

109TH CONGRESS
2D SESSION

S. 2665

To amend title XVIII of the Social Security Act to simplify and improve the Medicare prescription drug program.

IN THE SENATE OF THE UNITED STATES

APRIL 27, 2006

Mr. BAUCUS (for himself, Mr. WYDEN, Mrs. LINCOLN, Mr. CONRAD, and Mr. JEFFORDS) introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

To amend title XVIII of the Social Security Act to simplify and improve the Medicare prescription drug program.

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

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

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

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

Sec. 1. Short title; table of contents.

TITLE I—BENEFITS SIMPLIFICATION AND IMPROVEMENT

Subtitle A—Simplification

Sec. 101. Establishment of national uniform part D benefit packages.

Subtitle B—Formulary Requirements and Improvements

- Sec. 111. Limitation on removal or change of coverage of covered part D drugs under a formulary under a prescription drug plan or an MA-PD plan.
- Sec. 112. Formulary requirement with respect to certain categories and classes of drugs.
- Sec. 113. Certainty regarding excluded drugs.
- Sec. 114. Pharmacy and therapeutic committee improvements.

Subtitle C—Funding Certain Costs for Administrative Improvements

- Sec. 121. Additional funding for enrollment assistance.

TITLE II—BENEFICIARY PROTECTION IMPROVEMENTS

- Sec. 201. Improved plan information.
- Sec. 202. Standardized definition for cost and utilization management tools and nomenclature for distinguishing between excluded and nonformulary drugs.
- Sec. 203. Standardized enrollee notice regarding coverage determinations.
- Sec. 204. Standardized and simplified processes for reconsiderations, exceptions, and appeals.
- Sec. 205. Standardized marketing and licensing protections; State certification prior to waiver of licensure requirements.
- Sec. 206. Authority to waive late enrollment penalty in certain circumstances.
- Sec. 207. Integrated application and enrollment process for certain subsidy-eligible individuals.
- Sec. 208. GAO study and report on cost and utilization management tools used under prescription drug plans and MA-PD plans.

TITLE III—PERFORMANCE AND QUALITY

- Sec. 301. Requirements for comparative information regarding performance of plans under Medicare part D.
- Sec. 302. Required quality for approval of plan.
- Sec. 303. MedPAC study and report regarding a value-based purchasing program for plans offering part D prescription drug coverage.

1 TITLE I—BENEFITS SIMPLIFICATION AND IMPROVEMENT

2

3 Subtitle A—Simplification

4 SEC. 101. ESTABLISHMENT OF NATIONAL UNIFORM PART D

5 BENEFIT PACKAGES.

- 6 (a) IN GENERAL.**—Section 1860D–2 of the Social
- 7 Security Act (42 U.S.C. 1395w–102) is amended by add-**
- 8 ing at the end the following new subsection:**

1 “(f) SIMPLIFICATION OF COVERAGE.—

2 “(1) REQUIREMENT.—Beginning January 1,
3 2008, qualified prescription drug coverage (other
4 than coverage that is standard prescription drug
5 coverage (as defined in subsection (b)) may only be
6 offered by a prescription drug plan or an MA–PD
7 plan through the benefit packages established by the
8 Secretary under paragraph (2).

9 “(2) ESTABLISHMENT OF NATIONAL UNIFORM
10 BENEFIT PACKAGES.—The Secretary, in consultation
11 with the entities and individuals described in para-
12 graph (5), shall establish 5 national uniform benefit
13 packages (that are in addition to standard prescrip-
14 tion drug coverage) as follows:

15 “(A) THREE BASIC PACKAGES.—

16 “(i) IN GENERAL.—Three of the ben-
17 efit packages shall only provide basic pre-
18 scription drug coverage described in sub-
19 section (a)(3)(B).

20 “(ii) SPECIFICATION.—Of the benefit
21 packages described in clause (i)—

22 “(I) one package shall have no
23 annual deductible and coinsurance,
24 specified by the Secretary, for costs
25 up to the initial coverage limit;

1 “(II) one package, other than the
 2 package described in subclause (I),
 3 shall include a deductible that is equal
 4 to the amount determined under sec-
 5 tion 1860D–2(b)(1)(A)(ii) and provide
 6 for copayment amounts, specified by
 7 the Secretary, rather than coinsur-
 8 ance, for costs above the annual de-
 9 ductible and up to the initial coverage
 10 limit; and

11 “(III) one package, other than
 12 the packages described in subclauses
 13 (I) and (II), shall have no deductible
 14 and provide for copayment amounts,
 15 specified by the Secretary, rather than
 16 coinsurance, for costs up to the initial
 17 coverage limit.

18 “(B) TWO SUPPLEMENTAL PACKAGES.—

19 “(i) IN GENERAL.—Two of the benefit
 20 packages shall include supplemental pre-
 21 scription drug coverage described in sub-
 22 section (a)(2)(A).

23 “(ii) SPECIFICATION.—Of the benefit
 24 packages described in clause (i)—

1 “(I) one package shall include a
 2 meaningful level of coverage of costs
 3 incurred with respect to covered part
 4 D drugs after the initial coverage
 5 limit has been reached but before the
 6 annual out-of-pocket threshold has
 7 been reached; and

8 “(II) one package, other than the
 9 package described in subclause (I),
 10 shall include an increase in the initial
 11 coverage limit with respect to covered
 12 part D drugs so that such limit is
 13 equal to the annual out-of-pocket
 14 threshold.

15 “(3) REQUIREMENT FOR ACTUARIAL VALUE OF
 16 PACKAGES.—

17 “(A) BASIC PACKAGES.—The Secretary
 18 shall ensure that the 3 packages described in
 19 paragraph (2)(A) meet the following require-
 20 ments:

21 “(i) ASSURING EQUIVALENT VALUE
 22 OF TOTAL COVERAGE.—The actuarial value
 23 of the total coverage is equal to the actu-
 24 arial value of standard prescription drug
 25 coverage, as estimated by the Chief Actu-

ary of the Centers for Medicare & Medicaid Services.

“(ii) ASSURING EQUIVALENT UNSUBSIDIZED VALUE OF COVERAGE.—The unsubsidized value of the coverage is equal to the unsubsidized value of standard prescription drug coverage, as estimated by the Chief Actuary of the Centers for Medicare & Medicaid Services. For purposes of this subparagraph, the unsubsidized value of coverage is the amount by which the actuarial value of the coverage exceeds the actuarial value of the subsidy payments under section 1860D–15 with respect to such coverage.

“(iii) ASSURING STANDARD PAYMENT FOR COSTS AT INITIAL COVERAGE LIMIT.—The coverage is designed, based upon an actuarially representative pattern of utilization, to provide for the payment, with respect to costs incurred that are equal to the initial coverage limit under subsection (b)(3) for the year, of an amount equal to the product of—

1 “(I) the amount by which the ini-
 2 tial coverage limit described in sub-
 3 section (b)(3) for the year exceeds the
 4 deductible described in subsection
 5 (b)(1) for the year; and

6 “(II) 100 percent minus the coin-
 7 surance percentage specified in sub-
 8 section (b)(2)(B).

9 “(B) SUPPLEMENTAL PACKAGES.—The
 10 Secretary shall ensure that the 2 packages de-
 11 scribed in paragraph (2)(B) have actuarial val-
 12 ues that are progressively greater than the ac-
 13 tuarial value of standard prescription drug cov-
 14 erage, as estimated by the Chief Actuary of the
 15 Centers for Medicare & Medicaid Services.

