

108TH CONGRESS
1ST SESSION

H. R. 3332

To amend title XVIII of the Social Security Act to establish a safety net Medicare outpatient prescription drug program for indigent beneficiaries without other outpatient prescription drug coverage.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 17, 2003

Mr. BURTON of Indiana 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

A BILL

To amend title XVIII of the Social Security Act to establish a safety net Medicare outpatient prescription drug program for indigent beneficiaries without other outpatient prescription drug coverage.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Medicare Safety Net Prescription Drug Coverage Act of
6 2003”.

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

Sec. 1. Short title; table of contents.

Sec. 2. Safety net medicare outpatient prescription drug program for indigent,
 uncovered beneficiaries.

“PART D—SAFETY NET MEDICARE OUTPATIENT PRESCRIPTION DRUG
 PROGRAM FOR INDIGENT, UNCOVERED BENEFICIARIES

“Sec. 1860D–1. Establishment of program.

“Sec. 1860D–2. Enrollment.

“Sec. 1860D–3. Enrollee protections.

“Sec. 1860D–4. Benefits under the program.

“Sec. 1860D–5. Prescription drug accounts.

“Sec. 1860D–6. Safety Net Prescription Drug Account in the Federal
 Supplementary Medical Insurance Trust Fund.

“Sec. 1860D–7. Definitions.

Sec. 3. Exclusion of part D costs from determination of part B monthly pre-
 mium.

Sec. 4. Medicaid amendments.

Sec. 5. Importation of prescription drugs.

3 **SEC. 2. SAFETY NET MEDICARE OUTPATIENT PRESCRIP-**
 4 **TION DRUG PROGRAM FOR INDIGENT, UN-**
 5 **COVERED BENEFICIARIES.**

6 (a) ESTABLISHMENT OF PROGRAM.—Title XVIII of
 7 the Social Security Act (42 U.S.C. 1395 et seq.) is amend-
 8 ed by redesignating part D as part E and by inserting
 9 after part C the following new part:

10 “PART D—SAFETY NET MEDICARE OUTPATIENT PRE-
 11 SCRIPTON DRUG PROGRAM FOR INDIGENT, UNCOV-
 12 ERED BENEFICIARIES

13 “ESTABLISHMENT OF PROGRAM

14 “SEC. 1860D–1. (a) PROVISION OF BENEFIT.—The
 15 Secretary shall establish a Medicare Safety Net Out-
 16 patient Prescription Drug Program under this part under

1 which an eligible beneficiary who voluntarily enrolls under
2 this part is provided—

3 “(1) access to negotiated prices for costs before
4 catastrophic threshold;

5 “(2) catastrophic coverage under this part; and

6 “(3) a prescription drug account and a public
7 contribution into such an account.

8 “(b) ELIGIBLE BENEFICIARY; ELIGIBLE ENTITY;
9 PRESCRIPTION DRUG ACCOUNT.—For purposes of this
10 part:

11 “(1) ELIGIBLE BENEFICIARY.—The term ‘eli-
12 ble beneficiary’ means an individual who—

13 “(A) is eligible for benefits under part A or
14 enrolled under part B, regardless of whether or
15 not the individual is enrolled with a plan under
16 part C;

17 “(B) does not have, and is not eligible for,
18 any prescription drug coverage under title XIX,
19 under a group health plan, under part C, under
20 individual health insurance coverage, under a
21 medicare supplemental policy, under a State
22 pharmaceutical assistance program, or under
23 chapter 17 of title 38, United States Code (re-
24 lating to Veterans benefits); and

1 “(C) has current income (as defined and
2 determined by the Secretary) to be less than
3 250 percent of the official poverty line.

4 “(2) PRESCRIPTION DRUG ACCOUNT.—The
5 term ‘prescription drug account’ means, with respect
6 to an eligible beneficiary, an account established for
7 the benefit of that beneficiary under section 1860D–
8 5.

9 “(c) IMPLEMENTATION OF PROGRAM.—

10 “(1) DEADLINE FOR IMPLEMENTATION.—The
11 Secretary shall establish the program under this
12 part in a manner so that benefits with respect to
13 contributions to a prescription drug account and cat-
14 astrophic coverage shall begin with the month of
15 January 2005.

16 “(2) ADMINISTRATION THROUGH NEW DIVISION
17 WITHIN HHS.—The Secretary shall provide for es-
18 tablishment of a separate division within the Depart-
19 ment of Health and Human Services that shall be
20 responsible for the administration of this part.

