)(5)(A)(ii)” after “Subject to  
13           subsection (g)”.

14           (e)    APPLICATION    OF    COST-SHARING.—Section  
15           1902(n)(2) (42 U.S.C. 1396a(n)(2)) is amended by add-  
16           ing at the end the following: “The previous sentence shall  
17           not apply to medicare cost-sharing relating to benefits  
18           under part D of title XVIII.”.

19           (f)    EFFECTIVE DATE.—The amendments made by  
20           this section apply to medical assistance for premiums and  
21           cost-sharing incurred on or after January 1, 2006, with  
22           regard to whether regulations to implement such amend-  
23           ments are promulgated by such date.

1 **SEC. 105. EXPANSION OF MEMBERSHIP AND DUTIES OF**  
2 **MEDICARE PAYMENT ADVISORY COMMISSION**  
3 **(MEDPAC).**

4 (a) EXPANSION OF MEMBERSHIP.—

5 (1) IN GENERAL.—Section 1805(c) (42 U.S.C.  
6 1395b–6(c)) is amended—

7 (A) in paragraph (1), by striking “17” and  
8 inserting “19”; and

9 (B) in paragraph (2)(B), by inserting “ex-  
10 perts in the area of pharmacology and prescrip-  
11 tion drug benefit programs,” after “other  
12 health professionals,”.

13 (2) INITIAL TERMS OF ADDITIONAL MEM-  
14 BERS.—

15 (A) IN GENERAL.—For purposes of stag-  
16 gering the initial terms of members of the  
17 Medicare Payment Advisory Commission under  
18 section 1805(c)(3) of the Social Security Act  
19 (42 U.S.C. 1395b–6(c)(3)), the initial terms of  
20 the 2 additional members of the Commission  
21 provided for by the amendment under para-  
22 graph (1)(A) are as follows:

23 (i) One member shall be appointed for  
24 1 year.

25 (ii) One member shall be appointed  
26 for 2 years.

1 (B) COMMENCEMENT OF TERMS.—Such  
2 terms shall begin on January 1, 2006.

3 (b) EXPANSION OF DUTIES.—Section 1805(b)(2) (42  
4 U.S.C. 1395b–6(b)(2)) is amended by adding at the end  
5 the following new subparagraph:

6 “(D) PRESCRIPTION DRUG BENEFIT PRO-  
7 GRAM.—Specifically, the Commission shall re-  
8 view, with respect to the prescription drug ben-  
9 efit program under part D, the following:

10 “(i) The methodologies used for the  
11 management of costs and utilization of  
12 prescription drugs.

13 “(ii) The prices negotiated and paid,  
14 including trends in such prices and appli-  
15 cable discounts and comparisons with  
16 prices under section 1860D–6(a)(2)(E).

17 “(iii) The relationship of pharmacy  
18 acquisition costs to the prices so negotiated  
19 and paid.

20 “(iv) The methodologies used to en-  
21 sure access to covered outpatient prescrip-  
22 tion drugs and to ensure quality in the ap-  
23 propriate dispensing and utilization of such  
24 drugs.

1                   “(v) The impact of the program on  
2                   promoting the development of break-  
3                   through drugs.”.

4                   **TITLE II—AFFORDABLE**  
5                   **PHARMACEUTICALS**  
6                   **Subtitle A—Importation of**  
7                   **Prescription Drugs**

8   **SEC. 201. SHORT TITLE.**

9                   This subtitle may be cited as the “Pharmaceutical  
10                  Market Access Act of 2005”.

11   **SEC. 202. FINDINGS.**

12                  The Congress finds as follows:

13                   (1) Americans unjustly pay up to 1000 percent  
14                   more to fill their prescriptions than consumers in  
15                   other countries.

16                   (2) The United States is the world’s largest  
17                   market for pharmaceuticals yet consumers still pay  
18                   the world’s highest prices.