16 “(4) RESTRICTION ON NUMBER OF TIERS OR
 17 LEVELS OF COST-SHARING.—

18 “(A) IN GENERAL.—Subject to clause (ii),
 19 a package described in paragraph (2) may not
 20 include more than 3 distinct tiers or levels of
 21 cost-sharing.

22 “(B) EXCEPTION.—A package described in
 23 paragraph (2) may include a fourth distinct tier
 24 or level of cost-sharing that may only be used
 25 for specialty or high cost covered part D drugs

(as determined by the Secretary) if the PDP sponsor of the prescription drug plan or the Medicare Advantage organization offering the MA–PD plan has an exceptions process under subsection (g) with respect to the 4th tier or level.

“(5) BALANCING OF OBJECTIVES.—In establishing the benefit packages under paragraph (2), the Secretary shall balance the objectives of—

“(A) simplifying the benefit structures to facilitate comparisons among plans;

“(B) avoiding adverse selection;

“(C) ensuring meaningful differences between benefit packages;

“(D) providing program stability; and

“(E) promoting competition among plans.

“(6) STANDARDIZED LANGUAGE, NOMENCLATURE, DEFINITIONS, AND FORMAT.—

“(A) IN GENERAL.—In establishing the benefit packages under paragraph (2), the Secretary shall develop—

“(i) standardized language, nomenclature, and definitions to be used by the Secretary and PDP sponsors and MA–PD

1 organizations with respect to such benefit
2 packages; and

3 “(ii) a standardized format to be used
4 by PDP sponsors and MA–PD organiza-
5 tions with respect to such benefit packages.

6 “(B) REQUIREMENT.—In developing
7 standardized language, nomenclature, and defi-
8 nitions and a standardized format under sub-
9 paragraph (A), the Secretary shall ensure that
10 such language, nomenclature, definitions, and
11 format clearly distinguishes between—

12 “(i) a plan that offers only basic pre-
13 scription drug coverage (as described in
14 subsection (a)(3)) and a plan that offers
15 supplemental prescription drug coverage
16 (as described in subsection (a)(2)(A));

17 “(ii) a plan that offers coinsurance
18 and a plan that offers flat copayments;

19 “(iii) a plan that covers all covered
20 part D drugs and a plan that covers less
21 than all such drugs; and

22 “(iv) prescription drug plans and
23 MA–PDs, especially on terms of how en-
24 rollment in those plans would affect access
25 to items and services under the original

1 medicare fee-for-service program under
2 parts A and B.

3 “(7) ADVISORY COMMITTEE.—

4 “(A) ESTABLISHMENT.—The Secretary
5 shall establish a Benefit Advisory Committee
6 (in this paragraph referred to as the Com-
7 mittee).

8 “(B) MEMBERSHIP.—The Committee shall
9 be composed of 15 members to be appointed by
10 the Secretary. The Secretary shall ensure that
11 the following individuals are appointed to the
12 Committee:

13 “(i) Two representatives appointed
14 upon recommendation of the National As-
15 sociation of Insurance Commissioners.

16 “(ii) The Chief Actuary of the Centers
17 for Medicare & Medicaid Services.

18 “(iii) Two individuals with expertise
19 in consumer choice.

20 “(iv) Two individuals with expertise in
21 health economics.

22 “(v) Two individuals with expertise in
23 actuarial sciences.

24 “(vi) Two individuals with expertise in
25 pharmacy benefit management.

1 “(vii) Two representatives of health
 2 insurers, health care providers, and con-
 3 sumers.

4 “(viii) Two other individuals or enti-
 5 ties determined appropriate by the Sec-
 6 retary.

7 “(C) CONSULTATION.—In establishing the
 8 benefit packages under paragraph (2) (includ-
 9 ing determinations under paragraph (3)), the
 10 Secretary shall consult with the Committee.

11 “(8) UPDATING OF BENEFIT PACKAGES.—Not
 12 less than once every 3 years, the Secretary shall re-
 13 view the benefit packages established under this sub-
 14 section, and, subject to the requirements under
 15 paragraph (2), shall update the content of such
 16 packages as appropriate.

17 “(9) NO EFFECT ON REQUIREMENT TO OFFER
 18 A PLAN THAT ONLY PROVIDES BASIC PRESCRIPTION
 19 DRUG COVERAGE.—Nothing in this subsection shall
 20 be construed to effect the requirement under sub-
 21 section (a)(2)(B).”.

22 (b) CONFORMING AMENDMENTS.—Section 1860D–2
 23 of the Social Security Act (42 U.S.C. 1395w–102) is
 24 amended—

25 (1) in subsection (a)—

1 (A) in paragraph (1)—

2 (i) in the matter preceding subpara-
3 graph (A), by striking “For purposes” and
4 inserting “Subject to subsection (f), for
5 purposes”;

6 (ii) in subparagraph (B), by striking
7 “which meets the alternative” and all that
8 follows through the period at the end and
9 inserting the following: “which—

10 “(i) with respect to plan years begin-
11 ning prior to January 1, 2008, meets the
12 alternative prescription drug requirements
13 of subsection (c) and access to negotiated
14 prices under subsection (d), but only if the
15 benefit design of such coverage is approved
16 by the Secretary, as provided under sub-
17 section (c); or

18 “(ii) with respect to plan years begin-
19 ning on or after January 1, 2008, meets
20 the requirements of subsection (f) and ac-
21 cess to negotiated prices under subsection
22 (d), but only if the benefit design of such
23 coverage is approved by the Secretary, in
24 accordance with subsection (f).”.

1 (B) in paragraph (2)(A), in the matter
 2 preceding clause (i), by inserting “and sub-
 3 section (f)” after “subparagraph (B)”;

4 (2) in subsection (b), by striking paragraph (2)
 5 and inserting the following:

6 “(2) 25 PERCENT COINSURANCE.—The cov-
 7 erage has coinsurance (for costs above the annual
 8 deductible specified in paragraph (1) and up to the
 9 initial coverage limit under paragraph (3)) that is—

10 “(A) prior to January 1, 2008—

11 “(i) equal to 25 percent; or

12 “(ii) actuarially equivalent (using
 13 processes and methods established under
 14 section 1860D–11(c)) to an average ex-
 15 pected payment of 25 percent of such
 16 costs; or

17 “(B) beginning on January 1, 2008, is
 18 equal to 25 percent.”.

1 **Subtitle B—Formulary**
 2 **Requirements and Improvements**

3 **SEC. 111. LIMITATION ON REMOVAL OR CHANGE OF COV-**
 4 **ERAGE OF COVERED PART D DRUGS UNDER**
 5 **A FORMULARY UNDER A PRESCRIPTION**
 6 **DRUG PLAN OR AN MA-PD PLAN.**

7 (a) **LIMITATION ON REMOVAL OR CHANGE.**—Section
 8 1860D–4(b)(3)(E) of the Social Security Act (42 U.S.C.
 9 1395w–104(b)(3)(E)) is amended to read as follows:

10 “(E) **REMOVING OR CHANGING A DRUG ON**
 11 **A FORMULARY.**—

12 “(i) **LIMITATION.**—Subject to clause
 13 (ii), with respect to plan years beginning
 14 on or after January 1, 2007, the PDP
 15 sponsor of a prescription drug plan may
 16 not remove a covered part D drug from the
 17 plan formulary, apply a cost or utilization
 18 management tool that imposes a restriction
 19 or limitation on the coverage of such a
 20 drug (such as through the application of a
 21 preferred status, usage restriction, step
 22 therapy, prior authorization, or quantity
 23 limitation), or increase the cost-sharing of
 24 such a drug (such as through placement of
 25 a drug on a tier that would result in high-

er cost-sharing for a beneficiary) other than the date on which PDP sponsors may begin marketing their plans with respect to the immediately succeeding plan year, as determined by the Secretary.