21 “(d) VOLUNTARY NATURE OF PROGRAM.—Nothing
22 in this part shall be construed as requiring an eligible ben-
23 eficiary to enroll in the program under this part.

24 “(e) FINANCING.—The costs of providing benefits
25 under this part shall be payable from the Safety Net Pre-

1 scription Drug Account established within the Federal
 2 Supplementary Medical Insurance Trust Fund under sec-
 3 tion 1860D-6.

4 “ENROLLMENT; SELECTION OF ELIGIBLE ENTITY

5 “SEC. 1860D-2. (a) ENROLLMENT UNDER PART
 6 D.—

7 “(1) ESTABLISHMENT OF PROCESS.—

8 “(A) IN GENERAL.—The Secretary shall
 9 establish a process through which an eligible
 10 beneficiary may make an election to enroll
 11 under this part. Under such process—

12 “(i) a beneficiary may enroll at any
 13 time during a year (or during an initial en-
 14 rollment period beginning on October 1,
 15 2004, for 2005);

16 “(ii) once first enrolled with respect to
 17 a year, a beneficiary is eligible for benefits
 18 for the remainder of the year; and

19 “(iii) for succeeding years, a bene-
 20 ficiary must recertify eligibility on an an-
 21 nual basis (as specified by the Secretary)
 22 to remain eligible for benefits under this
 23 part.

24 “(B) REQUIREMENT OF ENROLLMENT.—

25 An eligible beneficiary must be enrolled under

1 this part for a year in order to be eligible to re-
2 ceive the benefits under this part for that year.

3 “(C) TERMINATION OF ENROLLMENT.—An
4 enrollee under this part shall be disenrolled—

5 “(i) upon termination of coverage
6 under part A or part B;

7 “(ii) upon notice submitted to the
8 Secretary in such form, manner, and time
9 as the Secretary shall provide; and

10 “(iii) upon failure to have eligibility
11 recertified in accordance with subpara-
12 graph (A)(iii).

13 Terminations of enrollment under this subpara-
14 graph shall be effective as specified by the Sec-
15 retary in regulations.

16 “(2) PERIOD OF COVERAGE.—Individuals en-
17 rolled under this part after the beginning of a year,
18 are eligible for benefits beginning on the first day of
19 the month following the month in which such enroll-
20 ment occurs.

21 “(b) PROVIDING ENROLLMENT AND COVERAGE IN-
22 FORMATION TO BENEFICIARIES.—The Secretary shall
23 provide for activities under this part to broadly dissemi-
24 nate information to eligible beneficiaries (and prospective
25 eligible beneficiaries) regarding enrollment under this part

1 and the prescription drug coverage made available under
2 this part.

3 “(c) NO ENROLLMENT FEE.—There shall be no fee
4 for enrollment under this part.

5 “(d) ISSUANCE OF CARD AND COORDINATION.—The
6 Secretary shall—

7 “(1) issue to each enrolled beneficiary a card
8 and an enrollment number that establishes proof of
9 enrollment and that can be used in a coordinated
10 manner—

11 “(A) to identify the beneficiary for pur-
12 poses of this part, including tracking expendi-
13 tures that count against the catastrophic cov-
14 erage threshold; and

15 “(B) to make deposits to and withdrawals
16 from a prescription drug account under section
17 1860D–5; and

18 “(2) provide for electronic methods to coordi-
19 nate with such prescription drug accounts.

20 “ENROLLEE PROTECTIONS

21 “SEC. 1860D–3. (a) DISSEMINATION OF INFORMA-
22 TION.—

23 “(1) GENERAL INFORMATION.—The Secretary
24 shall disclose, in a clear, accurate, and standardized
25 manner to eligible beneficiaries enrolled under this

1 part, information relating to prescription drug cov-
2 erage under this part.

3 “(2) DISCLOSURE UPON REQUEST OF GENERAL
4 COVERAGE, UTILIZATION, AND GRIEVANCE INFORMA-
5 TION.—Upon request of an eligible beneficiary, the
6 Secretary shall provide the information described in
7 section 1852(c)(2) (other than subparagraph (D)) to
8 such beneficiary.

9 “(3) RESPONSE TO BENEFICIARY QUESTIONS.—
10 The Secretary shall have a mechanism (including a
11 toll-free telephone number) for providing upon re-
12 quest specific information (such as negotiated prices,
13 including discounts) to beneficiaries enrolled under
14 this part.

15 “(4) COORDINATION WITH CATASTROPHIC COV-
16 ERAGE AND PRESCRIPTION DRUG ACCOUNT BENE-
17 FITS.—The Secretary shall provide for coordination
18 of such information as the Secretary may specify to
19 carry out sections 1860D–4(b) and 1860D–5.