19                   (3) An unaffordable drug is neither safe nor ef-  
20                   fective. Allowing and structuring the importation of  
21                   prescription drugs ensures access to affordable  
22                   drugs, thus providing a level of safety to American  
23                   consumers they do not currently enjoy.

1           (4) According to the Congressional Budget Of-  
2           fice, American seniors alone will spend \$1.8 trillion  
3           dollars on pharmaceuticals over the next ten years.

4           (5) Allowing open pharmaceutical markets  
5           could save American consumers at least \$635 billion  
6           of their own money each year.

7 **SEC. 203. PURPOSES.**

8           The purposes of this subtitle are as follows:

9           (1) RELIEF FROM HIGH DRUG COSTS.—To give  
10          all Americans immediate relief from the outrageously  
11          high cost of pharmaceuticals.

12          (2) CORRECT ECONOMICS OF DRUG MARKET.—  
13          To reverse the perverse economics of the American  
14          pharmaceutical markets.

15          (3) LIMITING IMPORTATION OF DRUGS TO  
16          THOSE ONLY APPROVED BY THE FDA.—To allow the  
17          importation of drugs only if the drugs and the facili-  
18          ties where they are manufactured are approved by  
19          the Food and Drug Administration, and to exclude  
20          pharmaceutical narcotics.

21          (4) USE OF COUNTERFEIT-RESISTANT PACK-  
22          AGING.—To require that imported prescription drugs  
23          be packaged and shipped using counterfeit-resistant  
24          technologies approved by the Bureau of Engraving

1 and Printing (technologies similar to those used to  
2 secure United States currency).

3 **SEC. 204. IMPORTATION OF PRESCRIPTION DRUGS.**

4 (a) RESTORATION OF FORMER TEXT.—The Federal  
5 Food, Drug, and Cosmetic Act is amended—

6 (1) in section 804 (21 U.S.C. 384), by amend-  
7 ing the section to read as if section 1121(a) of the  
8 Medicare Prescription Drug, Improvement, and  
9 Modernization Act of 2003 (Public Law 108–173)  
10 had not been enacted;

11 (2) in section 301 (21 U.S.C. 331), by amend-  
12 ing the section to read as if section 1121(b)(1) of  
13 such Act had not been enacted; and

14 (3) in section 303 (21 U.S.C. 333), by amend-  
15 ing the section to read as if section 1121(b)(2) of  
16 such Act had not been enacted.

17 (b) IMPORTATION OF PRESCRIPTION DRUGS.—Sec-  
18 tion 804 of the Federal Food, Drug, and Cosmetic Act,  
19 as amended by subsection (a), is amended—

20 (1) in subsection (a)—

21 (A) by striking “The Secretary” and in-  
22 sserting “Not later than 180 days after the date  
23 of the enactment of the Pharmaceutical Market  
24 Access Act of 2005, the Secretary”; and

1           (B) by striking “pharmacists and whole-  
2           salers” and inserting “pharmacists, wholesalers,  
3           and qualifying individuals”;

4           (2) in subsection (b)—

5           (A) by amending paragraph (1) to read as  
6           follows:

7           “(1) require that each covered product imported  
8           pursuant to such subsection complies with sections  
9           501, 502, and 505, and other applicable require-  
10          ments of this Act; and”;

11          (B) in paragraph (2), by striking “, includ-  
12          ing subsection (d); and” and inserting a period;  
13          and

14          (C) by striking paragraph (3);

15          (3) in subsection (c), by inserting “by phar-  
16          macists and wholesalers (but not qualifying individ-  
17          uals)” after “importation of covered products”;

18          (4) in subsection (d)—

19          (A) by striking paragraphs (3) and (10);

20          (B) in paragraph (5), by striking “, includ-  
21          ing the professional license number of the im-  
22          porter, if any”;

23          (C) in paragraph (6)—

1 (i) in subparagraph (C), by inserting  
2 “(if required under subsection (e))” before  
3 the period;

4 (ii) in subparagraph (D), by inserting  
5 “(if required under subsection (e))” before  
6 the period; and

