109TH CONGRESS
2D SESSION

S. _____

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

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

A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

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

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

TITLE I—BENEFITS SIMPLIFICATION AND IMPROVEMENT

Subtitle A—Simplification

SEC. 101. ESTABLISHMENT OF NATIONAL UNIFORM PART D BENEFIT PACKAGES.

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

''(f) SIMPLIFICATION OF COVERAGE.—

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

''(2) ESTABLISHMENT OF NATIONAL UNIFORM BENEFIT PACKAGES.—The Secretary, in consultation with the entities and individuals described in paragraph (5), shall establish 5 national uniform benefit packages (that are in addition to standard prescription drug coverage) as follows:

''(A) THREE BASIC PACKAGES.—

''(i) IN GENERAL.—Three of the benefit packages shall only provide basic prescription drug coverage described in subsection (a)(3)(B).

''(ii) SPECIFICATION.—Of the benefit packages described in clause (i)—

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

''(II) one package, other than the package described in subclause (I), shall include a deductible that is equal to the amount determined under section 1860D–2(b)(1)(A)(ii) and provide for copayment amounts, specified by the Secretary, rather than coinsurance, for costs above the annual deductible and up to the initial coverage limit; and

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

''(B) TWO SUPPLEMENTAL PACKAGES.—

''(i) IN GENERAL.—Two of the benefit packages shall include supplemental prescription drug coverage described in subsection (a)(2)(A).

''(ii) SPECIFICATION.—Of the benefit packages described in clause (i)—

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

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

''(3) REQUIREMENT FOR ACTUARIAL VALUE OF PACKAGES.—

''(A) BASIC PACKAGES.—The Secretary shall ensure that the 3 packages described in paragraph (2)(A) meet the following requirements:

''(i) ASSURING EQUIVALENT VALUE OF TOTAL COVERAGE.—The actuarial value of the total coverage is equal to the actuarial value of standard prescription drug 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—

''(I) the amount by which the initial coverage limit described in subsection (b)(3) for the year exceeds the deductible described in subsection (b)(1) for the year; and

''(II) 100 percent minus the coinsurance percentage specified in subsection (b)(2)(B).

''(B) SUPPLEMENTAL PACKAGES.—The Secretary shall ensure that the 2 packages described in paragraph (2)(B) have actuarial values that are progressively greater than the actuarial value of standard prescription drug coverage, as estimated by the Chief Actuary of the Centers for Medicare & Medicaid Services.

''(4) RESTRICTION ON NUMBER OF TIERS OR LEVELS OF COST-SHARING.—

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

''(B) EXCEPTION.—A package described in paragraph (2) may include a fourth distinct tier or level of cost-sharing that may only be used 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

organizations with respect to such benefit packages; and

''(ii) a standardized format to be used by PDP sponsors and MA–PD organizations with respect to such benefit packages.

''(B) REQUIREMENT.—In developing standardized language, nomenclature, and definitions and a standardized format under subparagraph (A), the Secretary shall ensure that such language, nomenclature, definitions, and format clearly distinguishes between—

''(i) a plan that offers only basic prescription drug coverage (as described in subsection (a)(3)) and a plan that offers supplemental prescription drug coverage (as described in subsection (a)(2)(A));

''(ii) a plan that offers coinsurance and a plan that offers flat copayments;

''(iii) a plan that covers all covered part D drugs and a plan that covers less than all such drugs; and

''(iv) prescription drug plans and MA–PDs, especially on terms of how enrollment in those plans would affect access to items and services under the original

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

''(7) ADVISORY COMMITTEE.—

''(A) ESTABLISHMENT.—The Secretary shall establish a Benefit Advisory Committee (in this paragraph referred to as the Committee).

''(B) MEMBERSHIP.—The Committee shall be composed of 15 members to be appointed by the Secretary. The Secretary shall ensure that the following individuals are appointed to the Committee:

''(i) Two representatives appointed upon recommendation of the National Association of Insurance Commissioners.

''(ii) The Chief Actuary of the Centers for Medicare & Medicaid Services.

''(iii) Two individuals with expertise in consumer choice.

''(iv) Two individuals with expertise in health economics.

''(v) Two individuals with expertise in actuarial sciences.

''(vi) Two individuals with expertise in pharmacy benefit management.