20 “(b) ACCESS TO COVERED BENEFITS.—

21 “(1) ENSURING PHARMACY ACCESS.—

22 “(A) PARTICIPATION OF ANY WILLING
23 PHARMACY.—The Secretary shall permit the
24 participation of any pharmacy that meets terms

1 and conditions that the Secretary has estab-
2 lished.

3 “(B) NEGOTIATION OF PRICES.—The Sec-
4 retary may negotiate with different vendors dif-
5 ferent prices to be paid for outpatient prescrip-
6 tion drugs.

7 “(2) ACCESS TO NEGOTIATED PRICES FOR PRE-
8 SCRIPTION DRUGS.—For requirements relating to
9 the access of an eligible beneficiary to negotiated
10 prices (including applicable discounts), see section
11 1860D–4(a).

12 “(c) COST AND UTILIZATION MANAGEMENT; QUAL-
13 ITY ASSURANCE; MEDICATION THERAPY MANAGEMENT
14 PROGRAM.—

15 “(1) IN GENERAL.—For purposes of providing
16 access to negotiated benefits under section 1860D–
17 4(a) and the catastrophic benefit described in sec-
18 tion 1860D–4(b), the Secretary may establish—

19 “(A) an effective cost and drug utilization
20 management program, including appropriate in-
21 centives to use generic drugs, when appropriate;

22 “(B) quality assurance measures and sys-
23 tems to reduce medical errors and adverse drug
24 interactions, including a medication therapy

1 management program described in paragraph
2 (2); and

3 “(C) a program to control fraud, abuse,
4 and waste.

5 “(2) MEDICATION THERAPY MANAGEMENT PRO-
6 GRAM.—

7 “(A) IN GENERAL.—A medication therapy
8 management program described in this para-
9 graph is a program of drug therapy manage-
10 ment and medication administration that may
11 be furnished by a pharmacy provider and that
12 is designed to assure, with respect to bene-
13 ficiaries at risk for potential medication prob-
14 lems, such as beneficiaries with complex or
15 chronic diseases (such as diabetes, asthma, hy-
16 pertension, and congestive heart failure) or
17 multiple prescriptions, that covered outpatient
18 drugs are appropriately used to optimize thera-
19 peutic outcomes through improved medication
20 use and reduce the risk of adverse events, in-
21 cluding adverse drug interactions. Such pro-
22 grams may distinguish between services in am-
23 bulatory and institutional settings.

24 “(B) ELEMENTS.—Such program may in-
25 clude—

1 “(i) enhanced beneficiary under-
2 standing to promote the appropriate use of
3 medications by beneficiaries and to reduce
4 the risk of potential adverse events associ-
5 ated with medications, through beneficiary
6 education, counseling, case management,
7 disease state management programs, and
8 other appropriate means;

9 “(ii) increased beneficiary adherence
10 with prescription medication regimens
11 through medication refill reminders, special
12 packaging, and other compliance programs
13 and other appropriate means; and

14 “(iii) detection of patterns of overuse
15 and underuse of prescription drugs.

16 “(C) DEVELOPMENT OF PROGRAM IN CO-
17 OPERATION WITH LICENSED PHARMACISTS.—
18 The program shall be developed in cooperation
19 with licensed and practicing pharmacists and
20 physicians.

21 “(D) CONSIDERATIONS IN PHARMACY
22 FEES.—The Secretary may take into account,
23 in establishing fees for pharmacists and others
24 providing services under the medication therapy

1 management program, the resources and time
2 used in implementing the program.

3 “(d) GRIEVANCE MECHANISM, COVERAGE DETER-
4 MINATIONS, AND RECONSIDERATIONS.—Subsections (f)
5 and (g) of section 1852 shall apply with respect to benefits
6 for drugs through the Secretary under this part in the
7 same manner as such requirements apply to an organiza-
8 tion with respect to benefits it offers under a plan under
9 part C.

10 “BENEFITS UNDER THE PROGRAM

11 “SEC. 1860D–4. (a) SAVINGS TO ENROLLEES
12 THROUGH NEGOTIATED PRICES.—

13 “(1) ACCESS TO NEGOTIATED PRICES.—

14 “(A) IN GENERAL.—Subject to paragraph
15 (2), the Secretary shall provide each eligible
16 beneficiary enrolled under this part with access
17 to negotiated prices (including applicable dis-
18 counts) for prescription drugs.