“(ii) EXCEPTIONS TO LIMITATION ON REMOVAL.—Subject to clause (iii), clause (i) shall not apply with respect to a covered part D drug that—

“(I) is a brand name drug for which there is a generic drug approved under section 505(j) of the Food and Drug Cosmetic Act that is placed on the market during the period in which there are limitations on removal or change in the formulary under clause (i);

“(II) is a drug for which the Commissioner of Food and Drugs issues a safety warning that would impose a restriction on the drug or require a drug label warning during the plan year;

“(III) is a drug that the Pharmacy and Therapeutic Committee of

1 the plan determines, based directly on
2 evidence from peer-reviewed research,
3 has a lower safety profile than is ap-
4 propriate or is ineffective; or

5 “(IV) for which the Secretary es-
6 tablishes a specific exception through
7 the promulgation of regulations relat-
8 ing to plan formularies.

9 “(iii) LIMITED APPLICATION OF EX-
10 CEPTIONS TO DRUGS IN CERTAIN CAT-
11 EGORIES AND CLASSES.—For 2007 and
12 2008, subclauses (I), (II), (IV), and (V) of
13 clause (ii) shall not apply to a drug in a
14 category or class described in section
15 1860D–4(b)(3)(H)(i).

16 “(iv) NOTICE OF REMOVAL UNDER
17 APPLICATION OF EXCEPTION TO LIMITA-
18 TION.—The PDP sponsor of a prescription
19 drug plan shall provide appropriate notice
20 (such as under subsection (a)(3) and in-
21 cludes the annual notice under subsection
22 (a)(5)) of any removal or change under
23 clause (ii) to the Secretary, affected enroll-
24 ees, physicians, pharmacies, and phar-
25 macists.”.

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

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

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

16 (2) EFFECTIVE DATE.—The amendment made
 17 by paragraph (1) shall apply to annual coordinated
 18 election periods beginning on or after November 15,
 19 2006.

20 **SEC. 112. FORMULARY REQUIREMENT WITH RESPECT TO**
 21 **CERTAIN CATEGORIES AND CLASSES OF**
 22 **DRUGS.**

23 (a) REQUIRED INCLUSION.—Section 1860D–4(b)(3)
 24 of the Social Security Act (42 U.S.C. 1395w–104(b)(3))
 25 is amended—

(1) in subparagraph (C)(i), by striking “The formulary” and inserting “Subject to subparagraph (G), the formulary”; and

(2) by inserting after subparagraph (F) the following new subparagraph:

“(G) REQUIRED INCLUSION OF DRUGS IN CERTAIN CATEGORIES AND CLASSES.—

“(i) FOR 2007 AND 2008.—For 2007 and 2008, the formulary must include all or substantially all drugs in the following 6 categories that are available as of June 1 of the prior year:

“(I) Immunosuppressant.

“(II) Antidepressant.

“(III) Antipsychotic.

“(IV) Anticonvulsant.

“(V) Antiretroviral.

“(VI) Antineoplastic.

A PDP sponsor of a prescription drug plan may not apply a utilization management tool, such as prior authorization or step therapy, to a drug required to be included on the formulary pursuant to the preceding sentence with respect to an enrollee if the

1 enrollee was taking such drug prior to the
2 application of such tool.

3 “(ii) SUBSTANTIALLY ALL DE-
4 FINED.—For purposes of clause (i), the
5 term ‘substantially all’ means all drugs
6 and unique dosage forms in the categories
7 described in such clause except for—

8 “(I) multi-source brands of the
9 identical molecular structure;

10 “(II) extended release products
11 when the immediate-release product is
12 included on the formulary;

13 “(III) products that have the
14 same active ingredient; and

15 “(IV) multiple dosage forms that
16 do not provide a unique route of ad-
17 ministration, such as tablets and cap-
18 sules.

19 “(iii) FOR 2009 AND SUBSEQUENT
20 YEARS.—

21 “(I) AUTHORITY.—Beginning
22 with the plan year beginning on Janu-
23 ary 1, 2009, the Secretary, taking
24 into account the results of the study
25 conducted under section 113(b) of the

1 Medicare Prescription Drug Sim-
 2 plication Act of 2006, may require
 3 that the formulary include coverage of
 4 covered part D drugs within certain
 5 categories or classes of drugs.

6 “(II) REQUIREMENT FOR USE OF
 7 AUTHORITY.—The Secretary shall
 8 promulgate regulations to exercise the
 9 authority under subclause (I) and
 10 may not exercise such authority
 11 through program guidance.”.

12 (b) INSTITUTE OF MEDICINE STUDY AND REPORT
 13 ON PROTECTED CATEGORIES AND CLASSES OF DRUGS.—

14 (1) STUDY.—

15 (A) IN GENERAL.—Not later than the date
 16 that is 2 months after the date of the enact-
 17 ment of this Act, the Secretary of Health and
 18 Human Services (in this subsection referred to
 19 as the “Secretary”) shall enter into an arrange-
 20 ment under which the Institute of Medicine of
 21 the National Academy of Sciences (in this sub-
 22 section referred to as the “Institute”) shall con-
 23 duct a study on issues related to requiring any
 24 formulary used under prescription drug plans
 25 under part D of title XVIII of the Social Secu-

1 rity Act or under MA–PD plans under part C
2 of such title to cover drugs within certain cat-
3 egories or classes.

4 (B) REQUIRED ITEMS TO BE EVALU-
5 ATED.—The study conducted under subpara-
6 graph (A) shall include an evaluation of—

7 (i) whether all or substantially all
8 drugs within certain drug categories or
9 classes of drugs should be required by the
10 Secretary on any formulary used under a
11 prescription drug plan or an MA–PD plan
12 in order to protect enrollees from undue
13 medical risk and complication, including
14 life threatening interruptions in, or lack of
15 access to, medication therapy, and if so,
16 what the protected categories or classes
17 should be; and

18 (ii) options for processes by which the
19 Secretary could reevaluate requirements
20 with respect to the matters described in
21 clause (i) on an ongoing basis.

22 (2) REPORT.—Not later than the date that is
23 12 months after the Secretary enters into the ar-
24 rangement with the Institute under paragraph (1),
25 the Institute shall submit to the Secretary and to

1 Congress a report on the study conducted under
2 such paragraph.

3 (3) FACTORS FOR IOM TO CONSIDER.—In con-
4 ducting the study required by this subsection, the
5 Institute shall consider—

6 (A) the existing regulatory and statutory
7 framework for beneficiary protections under
8 part D of title XVIII of the Social Security Act,
9 including the coverage determination and ap-
10 peals processes under such part;

11 (B) the role of Pharmacy and Therapeutic
12 Committees in selecting drugs to be included on
13 the formulary of a prescription drug plan or an
14 MA–PD plan; and

15 (C) the implications of the presence or ab-
16 sence of such drug/drug category or class pro-
17 tections on spending under the Medicare pro-
18 gram, including spending on non-drug services,
19 such as hospital and physician care.