7 (iii) in subparagraph (E), by striking  
8 “labeling”;  
9 (D) in paragraph (7)—

10 (i) in subparagraph (A), by inserting  
11 “(if required under subsection (e))” before  
12 the period; and

13 (ii) by amending subparagraph (B) to  
14 read as follows:

15 “(B) Certification from the importer or  
16 manufacturer of such product that the product  
17 meets all requirements of this Act.”; and

18 (E) by redesignating paragraphs (4)  
19 through (9) as paragraphs (3) through (8), re-  
20 spectively;

21 (5) by amending subsection (e) to read as fol-  
22 lows:

23 “(e) TESTING.—

24 “(1) IN GENERAL.—Subject to paragraph (2),  
25 regulations under subsection (a) shall require that

1 testing referred to in paragraphs (5) through (7) of  
2 subsection (d) be conducted by the importer of the  
3 covered product, unless the covered product is a pre-  
4 scription drug subject to the requirements of section  
5 505C for counterfeit-resistant technologies.

6 “(2) EXCEPTION.—The testing requirements of  
7 paragraphs (5) through (7) of subsection (d) shall  
8 not apply to an importer unless the importer is a  
9 wholesaler.”;

10 (6) in subsection (f), by striking “or designated  
11 by the Secretary, subject to such limitations as the  
12 Secretary determines to be appropriate to protect  
13 the public health”;

14 (7) in subsection (g)—

15 (A) by striking “counterfeit or”; and

16 (B) by striking “and the Secretary deter-  
17 mines that the public is adequately protected  
18 from counterfeit and violative covered products  
19 being imported pursuant to subsection (a)”;

20 (8) in subsection (i)(1)—

21 (A) by amending subparagraph (A) to read  
22 as follows:

23 “(A) IN GENERAL.—The Secretary shall  
24 conduct, or contract with an entity to conduct,  
25 a study on the imports permitted pursuant to

1 subsection (a), including consideration of the  
2 information received under subsection (d). In  
3 conducting such study, the Secretary or entity  
4 shall evaluate the compliance of importers with  
5 regulations under subsection (a), and the inci-  
6 dence of shipments pursuant to such sub-  
7 section, if any, that have been determined to be  
8 misbranded or adulterated, and determine how  
9 such compliance contrasts with the incidence of  
10 shipments of prescription drugs transported  
11 within the United States that have been deter-  
12 mined to be misbranded or adulterated.”; and

13 (B) in subparagraph (B), by striking “Not  
14 later than 2 years after the effective date of  
15 final regulations under subsection (a),” and in-  
16 serting “Not later than 18 months after the  
17 date of the enactment of the Pharmaceutical  
18 Market Access Act of 2005,”;

19 (9) in subsection (k)(2)—

20 (A) by redesignating subparagraphs (D)  
21 and (E) as subparagraphs (E) and (F), respec-  
22 tively; and

23 (B) by inserting after subparagraph (C)  
24 the following:

1           “(D) The term ‘qualifying individual’  
2           means an individual who is not a pharmacist or  
3           a wholesaler.”; and  
4           (10) by striking subsections (l) and (m).

5 **SEC. 205. USE OF COUNTERFEIT-RESISTANT TECH-**  
6 **NOLOGIES TO PREVENT COUNTERFEITING.**

7           (a) MISBRANDING.—Section 502 of the Federal  
8 Food, Drug, and Cosmetic Act (21 U.S.C. 352; deeming  
9 drugs and devices to be misbranded) is amended by adding  
10 at the end the following:

11           “(x) If it is a drug subject to section 503(b), unless  
12 the packaging of such drug complies with the require-  
13 ments of section 505C for counterfeit-resistant tech-  
14 nologies.”.