19 “(B) SCOPE OF ACCESS.—For purposes of
20 this paragraph, the term ‘prescription drugs’ is
21 not limited to covered outpatient drugs, but
22 does not include any over-the-counter drug that
23 is not a covered outpatient drug.

24 “(C) EXEMPTION FROM COMPUTATION OF
25 BEST PRICE UNDER MEDICAID PROGRAM.—The
26 prices negotiated by the Secretary under this

paragraph shall (notwithstanding any other provision of law) not be taken into account for the purposes of establishing the best price under section 1927(c)(1)(C).

“(2) PROHIBITION ON CHARGES FOR REQUIRED SERVICES.—The Secretary (and any pharmacy contracting with the Secretary for the provision of a discount under this part) may not charge a beneficiary any amount for any services required to be provided under this part.

“(b) CATASTROPHIC COVERAGE.—

“(1) SCOPE OF COVERAGE.—

“(A) SCOPE.—

“(i) IN GENERAL.—Subject to paragraph (4), the catastrophic coverage under this section shall consist of payment under this part for incurred expenses for covered outpatient drugs for an enrollee after the enrollee has incurred in a year expenses that equal the catastrophic coverage threshold specified in subparagraph (C) or (D) for the enrollee and year involved.

“(ii) PAYMENT RATE.—The rate of payment negotiated by the Secretary with the manufacturer for a covered outpatient

1 drug shall be the amount paid under this
2 part on behalf of the individual for the
3 drug.

4 “(B) APPLICATION.—In applying subpara-
5 graph (A)—

6 “(i) incurred expenses shall only in-
7 clude costs incurred for the catastrophic
8 coverage threshold; and

9 “(ii) expenses that are not paid di-
10 rectly from a prescription drug account
11 shall be counted under clause (i) only if,
12 under such process as the Secretary shall
13 recognize, the account number of the indi-
14 vidual’s prescription drug account is part
15 of the transaction involved.

16 “(C) CATASTROPHIC COVERAGE THRESH-
17 OLDS.—

18 “(i) INITIAL CATASTROPHIC COV-
19 ERAGE THRESHOLD.—Subject to clause (ii)
20 and subsection (e)(3), the catastrophic cov-
21 erage threshold is \$3,000.

22 “(ii) INFLATION ADJUSTMENT.—The
23 provisions of subsection (c)(2)(B) shall
24 apply with respect to the catastrophic cov-
25 erage threshold under clause (i) for a year

1 after 2004 in the same manner as it ap-
2 plied to the annual Federal contribution
3 amount for that year, except that, for pur-
4 poses of this subparagraph, any reference
5 in subsection (c)(2)(B)(ii) to ‘\$1’ is
6 deemed a reference to ‘\$100’.

7 “(2) ADMINISTRATION.—Insofar as the Sec-
8 retary does not provide for the catastrophic coverage
9 under this subsection through a contract with a
10 qualifying private entity, the Secretary is authorized
11 to enter into such agreements with entities as may
12 be required to provide for the benefits under this
13 subsection. Such entities may be eligible entities,
14 carriers under part B, fiscal intermediaries under
15 part A, or other qualified entities.

16 “(c) CONTRIBUTION INTO PRESCRIPTION DRUG AC-
17 COUNT.—

18 “(1) IN GENERAL.—In the case of an individual
19 enrolled under this part, the Secretary shall—

20 “(A) establish a prescription drug account
21 for the individual under section 1860D–5; and

22 “(B) make deposits into such account in
23 accordance with subsection (c) of such section.

1 Amounts so deposited shall not be treated as income
2 to the accountholder for purposes of the Internal
3 Revenue Code of 1986.

4 “(2) ANNUAL FEDERAL CONTRIBUTION
5 AMOUNT.—

6 “(A) INITIAL AMOUNT.—Subject to sub-
7 paragraph (B) and subsections (d) and (e)(3),
8 in the case of an accountholder whose modified
9 adjusted gross income is—

10 “(i) not more than 100 percent of the
11 poverty line, the annual Federal contribu-
12 tion amount is \$2,500;

13 “(ii) more than 100 percent, but less
14 than 125 percent, of the poverty line, the
15 annual Federal contribution amount is
16 \$1,500;

17 “(iii) more than 125 percent, but less
18 than 175 percent, of the poverty line, the
19 annual Federal contribution amount is
20 \$1,100; and

21 “(iv) at least 175 percent, but less
22 than 250 percent, of the poverty line, the
23 annual Federal contribution amount is
24 \$600.