20 (4) COMMITTEE.—The committee appointed by
21 the Institute to conduct the study and prepare the
22 report required by this subsection shall include indi-
23 viduals with expertise in economics, clinical pharma-
24 cology, actuarial sciences, pharmacy benefit design,
25 and medicine.

1 (5) AUTHORIZATION OF APPROPRIATIONS.—

2 There are authorized to be appropriated such sums
3 as may be necessary for purposes of conducting the
4 study and preparing the report required by this sub-
5 section.

6 **SEC. 113. CERTAINTY REGARDING EXCLUDED DRUGS.**

7 Section 1860D–2(e) of the Social Security Act (42
8 U.S.C. 1395w–102(e)) is amended by adding at the end
9 the following new paragraphs:

10 “(4) ANNUAL PUBLICATION.—By not later than
11 April 1 of each year (beginning with 2007), the Sec-
12 retary shall identify and cause to have published in
13 the Federal Register the list of drugs that are ex-
14 cluded under paragraph (2)(A) for the subsequent
15 year. Such list shall describe the drugs by National
16 Drug Code Directory level.

17 “(5) BENEFICIARY NOTICE.—With respect to
18 activities conducted under section 1860D–1(c)(1) for
19 each plan year (beginning with plan year 2007), the
20 Secretary shall inform eligible part D individuals
21 (and prospective part D eligible individuals) of the
22 types of drugs excluded under paragraph (2)(A) in
23 conducting such activities.”.

1 **SEC. 114. PHARMACY AND THERAPEUTIC COMMITTEE IM-**
2 **PROVEMENTS.**

3 (a) DISCLOSURE OF CONFLICTS OF INTEREST FOR
4 MEMBERS OF PHARMACY AND THERAPEUTIC COM-
5 MITTEE.—Section 1860D–4(b)(3)(A) of the Social Secu-
6 rity Act (42 U.S.C. 1395w–104(b)(3)(A)) is amended by
7 adding at the end the following new clause:

8 “(iii) DISCLOSURE.—Beginning No-
9 vember 1, 2006, such committee shall an-
10 nually disclose to the Secretary, and, upon
11 request, to the public, any conflict of inter-
12 est members have with a pharmaceutical
13 company, an insurer, a PDP sponsor or an
14 MA organization, or any other relevant en-
15 tity.”.

16 (b) DISCLOSURE OF DECISIONS AND BASES FOR DE-
17 CISIONS.—Section 1860D–4(b)(3)(B) of the Social Secu-
18 rity Act (42 U.S.C. 1395w–104(b)(3)(B)) is amended by
19 adding at the end the following flush sentence:

20 “With respect to decisions made by such Com-
21 mittee regarding the formulary for plan years
22 beginning on or after January 1, 2007, the
23 committee shall disclose such decisions (and the
24 bases for such decisions) to the Secretary, and,
25 upon request, to the public.”.

1 **Subtitle C—Funding Certain Costs**
 2 **for Administrative Improvements**

3 **SEC. 121. ADDITIONAL FUNDING FOR ENROLLMENT ASSIST-**
 4 **ANCE.**

5 (a) IN GENERAL.—There are appropriated, to be
 6 transferred from the Federal Supplementary Medical In-
 7 surance Trust Fund, not to exceed \$120,000,000 for the
 8 Centers for Medicare & Medicaid Services, for the purpose
 9 of ensuring that individuals have adequate access to im-
 10 partial advice and assistance in enrolling in the prescrip-
 11 tion drug program under part D of title XVIII of the So-
 12 cial Security Act.

13 (b) USE OF FUNDS.—Amounts provided under sub-
 14 section (a) shall be used for the following purposes:

15 (1) GRANTS TO STATE HEALTH INSURANCE AS-
 16 SISTANCE PROGRAMS.—To provide additional grants
 17 to State health insurance counseling programs (re-
 18 ceiving assistance under section 4360 of the Omni-
 19 bus Reconciliation Act of 1990) to broaden their ca-
 20 pacity to—

21 (A) provide personal and impartial assist-
 22 ance to individuals seeking to enroll in a pre-
 23 scription drug plan or an MA–PD plan under
 24 such program;

1 (B) educate and assist individuals in ap-
2 plying for a low-income subsidy under section
3 1860D–14 of such Act (42 U.S.C. 1395w–114);
4 and

5 (C) assist individuals in accessing benefits
6 under such a prescription drug plan or such an
7 MA–PD plan once they are enrolled in a plan.

8 (2) GRANTS FOR INNOVATIVE PROGRAMS.—To
9 provide grants to eligible States to conduct innova-
10 tive programs that provide any of the services de-
11 scribed in subparagraphs (A), (B), and (C) of para-
12 graph (1). A State is eligible for a grant under this
13 paragraph if the level of enrollment in the State in
14 the prescription drug program under such part is
15 below the national average.

16 (3) PROMOTION.—To widely promote and dis-
17 seminate information about the existence of, and
18 services provided by, State health insurance coun-
19 seling programs.

20 (c) PRIORITY.—In awarding grants under para-
21 graphs (1) and (2) of subsection (b), priority shall be given
22 to States, and State health insurance counseling programs
23 located in States, with the lowest percentage of part D
24 eligible individuals enrolled in such prescription drug pro-
25 gram.

1 (d) AVAILABILITY.—Amounts provided under sub-
 2 section (a) shall remain available until December 31,
 3 2010.

4 **TITLE II—BENEFICIARY** 5 **PROTECTION IMPROVEMENTS**

6 **SEC. 201. IMPROVED PLAN INFORMATION.**

7 (a) COMPARATIVE INFORMATION PROVIDED BY THE
 8 SECRETARY.—

9 (1) IN GENERAL.—Section 1860D–1(c)(3) of
 10 the Social Security Act (42 U.S.C. 1395w–
 11 101(c)(3)) is amended—

12 (A) in subparagraph (A), by adding at the
 13 end the following new clause:

14 “(vi) COST AND UTILIZATION MAN-
 15 AGEMENT TOOLS.—A clear and prominent
 16 display of the cost and utilization manage-
 17 ment tools used under the plan to impose
 18 a restriction or limitation on the coverage
 19 of a drug on the formulary of the plan.”;
 20 and

21 (B) by adding at the end the following new
 22 subparagraph:

23 “(C) REQUIREMENTS.—In disseminating
 24 comparative information under paragraph
 25 (2)(A), the Secretary shall—

1 “(i) ensure that such information
2 clearly distinguishes between—

3 “(I) plans that offer only basic
4 prescription drug coverage and plans
5 that offer supplemental prescription
6 drug coverage;

7 “(II) plans that offer coinsurance
8 and plans that offer flat copayments;
9 and

10 “(III) plans that cover all cov-
11 ered part D drugs and plans that
12 cover less than all such drugs;

13 “(ii) to the extent that comparative
14 information is linked on the Internet to an
15 Internet website of a prescription drug
16 plan or an MA–PD plan, ensure that the
17 information, including information relating
18 to the formulary of the plan, is directly
19 linked to the relevant page of the plan
20 Internet website and not the homepage of
21 such website; and

22 “(iii) use the standardized definitions,
23 nomenclature, language, and format devel-
24 oped under sections 1860D–2(f)(4) and
25 1860D–4(l).”.