15           (b) REQUIREMENTS.—Title V of the Federal Food,  
16 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-  
17 ed by inserting after section 505B the following:

18 **“SEC. 505C. COUNTERFEIT-RESISTANT TECHNOLOGIES.**

19           “(a) INCORPORATION OF COUNTERFEIT-RESISTANT  
20 TECHNOLOGIES INTO PRESCRIPTION DRUG PACK-  
21 AGING.—The Secretary shall require that the packaging  
22 of any drug subject to section 503(b) incorporate—

23           “(1) overt optically variable counterfeit-resist-  
24 ant technologies that are described in subsection (b)  
25 and comply with the standards of subsection (c); or

1           “(2) technologies that have an equivalent func-  
2           tion of security, as determined by the Secretary.

3           “(b) ELIGIBLE TECHNOLOGIES.—Technologies de-  
4           scribed in this subsection—

5           “(1) shall be visible to the naked eye, providing  
6           for visual identification of product authenticity with-  
7           out the need for readers, microscopes, lighting de-  
8           vices, or scanners;

9           “(2) shall be similar to that used by the Bureau  
10          of Engraving and Printing to secure United States  
11          currency;

12          “(3) shall be manufactured and distributed in a  
13          highly secure, tightly controlled environment; and

14          “(4) should incorporate additional layers of  
15          non-visible covert security features up to and includ-  
16          ing forensic capability.

17          “(c) STANDARDS FOR PACKAGING.—

18          “(1) MULTIPLE ELEMENTS.—For the purpose  
19          of making it more difficult to counterfeit the pack-  
20          aging of drugs subject to section 503(b), manufac-  
21          turers of the drugs shall incorporate the technologies  
22          described in subsection (b) into multiple elements of  
23          the physical packaging of the drugs, including blister  
24          packs, shrink wrap, package labels, package seals,  
25          bottles, and boxes.

1           “(2) LABELING OF SHIPPING CONTAINER.—  
2           Shipments of drugs described in subsection (a) shall  
3           include a label on the shipping container that incor-  
4           porates the technologies described in subsection (b),  
5           so that officials inspecting the packages will be able  
6           to determine the authenticity of the shipment. Chain  
7           of custody procedures shall apply to such labels and  
8           shall include procedures applicable to contractual  
9           agreements for the use and distribution of the labels,  
10          methods to audit the use of the labels, and database  
11          access for the relevant governmental agencies for  
12          audit or verification of the use and distribution of  
13          the labels.”.

14       **Subtitle B—Quality Control and**  
15       **Cost Containment Blue Ribbon**  
16       **Task Force**

17       **SEC. 211. TASK FORCE.**

18           (a) ESTABLISHMENT.—There is established a perma-  
19          nent bipartisan advisory committee (appointed by the con-  
20          gressional officials specified in subsection (c)), to be  
21          known as the Quality Control and Cost Containment Blue  
22          Ribbon Task Force (in this section referred to as the  
23          “Task Force”).

24           (b) DUTIES.—The duties of the Task Force shall be  
25          the following:

1 (1) To study the following:

2 (A) The most cost-effective ways to reduce  
3 the costs of prescription drug costs without  
4 compromising quality.

5 (B) The use of generic drugs and imported  
6 drugs to reduce the costs of prescription drugs  
7 under the medicare program.

8 (C) The effect of patents and other intel-  
9 lectual property rights on the costs of prescrip-  
10 tion drugs, including all possible options to re-  
11 duce such costs through more innovative and  
12 flexible patent laws.

13 (D) The impact of both government and  
14 private research and development on the costs  
15 of prescription drugs, including all possible op-  
16 tions to reduce such costs through more innova-  
17 tive and flexible ways to research and develop  
18 new prescription drugs.

19 (2) To provide testimony to the Congress on  
20 ways to contain prescription drug costs without com-  
21 promising quality.

22 (3) To submit an annual report under sub-  
23 section (f).

24 (c) MEMBERSHIP.—

1           (1) APPOINTMENT.—The Task Force shall be  
2 composed of 20 members, as follows:

3           (A) 5 members, appointed by the Chair-  
4 man of the Committee on Energy and Com-  
5 merce of the House of Representatives.