25 “(B) INFLATION ADJUSTMENT.—

1 “(i) IN GENERAL.—For a year after
 2 2004, the annual Federal contribution
 3 amount shall be the amount specified in
 4 subparagraph (A) increased by the per-
 5 centage (if any) by which—

6 “(I) the average per capita ag-
 7 gregate expenditures for covered out-
 8 patient drugs in the United States for
 9 medicare beneficiaries, as determined
 10 by the Secretary for the 12-month pe-
 11 riod ending in July of the previous
 12 year; exceeds

13 “(II) such aggregate expendi-
 14 tures for the 12-month period ending
 15 with July 2004.

16 “(ii) ROUNDING.—If an annual Fed-
 17 eral contribution amount determined under
 18 clause (i) is not a multiple of \$1, such in-
 19 crease shall be rounded to the nearest mul-
 20 tiple of \$1.

21 “(d) REQUIREMENT FOR VERIFICATION OF ELIGI-
 22 BILITY.—

23 “(1) IN GENERAL.—An individual shall not be
 24 treated as an eligible beneficiary for purposes of
 25 benefits under this part unless the individual—

1 “(A) provides such information as the Sec-
2 retary may require in order to determine eligi-
3 bility under section 1860D–1(b) and the appro-
4 priate category of benefits under subsection
5 (c)(2)(A); and

6 “(B) authorizes in a form and manner
7 specified by the Secretary the verification of the
8 individual’s income and prescription drug cov-
9 erage status by the Secretary through arrange-
10 ments with States or otherwise.

11 An arrangement with a State under subparagraph
12 (B) shall provide for the payment by the Secretary
13 under this part of the State’s reasonable costs of
14 conducting verifications under such arrangement.

15 “(2) PENALTIES FOR PROVISION OF FALSE IN-
16 FORMATION.—The provision of false information
17 under paragraph (1)(A) is subject to criminal pen-
18 alties under section 1128B.

19 “(3) PROCEDURES FOR DETERMINING IN-
20 COME.—The Secretary shall establish procedures for
21 determining the income of individuals seeking enroll-
22 ment under this part.

23 “(4) DISCLOSURE OF INFORMATION.—Notwith-
24 standing section 6103(a) of the Internal Revenue
25 Code of 1986, the Secretary of the Treasury may,

1 upon written request from the Secretary, disclose to
2 the Secretary such return information as is nec-
3 essary to make the determinations described in sub-
4 paragraph (A). Return information disclosed under
5 the preceding sentence may be used by the Secretary
6 only for the purposes of, and to the extent necessary
7 in, making such determinations.

8 “(5) INFORMATION REGARDING PRESCRIPTION
9 DRUG COVERAGE.—In order to verify compliance
10 with the eligibility requirement of section 1860D–
11 1(b)(1)(B), the Secretary is authorized to establish
12 procedures, in coordination with the Secretary of
13 Treasury and the Secretary of Labor, for deter-
14 mining whether eligible beneficiaries have prescrip-
15 tion drug coverage through insurance or otherwise,
16 or under a group health plan or other third-party
17 payment arrangement, and for alerting the Secretary
18 about such coverage or arrangements. The Secretary
19 may also periodically ask eligible beneficiaries en-
20 rolled under this part whether the beneficiaries are
21 eligible or have such coverage. A material misrepre-
22 sentation of the information described in the pre-
23 ceding sentence by a beneficiary (as defined in
24 standards set by the Secretary and determined
25 through a process established by the Secretary) shall

1 constitute grounds for termination of enrollment
2 under section 1860D–2(a)(1)(C).

3 “(e) CAPPED APPROPRIATIONS TO COVER PROGRAM
4 EXPENDITURES.—

5 “(1) IN GENERAL.—For the purpose of car-
6 rying out this part, there is appropriated, out of any
7 money in the Treasury not otherwise appropriated to
8 the Medicare Safety Net Prescription Drug Account
9 in the Federal Supplementary Medical Insurance
10 Trust Fund established under section 1841 the fol-
11 lowing amounts:

12 “(A) \$18,000,000,000 for fiscal year 2005.

13 “(B) \$19,000,000,000 for fiscal year 2006.

14 “(C) \$20,000,000,000 for fiscal year 2007.

15 “(D) \$21,000,000,000 for fiscal year
16 2008.

17 “(E) \$22,000,000,000 for fiscal year 2009.

18 “(F) \$23,000,000,000 for fiscal year 2010.

19 “(G) \$24,000,000,000 for fiscal year 2011.

20 “(H) \$25,000,000,000 for fiscal year
21 2012.

22 “(I) \$28,000,000,000 for fiscal year 2013.