1 (2) EFFECTIVE DATE.—The amendments made
 2 by this subsection shall apply with respect to com-
 3 parative information disseminated with respect to
 4 plan years beginning on or after January 1, 2007.

5 (b) INFORMATION PROVIDED BY PLANS.—

6 (1) DRUG SPECIFIC INFORMATION.—Section
 7 1860D–4(a)(1) of the Social Security Act (42
 8 U.S.C. 1395w–104(a)(1)) is amended—

9 (A) in subparagraph (A), by striking “sub-
 10 paragraph (B)” and inserting “subparagraphs
 11 (B), (C), (D), and (E)”;

12 (B) in subparagraph (B), by striking
 13 clauses (ii) and (iii) and inserting the following
 14 new clauses:

15 “(ii) How any formulary used by the
 16 sponsor functions, including, using the
 17 standard definitions developed under sub-
 18 section (l), how any cost and utilization
 19 management tools used to impose a restric-
 20 tion or limitation on the coverage of a drug
 21 on the formulary (such as through the ap-
 22 plication of the tools described in such sub-
 23 section) functions.

24 “(iii) Beneficiary cost-sharing require-
 25 ments, including the tiered or other copay-

1 ment level applicable for each drug (or
2 class of drugs).”; and

3 (C) by adding at the end the following new
4 subparagraphs:

5 “(C) BENEFIT PROCESS INFORMATION.—
6 The information described in this subparagraph
7 is information concerning the benefit process
8 under the plan, including an explanation of
9 what a coverage determination is and how to
10 file a grievance, reconsideration, exception, and
11 appeal.

12 “(D) CONTACT INFORMATION.—The infor-
13 mation described in this subparagraph is the
14 plan’s toll-free customer call line and Internet
15 website and the name, address, and phone num-
16 ber of the plan administrator.

17 “(E) SPECIFIC INFORMATION.—The infor-
18 mation described in this subparagraph is a de-
19 scription of—

20 “(i) the specific information, including
21 the information described in paragraph
22 (2)(A), an enrollee can request of the PDP
23 sponsor under the mechanism described in
24 paragraph (3)(A); and

1 “(ii) how the enrollee can make such
2 a request.”.

3 (2) DISCLOSURE UPON REQUEST OF CERTAIN
4 INFORMATION.—Section 1860D–4(a)(2) of the So-
5 cial Security Act (42 U.S.C. 1395w–104(a)(2)) is
6 amended to read as follows:

7 “(2) DISCLOSURE UPON REQUEST OF CERTAIN
8 INFORMATION.—Upon request of a part D eligible
9 individual who is eligible to enroll in a prescription
10 drug plan, the PDP sponsor offering such plan shall
11 provide such individual with—

12 “(A) information similar (as determined by
13 the Secretary) to the information described in
14 subparagraphs (A) and (C) of section
15 1852(c)(2); and

16 “(B) information disclosed to enrollees
17 under paragraphs (1) and (5).”.

18 (3) STANDARDIZED FORMAT FOR INFORMA-
19 TION.—Section 1860D–4(a) of the Social Security
20 Act (42 U.S.C. 1395w–104(a)), as amended by sec-
21 tion 111(b), is amended by adding at the end the
22 following new paragraph:

23 “(6) STANDARDIZED INFORMATION.—

24 “(A) IN GENERAL.—The Secretary shall
25 standardize the format of the presentation of

information by PDP sponsors of a prescription drug plan to enrollees pursuant to this subsection, including the covered part D drugs covered under the plan’s formulary and the cost and utilization management tools used under the plan.

“(B) WRITTEN AND ELECTRONIC INFORMATION.—Such standardized format shall apply to information presented in writing and electronically.”.

(4) EFFECTIVE DATE.—The amendments made by this subsection shall apply with respect to information provided with respect to plan years beginning on or after January 1, 2007.

SEC. 202. STANDARDIZED DEFINITION FOR COST AND UTILIZATION MANAGEMENT TOOLS AND NOMENCLATURE FOR DISTINGUISHING BETWEEN EXCLUDED AND NONFORMULARY DRUGS.

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

“(1) STANDARDIZED DEFINITIONS AND NOMENCLATURE.—The Secretary shall develop, and require PDP sponsors offering a prescription drug plan to use, the following:

1 “(1) DEFINITION OF COST AND UTILIZATION
 2 MANAGEMENT TOOLS.—A standard definition for
 3 any cost and utilization management tools used
 4 under the plan to impose a restriction or limitation
 5 on the coverage of a drug on the formulary (such as
 6 through the application of a preferred status or
 7 tiered formulary structure, usage restriction, step
 8 therapy, prior authorization, or quantity limitation).

9 “(2) NOMENCLATURE FOR EXCLUDED AND
 10 NONFORMULARY DRUGS.—A standard nomenclature
 11 for referring to, and distinguishing between—

12 “(A) drugs excluded from the definition of
 13 a covered part D drug pursuant to section
 14 1860D–2(e)(2); and

15 “(B) drugs not included on the formulary
 16 under the plan.”.

17 (b) EFFECTIVE DATE.—The Secretary of Health and
 18 Human Services shall provide for the standard definitions
 19 and nomenclature, and the required use of such definitions
 20 and nomenclature, under the amendment made by sub-
 21 section (a) by not later than January 1, 2007.

22 **SEC. 203. STANDARDIZED ENROLLEE NOTICE REGARDING**
 23 **COVERAGE DETERMINATIONS.**

24 (a) IN GENERAL.—Section 1860D–4 of the Social
 25 Security Act (42 U.S.C. 1395w–104), as amended by sec-

1 tion 202(a), is amended by adding at the end the following
 2 new subsection:

3 “(m) STANDARDIZED ENROLLEE NOTICE.—

4 “(1) IN GENERAL.—The Secretary shall develop
 5 a standard notice that PDP sponsors and Medicare
 6 Advantage organizations shall ensure is distributed
 7 by each pharmacy that dispenses a covered part D
 8 drug to an enrollee in a prescription drug plan or an
 9 MA–PD plan when—

10 “(A) a covered part D drug prescribed for
 11 the enrollee is not covered, or the coverage of
 12 such drug is otherwise restricted, by the plan;
 13 or

14 “(B) if the plan uses a tiered formulary
 15 structure, a covered part D drug prescribed for
 16 the enrollee is on a nonpreferred or specialty
 17 tier.

18 “(2) REQUIREMENT FOR NOTICE.—The stand-
 19 ard notice required under paragraph (1) shall in-
 20 clude—

21 “(A) an explanation of the coverage deci-
 22 sion;

23 “(B) information on how to request a re-
 24 consideration and an exception under subsection

1 (g) and how to file an appeal under subsection
2 (h); and

3 “(C) the contact name, address, and phone
4 number for the PDP sponsor of the plan or the
5 Medicare Advantage organization offering the
6 plan.

7 “(3) REQUIRED INFORMATION TO PHAR-
8 MACIES.—A PDP sponsor of a prescription drug
9 plan shall have in place procedures to provide phar-
10 macies with the information necessary for the phar-
11 macy to distribute the appropriate notice required
12 under paragraph (1).

13 “(4) REIMBURSEMENT OF PHARMACY COSTS.—
14 A PDP sponsor of a prescription drug plan shall
15 provide appropriate reimbursement to pharmacies
16 for the costs of the pharmacy in distributing the ap-
17 propriate notice required under paragraph (1)”.