"(vii) Two representatives of health insurers, health care providers, and consumers.

"(viii) Two other individuals or entities determined appropriate by the Secretary.

"(C) CONSULTATION.—In establishing the benefit packages under paragraph (2) (including determinations under paragraph (3)), the Secretary shall consult with the Committee.

"(8) UPDATING OF BENEFIT PACKAGES.—Not less than once every 3 years, the Secretary shall review the benefit packages established under this subsection, and, subject to the requirements under paragraph (2), shall update the content of such packages as appropriate.

"(9) NO EFFECT ON REQUIREMENT TO OFFER A PLAN THAT ONLY PROVIDES BASIC PRESCRIPTION DRUG COVERAGE.—Nothing in this subsection shall be construed to effect the requirement under subsection (a)(2)(B).".

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

(1) in subsection (a)—

(A) in paragraph (1)—

(i) in the matter preceding subparagraph (A), by striking ''For purposes'' and inserting ''Subject to subsection (f), for purposes'';

(ii) in subparagraph (B), by striking ''which meets the alternative'' and all that follows through the period at the end and inserting the following: ''which—

''(i) with respect to plan years beginning prior to January 1, 2008, meets the alternative prescription drug requirements of subsection (c) and access to negotiated prices under subsection (d), but only if the benefit design of such coverage is approved by the Secretary, as provided under subsection (c); or

''(ii) with respect to plan years beginning on or after January 1, 2008, meets the requirements of subsection (f) and access to negotiated prices under subsection (d), but only if the benefit design of such coverage is approved by the Secretary, in accordance with subsection (f).''.

(B) in paragraph (2)(A), in the matter preceding clause (i), by inserting ''and subsection (f)'' after ''subparagraph (B)'';

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

''(2) 25 PERCENT COINSURANCE.—The coverage has coinsurance (for costs above the annual deductible specified in paragraph (1) and up to the initial coverage limit under paragraph (3)) that is—

''(A) prior to January 1, 2008—

''(i) equal to 25 percent; or

''(ii) actuarially equivalent (using processes and methods established under section 1860D–11(c)) to an average expected payment of 25 percent of such costs; or

''(B) beginning on January 1, 2008, is equal to 25 percent.''.

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.

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

''(E) REMOVING OR CHANGING A DRUG ON A FORMULARY.—

''(i) LIMITATION.—Subject to clause (ii), with respect to plan years beginning on or after January 1, 2007, the PDP sponsor of a prescription drug plan may not remove a covered part D drug from the plan formulary, apply a cost or utilization management tool that imposes a restriction or limitation on the coverage of such a drug (such as through the application of a preferred status, usage restriction, step therapy, prior authorization, or quantity limitation), or increase the cost-sharing of such a drug (such as through placement of 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

the plan determines, based directly on evidence from peer-reviewed research, has a lower safety profile than is appropriate or is ineffective; or

''(IV) for which the Secretary establishes a specific exception through the promulgation of regulations relating to plan formularies.

''(iii) LIMITED APPLICATION OF EXCEPTIONS TO DRUGS IN CERTAIN CATEGORIES AND CLASSES.—For 2007 and 2008, subclauses (I), (II), (IV), and (V) of clause (ii) shall not apply to a drug in a category or class described in section 1860D–4(b)(3)(H)(i).

''(iv) NOTICE OF REMOVAL UNDER APPLICATION OF EXCEPTION TO LIMITATION.—The PDP sponsor of a prescription drug plan shall provide appropriate notice (such as under subsection (a)(3) and includes the annual notice under subsection (a)(5)) of any removal or change under clause (ii) to the Secretary, affected enrollees, physicians, pharmacies, and pharmacists.''.

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

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

''(5) ANNUAL NOTICE OF CHANGES IN FORMULARY AND OTHER RESTRICTIONS OR LIMITATIONS ON COVERAGE.—Each PDP sponsor offering a prescription drug plan shall furnish to each enrollee at the time of each annual coordinated election period (referred to in section 1860D–1(b)(1)(B)(iii)) for a plan year a notice of any changes in the formulary or other restrictions or limitations on coverage of any covered part D drug under the plan that will take effect for the plan year.''.