23 “(2) AVAILABILITY ON A CALENDAR YEAR
24 BASIS.—The amounts appropriated under paragraph
25 (1) for a fiscal year are authorized for obligation

1 during the calendar year beginning in such fiscal
2 year.

3 “(3) ASSURANCE OF MAINTENANCE OF PRO-
4 GRAM WITHIN FUNDING LIMITATIONS.—

5 “(A) ANNUAL ESTIMATION.—Before the
6 beginning of each year beginning with 2005),
7 the Secretary shall estimate—

8 “(i) the aggregate expenditures that
9 will be made under this part for that year
10 (without regard to any adjustment under
11 this paragraph); and

12 “(ii) the cumulative aggregate expend-
13 itures that were made under this part for
14 previous years (beginning with 2005).

15 “(B) ADJUSTMENT.—If the Secretary esti-
16 mates under subparagraph (A)(i) for a year
17 that such estimated aggregate expenditures will
18 exceed the amount authorized for obligation
19 during the year under paragraph (2) (as re-
20 duced by the amount by which the cumulative
21 aggregate expenditures for previous years under
22 subparagraph (A)(ii) are less than the amounts
23 authorized for obligations during the respective
24 years under paragraph (2)), the Secretary shall
25 take such of the following actions for that year

(or, at the Secretary's discretion, for the period, not to exceed 4 years, including that year) as will eliminate any such excess:

“(i) An increase in the catastrophic coverage threshold under subsection (b)(1)(C).

“(ii) A decrease in the Federal contribution amounts under subsection (c)(2).

“PRESCRIPTION DRUG ACCOUNTS

“SEC. 1860D–5. (a) ESTABLISHMENT OF ACCOUNTS.—

“(1) IN GENERAL.—The Secretary shall establish and maintain for each eligible beneficiary who is enrolled under this part at the time of enrollment a prescription drug account (in this section referred to as an ‘account’).

“(2) ACCOUNTHOLDER DEFINED.—In this section, the term ‘accountholder’ means an individual for whom an account or reserve account has been established under this section.

“(3) EXPENDITURES FROM ACCOUNT.—Nothing in this section shall be construed as requiring the Federal Government to obligate funds for amounts in any account until such time as a withdrawal from such account is authorized under this section.

1 “(b) USE OF ACCOUNTS.—

2 “(1) IN GENERAL.—Amounts credited to an ac-
3 count shall only be used for the purchase of covered
4 outpatient drugs for the accountholder. Any
5 amounts remaining at the end of a year remain
6 available for expenditures in succeeding years so
7 long as the eligible beneficiary remains enrolled
8 under this part.

9 “(2) TREATMENT OF WITHDRAWALS.—The
10 withdrawal of any amounts from an account in ac-
11 cordance with this section shall not be subject to in-
12 come or other tax.

13 “(c) AMOUNTS CREDITED IN ACCOUNT.—

14 “(1) IN GENERAL.—The Secretary shall credit
15 to a prescription drug account of an eligible bene-
16 ficiary Federal contributions described in section
17 1860D–4(c) in accordance with paragraph (2).

18 “(2) TIMING AND AMOUNT OF DEPOSIT.—In
19 the case of an eligible beneficiary who is enrolled
20 under this part at the beginning of a year, the entire
21 annual Federal contribution amount under section
22 1860D–4(c)(2) shall be made into the beneficiary’s
23 account at the beginning of the year. In the case of
24 an eligible beneficiary who is enrolled under this
25 part after the beginning of a year, the amount of

1 such contribution shall be pro-rated by the Secretary
2 and deposited into the beneficiary's account at the
3 time of enrollment.

4 “(3) TREATMENT OF CONTRIBUTIONS.—Such
5 contributions shall not be treated as income for pur-
6 poses of chapter 1 of the Internal Revenue Code of
7 1986.

8 “SAFETY NET PRESCRIPTION DRUG ACCOUNT IN THE
9 FEDERAL SUPPLEMENTARY MEDICAL INSURANCE
10 TRUST FUND

11 “SEC. 1860D–6. (a) ESTABLISHMENT.—

12 “(1) IN GENERAL.—There is created within the
13 Federal Supplementary Medical Insurance Trust
14 Fund established by section 1841 an account to be
15 known as the ‘Safety Net Prescription Drug Ac-
16 count’ (in this section referred to as the ‘Account’).

17 “(2) FUNDS.—The Account shall consist of
18 such gifts and bequests as may be made as provided
19 in section 201(i)(1), and such amounts as may be
20 deposited in, or appropriated to, the Account as pro-
21 vided in this part.