6           (B) 5 members, appointed by the ranking  
7 member of the Committee on Energy and Com-  
8 merce of the House of Representatives.

9           (C) 5 members, appointed by the Chair-  
10 man of the Committee on Commerce, Science,  
11 and Transportation of the Senate.

12           (D) 5 members, appointed by the ranking  
13 member of the Committee on Commerce,  
14 Science, and Transportation of the Senate.

15           (2) QUALIFICATIONS.—The members of the  
16 Task Force shall be appointed from among aca-  
17 demics, economists, physicians, representatives of  
18 nongovernmental organizations, and scientists, who  
19 are experts in the fields of business, economics, med-  
20 icine, and patent law.

21           (3) TERM.—Each member of the Task Force  
22 shall be appointed for a term of not more than 3  
23 years and may be reappointed for 1 or more addi-  
24 tional terms.

1           (4) VACANCIES.—Any member appointed to fill  
2 a vacancy occurring before the expiration of the  
3 term for which the member's predecessor was ap-  
4 pointed shall be appointed only for the remainder of  
5 that term. A member may serve after the expiration  
6 of that member's term until a successor has taken  
7 office. A vacancy in the Task Force shall be filled  
8 in the manner in which the original appointment was  
9 made.

10           (5) BASIC PAY; TRAVEL EXPENSES.—Members  
11 of the Task Force shall serve without pay, except  
12 that each member shall receive travel expenses, in-  
13 cluding per diem in lieu of subsistence, in accord-  
14 ance with applicable provisions under subchapter I  
15 of chapter 57 of title 5, United States Code.

16 (d) STAFF OF TASK FORCE.—

17           (1) APPOINTMENT.—The Task Force may ap-  
18 point and fix the pay of not more than 5 staff mem-  
19 bers.

20           (2) APPLICABILITY OF CERTAIN CIVIL SERVICE  
21 LAWS.—The staff of the Task Force may be ap-  
22 pointed without regard to the provisions of title 5,  
23 United States Code, governing appointments in the  
24 competitive service, and may be paid (to the extent  
25 and in the amounts provided in advance in appro-

1        priation Acts) without regard to the provisions of  
2        chapter 51 and subchapter III of chapter 53 of that  
3        title relating to classification and General Schedule  
4        pay rates.

5        (e) HEARINGS AND SESSIONS.—The Task Force  
6        may, for the purpose of carrying out this section, hold  
7        hearings, sit and act at times and places, take testimony,  
8        and receive evidence as the Task Force considers appro-  
9        priate.

10       (f) REPORTS.—

11            (1) IN GENERAL.—The Task Force shall pro-  
12        vide an annual report to the President, the Con-  
13        gress, and the Centers for Medicare & Medicaid  
14        Services on the results of the studies conducted by  
15        the Task Force under subsection (b).

16            (2) DISSENTING OPINIONS.—The Task Force  
17        shall give each Member of the Task Force an oppor-  
18        tunity to include a dissenting opinion in each annual  
19        report under this subsection.

20        (g) AUTHORIZATION OF APPROPRIATIONS.—To carry  
21        out this section, there are authorized to be appropriated  
22        \$400,000 for fiscal year 2006 and each subsequent fiscal  
23        year.

1                   **TITLE III—DEFENSE OF**  
2                   **MEDICARE**

3 **SEC. 301. ELIMINATION OF PRIVATIZATION OF MEDICARE.**

4           (a) REPEAL OF COMPARATIVE COST ADJUSTMENT  
5 (CCA) PROGRAM.—Subtitle E of title II of the Medicare  
6 Prescription Drug, Improvement, and Modernization Act  
7 of 2003, and the amendments made by such subtitle, are  
8 repealed.

9           (b) PROHIBITION OF PRIVATIZATION.—No provision  
10 of law, including the new prescription drug program under  
11 part D of title XVIII of the Social Security Act, shall be  
12 applied in a manner that prevents a medicare beneficiary  
13 from continuing to obtain benefits under a traditional fee-  
14 for-service medicare program.