18 (b) EFFECTIVE DATE.—The Secretary of Health and
19 Human Services shall provide for the standard notice, and
20 the use of such notice, under the amendment made by sub-
21 section (a) by not later than January 1, 2007.

1 **SEC. 204. STANDARDIZED AND SIMPLIFIED PROCESSES**
 2 **FOR RECONSIDERATIONS, EXCEPTIONS, AND**
 3 **APPEALS.**

4 (a) STANDARDIZED FORMS AND PROCESSES FOR RE-
 5 CONSIDERATIONS AND EXCEPTIONS.—Section 1860D–4
 6 of the Social Security Act (42 U.S.C. 1395w–104), as
 7 amended by section 203, is amended by adding at the end
 8 the following new subsection:

9 “(n) STANDARDIZED FORMS AND PROCESSES FOR
 10 RECONSIDERATIONS AND EXCEPTIONS.—

11 “(1) STANDARDIZED FORMS.—

12 “(A) IN GENERAL.—The Secretary shall
 13 develop standardized forms to be used under a
 14 prescription drug plan to request a reconsider-
 15 ation or an exception under subsection (g), with
 16 the goal of making such reconsideration and ex-
 17 ceptions process more simple, transparent, and
 18 efficient for enrollees and providers.

19 “(B) REQUIRED USE BY PLANS.—If a
 20 PDP sponsor of a prescription drug plan re-
 21 quires a request for a reconsideration or an ex-
 22 ception to be in writing, the sponsor shall use
 23 the standardized forms developed under sub-
 24 paragraph (A).

25 “(2) STANDARDIZED PROCESSES FOR RECON-
 26 siderations and exceptions.—

1 “(A) IN GENERAL.—The Secretary shall
 2 develop, and require PDP sponsors of prescrip-
 3 tion drug plans to use, a standardized process
 4 for reconsiderations and exceptions under sub-
 5 section (g).

6 “(B) REQUIREMENT.—The process devel-
 7 oped in subparagraph (A)—

8 “(i) shall require that determinations
 9 regarding medical necessity are based on
 10 professional medical judgement, the med-
 11 ical condition of the enrollee, the treating
 12 provider’s recommendation, and other med-
 13 ical evidence; and

14 “(ii) may not require an enrollee or a
 15 provider to submit extraneous information
 16 beyond the standardized form described in
 17 paragraph (1) as a condition for the plan
 18 to make a reconsideration or exception but
 19 shall permit the enrollee or provider to pro-
 20 vide additional information to the request
 21 if they so choose.”.

22 (b) IMPROVED APPEALS PROCESS FOR NONFOR-
 23 MULARY DRUGS.—Section 1860D–4(h)(2) of the Social
 24 Security Act (42 U.S.C. 1395w–104(h)(2)) is amended by
 25 striking “only if” and all that follows through the period

1 and inserting the following: “only if the prescribing physi-
 2 cian determines at least one of the following applies:

3 “(A) That all covered part D drugs on any
 4 tier of the formulary for treatment of the same
 5 condition would not be as effective for the indi-
 6 vidual.

7 “(B) That all covered part D drugs on any
 8 tier of the formulary for treatment of the same
 9 condition would have adverse effects for the in-
 10 dividual.

11 “(C) That the covered part D drug that is
 12 not on the formulary under the plan is the most
 13 effective drug for the individual and that the in-
 14 dividual would destabilize if coverage of the
 15 drug is not provided.”.

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

21 (2) The amendment made by subsection (b) shall
 22 apply to drugs dispensed on or after January 1, 2007.

1 **SEC. 205. STANDARDIZED MARKETING AND LICENSING**
 2 **PROTECTIONS; STATE CERTIFICATION PRIOR**
 3 **TO WAIVER OF LICENSURE REQUIREMENTS.**

4 (a) STANDARDIZED MARKETING REQUIREMENTS.—

5 (1) IN GENERAL.—Section 1860D–1 of the So-
 6 cial Security Act (42 U.S.C. 1395w–101) is amend-
 7 ed—

8 (A) in subsection (b)(1)(B)(vi), by striking
 9 “Section” and inserting “Subject to subsection
 10 (d), section”; and

11 (B) by adding at the end the following new
 12 subsection:

13 “(d) STANDARDIZED MARKETING REQUIREMENTS.—

14 “(1) DEVELOPMENT BY THE NAIC.—

15 “(A) REQUIREMENTS.—The Secretary
 16 shall request the National Association of Insur-
 17 ance Commissioners (in this subsection referred
 18 to as the ‘NAIC’) to—

19 “(i) develop standardized marketing
 20 requirements for prescription drug plans
 21 and MA–PD plans; and

22 “(ii) submit a report on such require-
 23 ments to the Secretary by not later than
 24 April 1, 2007.

25 “(B) PROHIBITED ACTIVITIES.—Such re-
 26 quirements shall prohibit the following:

1 “(i) Cross-selling of non-Medicare
 2 products or services with products or serv-
 3 ices offered by a prescription drug plan
 4 under this part or an MA–PD plan under
 5 part C.

6 “(ii) Up-selling from prescription drug
 7 plans to MA–PD plans.

8 “(iii) Telemarketing (including cold
 9 calling) conducted by a prescription drug
 10 plan or MA–PD plan (or agent of such
 11 plan).

12 “(C) OTHER ACTIVITIES TO ADDRESS.—
 13 Such requirements shall address the conduct of
 14 agents engaged in on-site promotion at a facil-
 15 ity of an organization with which the PDP
 16 sponsor or Medicare Advantage organization
 17 has a cobranding relationship and any other
 18 marketing practices that are determined to be
 19 inappropriate for the eligible part D individual
 20 population.

21 “(2) IMPLEMENTATION OF REQUIREMENTS.—

22 “(A) REQUIREMENTS BASED ON NAIC REC-
 23 OMMENDATIONS.—If the NAIC develops stand-
 24 ardized marketing requirements and submits
 25 the report pursuant to paragraph (1), the Sec-

1 retary shall promulgate regulations for stand-
2 ardized marketing requirements for prescription
3 drug plans and MA–PD plans that are based
4 on the NAIC recommendations contained in
5 such report. The Secretary shall ensure that
6 such regulations take effect not later than July
7 31, 2007.

8 “(B) REQUIREMENTS IF NAIC DOES NOT
9 SUBMIT REPORT.—If the NAIC does not de-
10 velop standardized marketing requirements and
11 submit the report pursuant to paragraph (1),
12 the Secretary shall promulgate regulations for
13 standardized marketing requirements for pre-
14 scription drug plans and MA–PD plans. Such
15 regulations shall prohibit the conduct described
16 in paragraph (1)(B) and address the conduct
17 described in paragraph (1)(C). The Secretary
18 shall ensure that such regulations take effect
19 not later than July 31, 2007.

20 “(3) STATE AUTHORITY TO ENFORCE STAND-
21 ARDIZED MARKETING REQUIREMENTS.—

22 “(A) STATE ENFORCEMENT AGAINST
23 AGENTS OF PRESCRIPTION DRUG PLANS.—Not-
24 withstanding any other provision of law, if a
25 State provides for the adoption of the standard-

1 ized marketing requirements under the regula-
 2 tions under subparagraph (A) or (B) of para-
 3 graph (2), the State may provide for the en-
 4 forcement of such requirements with respect to
 5 agents of prescription drug plans or MA–PD
 6 plans that are licensed within the State.