22 “(3) SEPARATE FROM REST OF TRUST FUND.—
23 Funds provided under this part to the Account shall
24 be kept separate from all other funds within the
25 Federal Supplementary Medical Insurance Trust
26 Fund.

1 “(b) PAYMENTS FROM ACCOUNT.—

2 “(1) IN GENERAL.—The Managing Trustee
3 shall pay from time to time from the Account such
4 amounts as the Secretary certifies are necessary to
5 make payments to operate the program under this
6 part, including payments with respect to administra-
7 tive expenses under this part in accordance with sec-
8 tion 201(g).

9 “(2) TREATMENT IN RELATION TO PART B PRE-
10 MIUM.—Amounts payable from the Account shall not
11 be taken into account in computing actuarial rates
12 or premium amounts under section 1839.

13 “(c) APPROPRIATIONS TO COVER BENEFITS AND
14 ADMINISTRATIVE COSTS.—There are appropriated to the
15 Account in a fiscal year, out of any moneys in the Treas-
16 ury not otherwise appropriated, an amount equal to the
17 payments and transfers made from the Account in the
18 year.

19 “DEFINITIONS

20 “SEC. 1860D–7. In this part:

21 “(1) COVERED OUTPATIENT DRUG.—

22 “(A) IN GENERAL.—Except as provided in
23 subparagraph (B), the term ‘covered outpatient
24 drug’ means—

25 “(i) a drug that may be dispensed
26 only upon a prescription and that is de-

1 scribed in clause (i) or (ii) of subparagraph
2 (A) of section 1927(k)(2); or

3 “(ii) a biological product or insulin de-
4 scribed in subparagraph (B) or (C) of such
5 section.

6 “(B) EXCLUSIONS.—

7 “(i) IN GENERAL.—The term ‘covered
8 outpatient drug’ does not include drugs or
9 classes of drugs, or their medical uses,
10 which may be excluded from coverage or
11 otherwise restricted under section
12 1927(d)(2), other than those restricted
13 under subparagraph (E) of such section
14 (relating to smoking cessation agents).

15 “(ii) AVOIDANCE OF DUPLICATE COV-
16 ERAGE.—A drug prescribed for an indi-
17 vidual that would otherwise be a covered
18 outpatient drug under this part shall not
19 be considered to be such a drug if payment
20 for the drug is available under part A or
21 B (but such drug shall be so considered if
22 such payment is not available because the
23 eligible beneficiary has exhausted benefits
24 under part A or B), without regard to

1 whether the individual is entitled to bene-
2 fits under part A or enrolled under part B.

3 “(2) POVERTY LINE.—The term ‘poverty line’
4 means the income official poverty line (as defined by
5 the Office of Management and Budget, and revised
6 annually in accordance with section 673(2) of the
7 Omnibus Budget Reconciliation Act of 1981) appli-
8 cable to a family of the size involved.”.

9 (b) CONFORMING REFERENCES TO PREVIOUS PART
10 D.—

11 (1) IN GENERAL.—Any reference in law (in ef-
12 fect before the date of enactment of this Act) to part
13 D of title XVIII of the Social Security Act is deemed
14 a reference to part F of such title (as in effect after
15 such date).

16 (2) SECRETARIAL SUBMISSION OF LEGISLATIVE
17 PROPOSAL.—Not later than 6 months after the date
18 of enactment of this section, the Secretary of Health
19 and Human Services shall submit to the appropriate
20 committees of Congress a legislative proposal pro-
21 viding for such technical and conforming amend-
22 ments in the law as are required by the provisions
23 of this section.

1 **SEC. 3. EXCLUSION OF PART D COSTS FROM DETERMINA-**
 2 **TION OF PART B MONTHLY PREMIUM.**

3 Section 1839(g) of the Social Security Act (42 U.S.C.
 4 1395r(g)) is amended—

5 (1) by striking “attributable to the application
 6 of section” and inserting “attributable to—

7 “(1) the application of section”;

8 (2) by striking the period and inserting “;
 9 and”; and

10 (3) by adding at the end the following new
 11 paragraph:

12 “(2) the Medicare Safety Net Outpatient Pre-
 13 scription Drug Program under part D.”.

14 **SEC. 4. MEDICAID AMENDMENTS.**

15 (a) VERIFICATION OF ELIGIBILITY FOR PART D
 16 BENEFITS.—

17 (1) REQUIREMENT.—Section 1902(a) (42
 18 U.S.C. 1396a(a)) is amended—

19 (A) by striking “and” at the end of para-
 20 graph (64);

21 (B) by striking the period at the end of
 22 paragraph (65) and inserting “; and”; and

23 (C) by inserting after paragraph (65) the
 24 following new paragraph:

25 “(66) provide for verification of income under
 26 section 1860D–4(d)(1)(B).”.