15 **SEC. 302. REPEAL OF MA REGIONAL PLAN STABILIZATION**  
16                   **FUND.**

17           (a) IN GENERAL.—Section 1858 of the Social Secu-  
18 rity Act, as added by section 221(c) of the Medicare Pre-  
19 scription Drug, Improvement, and Modernization Act of  
20 2003, is amended—

21                   (1) by striking subsection (e);

22                   (2) by redesignating subsections (f), (g), and  
23 (h) as subsections (e), (f), and (g), respectively; and

24                   (3) in subsection (e), as so redesignated, by  
25 striking “subject to subsection (e),”.

1 (b) CONFORMING AMENDMENT.—Section 1851(i)(2)  
2 of the Social Security Act (42 U.S.C. 1395w–21(i)(2)), as  
3 amended by section 221(d)(5) of the Medicare Prescrip-  
4 tion Drug, Improvement, and Modernization Act of 2003,  
5 is amended by striking “1858(h)” and inserting  
6 “1858(g)”.

7 **SEC. 303. REPEAL OF HEALTH SAVINGS ACCOUNTS.**

8 Section 1201 of the Medicare Prescription Drug, Im-  
9 provement, and Modernization Act of 2003, and the  
10 amendments made by such section, are repealed.

11 **SEC. 304. APPLICATION OF RISK ADJUSTMENT REFLECT-**  
12 **ING CHARACTERISTICS FOR THE ENTIRE**  
13 **MEDICARE POPULATION.**

14 Effective January 1, 2006, in applying risk adjust-  
15 ment factors to payment to organizations under section  
16 1853 of the Social Security Act (42 U.S.C. 1395w–23)  
17 in a budget neutral manner, the Secretary of Health and  
18 Human Services shall assure that such factors, in the ag-  
19 gregate, take into account the actuarial characteristics of  
20 the entire medicare population, and not merely the popu-  
21 lation of individuals enrolled under a plan under part C  
22 of title XVIII of such Act.

1 **SEC. 305. PHASE-IN TO PAYMENT AT 100 PERCENT OF FEE-**  
2 **FOR-SERVICE RATE.**

3 Notwithstanding any other provision of law, the Sec-  
4 retary of Health and Human Services shall provide, in a  
5 phased-in manner over a 5-year period beginning with  
6 2006, for adjustment of payment rates to organizations  
7 under section 1853 of the Social Security Act so that, at  
8 the end of such phase-in period, such payment rates reflect  
9 only the payment rate described in subsection (c)(1)(D)  
10 of such section (relating to 100 percent fee-for-service pay-  
11 ment).

12 **SEC. 306. REPEAL OF MEDICARE EXPENDITURE CAP.**

13 Subtitle A of title VIII of the Medicare Prescription  
14 Drug, Improvement, and Modernization Act of 2003 is re-  
15 pealed.

16 **SEC. 307. CONTINUOUS OPEN ENROLLMENT IN**  
17 **MEDICAREADVANTAGE PLANS.**

18 Section 1851(e)(2) of the Social Security Act (42  
19 U.S.C. 1395w-21(e)(2)) is amended to read as follows:

20 “(2) OPEN ENROLLMENT AND DISENROLLMENT  
21 OPPORTUNITIES.—Subject to paragraph (5), an MA  
22 eligible individual may change the election under  
23 subsection (a)(1) at any time and without any pen-  
24 alty or charge.”.

1 **SEC. 308. EFFECTIVE DATE.**

2 (a) IN GENERAL.—The amendments made by this  
3 title shall take effect as if included in the enactment of  
4 the Medicare Prescription Drug, Improvement, and Mod-  
5 ernization Act of 2003.

6 (b) APPLICATION OF LAWS.—If any amendment to  
7 any provision of any Act is repealed by this title, such pro-  
8 vision shall be restored, applied, and administered as if  
9 the amendment had never been enacted.

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