7 “(B) MEMORANDUM OF UNDERSTANDING
 8 PROVIDING ENFORCEMENT AGAINST PRESCRIP-
 9 TION DRUG PLANS.—Notwithstanding any other
 10 provision of law, the Secretary may enter into
 11 a memorandum of understanding with a State
 12 that provides for State enforcement of such
 13 standardized marketing requirements with re-
 14 spect to prescription drug plans and MA–PD
 15 plans that are licensed within the State.

16 “(C) STATE REPORTING OF VIOLATIONS
 17 OF STANDARDIZED MARKETING REQUIRE-
 18 MENTS.—The Secretary shall request that
 19 States report any violations of such standard-
 20 ized marketing requirements to national and re-
 21 gional offices of the Centers for Medicare &
 22 Medicaid Services.

23 “(D) REPORT.—The Secretary shall sub-
 24 mit an annual report to Congress on the en-
 25 forcement of such standardized marketing re-

quirements, together with such recommendations as the Secretary determines appropriate. Such report shall include—

“(i) a list of any alleged violations of such requirements reported to the Secretary by a State, a PDP sponsor, or a Medicare Advantage organization; and

“(ii) the disposition of such reported violations.”.

(2) REQUIRED COMPLIANCE WITH STANDARDIZED MARKETING REQUIREMENTS FOR PRESCRIPTION DRUG PLANS AND MA-PD PLANS.—

(A) PRESCRIPTION DRUG PLANS.—Section 1860D–12(b) of the Social Security Act (42 U.S.C. 1395w–112(b)) is amended by adding at the end the following new paragraph:

“(4) STANDARDIZED MARKETING REQUIREMENTS.—With respect to plan years beginning on or after January 1, 2008, each contract entered into with a PDP sponsor under this section with respect to a prescription drug plan offered by such sponsor shall provide that the plan (or agents of such plan) shall comply with the standardized marketing requirements under section 1860D–1(d)(2).”.

1 (B) MA–PD PLANS.—Section 1857(f) of
 2 the Social Security Act (42 U.S.C. 1395w–27)
 3 is amended by adding at the end the following
 4 new paragraph:

5 “(3) INCORPORATION OF PRESCRIPTION DRUG
 6 PLAN CONTRACT REQUIREMENT REGARDING MAR-
 7 KETING.—The provisions of section 1860D–12(b)(4)
 8 shall apply to a contract with a Medicare Advantage
 9 organization offering an MA–PD plan in the same
 10 manner as they apply to a contract with a PDP
 11 sponsor offering a prescription drug plan under part
 12 D.”.

13 (b) STATE CERTIFICATION PRIOR TO WAIVER OF LI-
 14 CENSURE REQUIREMENTS.—

15 (1) IN GENERAL.—Section 1860D–12(c) of the
 16 Social Security Act (42 U.S.C. 1395w–112(c)) is
 17 amended—

18 (A) in paragraph (1)(A), by striking “In
 19 the case” and inserting “Subject to paragraph
 20 (5), in the case”; and

21 (B) by adding at the end the following new
 22 paragraph:

23 “(5) STATE CERTIFICATION REQUIRED.—

24 “(A) IN GENERAL.—The Secretary may
 25 only grant a waiver under paragraph (1)(A) if

1 the Secretary has received a certification from
 2 the State insurance commissioner that the pre-
 3 scription drug plan has a substantially complete
 4 application pending in the State.

5 “(B) REVOCATION OF WAIVER UPON FIND-
 6 ING OF FRAUD AND ABUSE.—The Secretary
 7 shall revoke a waiver granted under paragraph
 8 (1)(A) if the State insurance commissioner sub-
 9 mits a certification to the Secretary that the re-
 10 cipient of such a waiver has—

11 “(i) committed fraud or abuse with
 12 respect to such waiver;

13 “(ii) failed to make a good faith effort
 14 to satisfy State licensing requirements; or

15 “(iii) was determined ineligible for li-
 16 censure by the State”.

17 (2) EFFECTIVE DATE.—The amendments made
 18 by paragraph (1) shall apply with respect to plan
 19 years beginning on or after January 1, 2007.

20 **SEC. 206. AUTHORITY TO WAIVE LATE ENROLLMENT PEN-**
 21 **ALTY IN CERTAIN CIRCUMSTANCES.**

22 (a) IN GENERAL.—Section 1860D–13(b) of the So-
 23 cial Security Act (42 U.S.C. 1395w–113(b)) is amended
 24 by adding at the end the following new paragraph:

1 “(8) AUTHORITY TO WAIVE PENALTY.—If the
 2 Secretary finds that a part D eligible individual’s
 3 nonenrollment in a prescription drug plan, an MA–
 4 PD plan, or another plan with creditable prescrip-
 5 tion drug coverage is based on exceptional cir-
 6 cumstances, such as an individual receiving erro-
 7 neous information regarding the program under this
 8 part, the Secretary may waive the application of this
 9 subsection with respect to the individual (or a cat-
 10 egory of individuals) as may be necessary to elimi-
 11 nate the effects of such nonenrollment.”.

12 (b) CONFORMING AMENDMENT TO SPECIAL ENROLL-
 13 MENT PERIODS.—Section 1860D–1(b)(3)(C) of the Social
 14 Security Act (42 U.S.C. 1395w–101(b)(3)(C)) is amended
 15 by inserting “, including the circumstances described in
 16 section 1860D–13(b)(8)” before the period at the end.

17 (c) EFFECTIVE DATE.—The amendments made by
 18 this section shall take effect on the date of enactment of
 19 this Act.

20 **SEC. 207. INTEGRATED APPLICATION AND ENROLLMENT**
 21 **PROCESS FOR CERTAIN SUBSIDY-ELIGIBLE**
 22 **INDIVIDUALS.**

23 (a) IN GENERAL.—Section 1860D–14(a)(3) of the
 24 Social Security Act (42 U.S.C. 1395w–114(a)(3)) is

1 amended by adding at the end the following new subpara-
 2 graph:

3 “(G) INTEGRATED APPLICATION AND EN-
 4 ROLLMENT PROCESS.—The Secretary, jointly
 5 with the Commissioner of Social Security, shall
 6 work to integrate processes and beneficiary in-
 7 formation for applying for a subsidy under this
 8 section and enrolling in a prescription drug
 9 plan or an MA–PD plan under section 1860D–
 10 1(b) in order to simplify steps for part D eligi-
 11 ble individuals who wish to participate in
 12 both.”.

13 (b) EFFECTIVE DATE.—The amendments made by
 14 this section shall take effect on the date of enactment of
 15 this Act.

16 **SEC. 208. GAO STUDY AND REPORT ON COST AND UTILIZA-**
 17 **TION MANAGEMENT TOOLS USED UNDER**
 18 **PRESCRIPTION DRUG PLANS AND MA–PD**
 19 **PLANS.**

20 (a) STUDY.—

21 (1) IN GENERAL.—The Comptroller General of
 22 the United States shall conduct a study on the cost
 23 and utilization management tools used under pre-
 24 scription drug plans under part D of title XVIII of
 25 the Social Security Act and MA–PD plans under

1 part C of such title to impose a restriction or limita-
 2 tion on the coverage of a drug on the formulary
 3 (such as through the application of a preferred sta-
 4 tus or tiered formulary structure, usage restriction,
 5 step therapy, prior authorization, or quantity limita-
 6 tion).