3 (A) by redesignating section 1935 as sec-
4 tion 1936; and

5 (B) by inserting after section 1934 the fol-
6 lowing new section:

7 “SPECIAL PROVISIONS RELATING TO MEDICARE PART D
8 BENEFITS

9 “SEC. 1935. (a) REQUIREMENT FOR VERIFICATION
10 OF ELIGIBILITY DETERMINATIONS FOR IMPROVED PART
11 D BENEFITS.—As a condition of its State plan under this
12 title under section 1902(a)(66) and receipt of any Federal
13 financial assistance under section 1903(a), a State shall
14 provide for verification of income statements in accordance
15 with arrangements under section 1860D–4(d)(1).

16 “(b) PAYMENTS FOR ADDITIONAL ADMINISTRATIVE
17 COSTS.—

“(1) IN GENERAL.—The amounts expended by a State in carrying out subsection (a) are, subject to paragraph (2), expenditures reimbursable under the appropriate paragraph of section 1903(a); except that, notwithstanding any other provision of such section, the applicable Federal matching rates with respect to such expenditures under such section shall be increased as follows (but in no case shall the rate as so increased exceed 100 percent):

1 “(A) For expenditures attributable to costs
2 incurred during 2004, the otherwise applicable
3 Federal matching rate shall be increased by 10
4 percent of the percentage otherwise payable
5 (but for this subsection) by the State.

6 “(B)(i) For expenditures attributable to
7 costs incurred during 2005 and each subse-
8 quent year through 2011, the otherwise applica-
9 ble Federal matching rate shall be increased by
10 the applicable percent (as defined in clause (ii))
11 of the percentage otherwise payable (but for
12 this subsection) by the State.

13 “(ii) For purposes of clause (i), the ‘appli-
14 cable percent’ for—

15 “(I) 2005 is 20 percent; or

16 “(II) a subsequent year is the applica-
17 ble percent under this clause for the pre-
18 vious year increased by 10 percentage
19 points.

20 “(C) For expenditures attributable to costs
21 incurred after 2011, the otherwise applicable
22 Federal matching rate shall be increased to 100
23 percent.

24 “(2) COORDINATION.—The State shall provide
25 the Secretary with such information as may be nec-

1 necessary to properly allocate administrative expendi-
 2 tures described in paragraph (1) that may otherwise
 3 be made for eligibility determinations.”.

4 (b) AMENDMENT TO BEST PRICE.—Section
 5 1927(c)(1)(C)(i) (42 U.S.C. 1396r–8(c)(1)(C)(i)) is
 6 amended—

7 (1) by striking “and” at the end of subclause
 8 (III);

9 (2) by striking the period at the end of sub-
 10 clause (IV) and inserting “; and”; and

11 (3) by adding at the end the following new sub-
 12 clause:

13 “(V) any prices charged which
 14 are negotiated by the Secretary under
 15 part D of title XVIII on behalf of eli-
 16 gible beneficiaries enrolled under such
 17 part.”.

18 **SEC. 5. IMPORTATION OF PRESCRIPTION DRUGS.**

19 Section 804 of the Federal Food, Drug, and Cosmetic
 20 Act (21 U.S.C. 384) is amended—

21 (1) in subsection (a)—

22 (A) by striking “The Secretary” and in-
 23 serting “Not later than 180 days after the date
 24 of the enactment of the Pharmaceutical Market
 25 Access Act of 2003, 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 505B 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 2003,”;

19 (9) in subsection (k)—

20 (A) in subparagraph (A) of paragraph
21 (1)—

22 (i) by striking “or a biological” and
23 inserting “, a biological”; and

24 (ii) by striking the period at the end
25 and inserting “, or any drug or biological

1 product approved by the Secretary for use
2 in connection with abortion, sex trans-
3 formation, sexual dysfunction, or sexual in-
4 adequacy.”; and
5 (B) in paragraph (2)—
6 (i) by redesignating subparagraphs
7 (D) and (E) as subparagraphs (E) and
8 (F), respectively; and
9 (ii) by inserting after subparagraph
10 (C) the following:
11 “(D) The term ‘qualifying individual’
12 means an individual who is not a pharmacist or
13 a wholesaler. ”; and
14 (10) by striking subsections (l) and (m).

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