7 (2) REQUIREMENTS.—The study conducted
 8 under paragraph (1) shall include—

9 (A) a comparison of such prescription drug
 10 plans and MA–PD plans regarding the range
 11 and extent of cost and utilization management
 12 tools used under such plans;

13 (B) a comparison of cost and utilization
 14 management tools used under such plans with
 15 the cost and utilization tools used by private in-
 16 surance plans in the commercial market and by
 17 plans under the Federal Employees Health
 18 Benefits Program under chapter 89 of title 5,
 19 United States Code;

20 (C) an assessment of the impact of the
 21 cost and utilization management tools used
 22 under such prescription drug plans and MA–
 23 PD plans on—

24 (i) enrollee access to recommended
 25 medications;

1 (ii) enrollee health;

2 (iii) providers; and

3 (iv) pharmacists;

4 (D) an assessment of the cost-effectiveness
5 of the cost and utilization management tools
6 used under such plans in general, as well as the
7 relative cost-savings and burden of specific
8 tools; and

9 (E) an assessment of the feasibility, advan-
10 tages, and disadvantages of implementing
11 standardized cost and utilization management
12 tools under such plans and standardized criteria
13 for the use of such tools.

14 (b) REPORT.—Not later than September 1, 2007, the
15 Comptroller General shall submit a report to Congress on
16 the study conducted under subsection (a) together with
17 such recommendations for legislation as the Comptroller
18 General considers appropriate.

1 **TITLE III—PERFORMANCE AND**
 2 **QUALITY**

3 **SEC. 301. REQUIREMENTS FOR COMPARATIVE INFORMA-**
 4 **TION REGARDING PERFORMANCE OF PLANS**
 5 **UNDER MEDICARE PART D.**

6 (a) IN GENERAL.—Section 1860D–1(c)(3) of the So-
 7 cial Security Act (42 U.S.C. 1395w–101(c)(3)), as amend-
 8 ed by section 201(a), is amended—

9 (1) in subparagraph (A), in the matter pre-
 10 ceding clause (i), by striking “subparagraph (B)”
 11 and inserting “subparagraphs (B) and (D)”; and

12 (2) by adding at the end the following new sub-
 13 paragraph:

14 “(D) REQUIREMENTS FOR COMPARATIVE
 15 INFORMATION REGARDING PERFORMANCE
 16 UNDER THE PLAN.—The comparative informa-
 17 tion regarding performance under the plan
 18 under subparagraph (A)(iii) shall include a
 19 comparison of the following:

20 “(i) The number of enrollees in the
 21 plan as of September 1 of the year prior
 22 to the plan year for which the information
 23 under this paragraph applies.

1 “(ii) The percentage of all drugs dis-
2 pensed under the plan that were generic
3 drugs.

4 “(iii) The total number of grievances
5 received under the plan.

6 “(iv) The total number of appeals re-
7 ceived under the plan and the percentage
8 of such appeals in which the appeal was
9 successful.

10 “(v) The total number of calls re-
11 ceived at customer service call centers.

12 “(vi) The average time on hold at cus-
13 tomer service call centers under the plan.

14 “(vii) The percentage of drugs dis-
15 pensed under the plan that required prior
16 authorization.

17 “(viii) The percentage of drugs dis-
18 pensed under the plan that required step
19 therapy.

20 “(ix) Any additional information re-
21 garding performance under the plan deter-
22 mined appropriate by the Secretary.

23 With respect to the information described in
24 clauses (ii) through (viii), the Secretary shall

1 specify the time period to be used for compiling
 2 the information.”.

3 (b) REQUIREMENT THAT ENROLLMENT AND AP-
 4 PEALS INFORMATION BE INCLUDED IN COMPARATIVE IN-
 5 FORMATION BEGINNING WITH THE SECOND PLAN
 6 YEAR.—Section 1860D–1(c)(3)(B)(ii) of the Social Secu-
 7 rity Act (42 U.S.C. 1395w–101(c)(3)(B)(ii)) is amended
 8 by striking “for” and inserting “except with respect to the
 9 comparative information under clauses (i), (v), (vi), (vii),
 10 and (viii) of subparagraph (D), for”.

11 (c) EFFECTIVE DATE.—The amendments made by
 12 this section shall apply to comparative information dis-
 13 seminated with respect to plan years beginning on or after
 14 January 1, 2007.

15 **SEC. 302. REQUIRED QUALITY FOR APPROVAL OF PLAN.**

16 Section 1860D–11(e)(2) of the Social Security Act
 17 (42 U.S.C. 1395W–111(e)(2)) is amended by adding at
 18 the end the following new subparagraph:

19 “(E) QUALITY PERFORMANCE.—

20 “(i) IN GENERAL.—With respect to
 21 plan years beginning on or after January
 22 1, 2007, the plan and the PDP sponsor
 23 demonstrate satisfactory quality of per-
 24 formance, as determined by the Secretary.

1 “(ii) DETERMINATION.—In making
2 the determination under clause (i), the
3 Secretary shall consider—

4 “(I) indicators of consumer serv-
5 ice (including grievances and appeals,
6 calls to customer service call centers,
7 errors in transition plans, and errors
8 in charges to enrollees) in the prior
9 year;

10 “(II) indicators of compliance
11 with pharmacy service (including
12 delays in payment) in the prior year;

13 “(III) incorporation by the plan
14 of reports on treatment effectiveness
15 developed by the Agency for
16 Healthcare Research and Quality;

17 “(IV) adverse consequences to
18 the health of enrollees as a con-
19 sequence of formulary, utilization
20 management, or transition policies in
21 the prior year;

22 “(V) indicators resulting from
23 the study conducted under section
24 303 of the Medicare Prescription
25 Drug Simplification Act of 2006;

1 “(VI) the negligent provision to
 2 the Secretary of inaccurate formulary
 3 information for inclusion in the com-
 4 parative information disseminated
 5 under section 1860D–1(c); and

6 “(VII) clinical quality indicators
 7 determined appropriate by the Sec-
 8 retary.”.

9 **SEC. 303. MEDPAC STUDY AND REPORT REGARDING A**
 10 **VALUE-BASED PURCHASING PROGRAM FOR**
 11 **PLANS OFFERING PART D PRESCRIPTION**
 12 **DRUG COVERAGE.**

13 (a) STUDY.—The Medicare Payment Advisory Com-
 14 mission shall conduct a study on the establishment and
 15 implementation of a value-based purchasing program
 16 under the Medicare program under title XVIII of the So-
 17 cial Security Act with respect to the provision of prescrip-
 18 tion drug coverage under part D of such title under pre-
 19 scription drug plans and fallback prescription drug plans
 20 under such part D, under Medicare Advantage plans
 21 under part C of such title, and under reasonable cost con-
 22 tracts under section 1876(h) of such Act (42 U.S.C.
 23 1395mm). Such study shall include an analysis of poten-
 24 tial clinical quality indicators and options for aligning pay-
 25 ments to such plans with performance with respect to the

1 provision of prescription drug coverage under such part
2 D.

3 (b) REPORT.—Not later than June 1, 2007, the Com-
4 mission shall submit a report to Congress and the Sec-
5 retary on the study conducted under subsection (a) to-
6 gether with recommendations for such legislation and ad-
7 ministrative actions as the Commission considers appro-
8 priate.

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