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

SEC. 112. FORMULARY REQUIREMENT WITH RESPECT TO CERTAIN CATEGORIES AND CLASSES OF DRUGS.

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

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

''(ii) SUBSTANTIALLY ALL DEFINED.—For purposes of clause (i), the term 'substantially all' means all drugs and unique dosage forms in the categories described in such clause except for—

''(I) multi-source brands of the identical molecular structure;

''(II) extended release products when the immediate-release product is included on the formulary;

''(III) products that have the same active ingredient; and

''(IV) multiple dosage forms that do not provide a unique route of administration, such as tablets and capsules.

''(iii) FOR 2009 AND SUBSEQUENT YEARS.—

''(I) AUTHORITY.—Beginning with the plan year beginning on January 1, 2009, the Secretary, taking into account the results of the study conducted under section 113(b) of the

Medicare Prescription Drug Simplification Act of 2006, may require that the formulary include coverage of covered part D drugs within certain categories or classes of drugs.

''(II) REQUIREMENT FOR USE OF AUTHORITY.—The Secretary shall promulgate regulations to exercise the authority under subclause (I) and may not exercise such authority through program guidance.''.

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

(1) STUDY.—

(A) IN GENERAL.—Not later than the date that is 2 months after the date of the enactment of this Act, the Secretary of Health and Human Services (in this subsection referred to as the ''Secretary'') shall enter into an arrangement under which the Institute of Medicine of the National Academy of Sciences (in this subsection referred to as the ''Institute'') shall conduct a study on issues related to requiring any formulary used under prescription drug plans under part D of title XVIII of the Social Secu-

rity Act or under MA–PD plans under part C of such title to cover drugs within certain categories or classes.

(B) REQUIRED ITEMS TO BE EVALUATED.—The study conducted under subparagraph (A) shall include an evaluation of—

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

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

(2) REPORT.—Not later than the date that is 12 months after the Secretary enters into the arrangement with the Institute under paragraph (1), the Institute shall submit to the Secretary and to

Congress a report on the study conducted under such paragraph.

(3) FACTORS FOR IOM TO CONSIDER.—In conducting the study required by this subsection, the Institute shall consider—

(A) the existing regulatory and statutory framework for beneficiary protections under part D of title XVIII of the Social Security Act, including the coverage determination and appeals processes under such part;

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

(C) the implications of the presence or absence of such drug/drug category or class protections on spending under the Medicare program, including spending on non-drug services, such as hospital and physician care.

(4) COMMITTEE.—The committee appointed by the Institute to conduct the study and prepare the report required by this subsection shall include individuals with expertise in economics, clinical pharmacology, actuarial sciences, pharmacy benefit design, and medicine.

(5) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary for purposes of conducting the study and preparing the report required by this subsection.

SEC. 113. CERTAINTY REGARDING EXCLUDED DRUGS.

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

''(4) ANNUAL PUBLICATION.—By not later than April 1 of each year (beginning with 2007), the Secretary shall identify and cause to have published in the Federal Register the list of drugs that are excluded under paragraph (2)(A) for the subsequent year. Such list shall describe the drugs by National Drug Code Directory level.

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

SEC. 114. PHARMACY AND THERAPEUTIC COMMITTEE IMPROVEMENTS.

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

"(iii) DISCLOSURE.—Beginning November 1, 2006, such committee shall annually disclose to the Secretary, and, upon request, to the public, any conflict of interest members have with a pharmaceutical company, an insurer, a PDP sponsor or an MA organization, or any other relevant entity.".

(b) DISCLOSURE OF DECISIONS AND BASES FOR DECISIONS.—Section 1860D–4(b)(3)(B) of the Social Security Act (42 U.S.C. 1395w–104(b)(3)(B)) is amended by adding at the end the following flush sentence:

"With respect to decisions made by such Committee regarding the formulary for plan years beginning on or after January 1, 2007, the committee shall disclose such decisions (and the bases for such decisions) to the Secretary, and, upon request, to the public.".

Subtitle C—Funding Certain Costs for Administrative Improvements

SEC. 121. ADDITIONAL FUNDING FOR ENROLLMENT ASSISTANCE.

(a) IN GENERAL.—There are appropriated, to be transferred from the Federal Supplementary Medical Insurance Trust Fund, not to exceed $120,000,000 for the Centers for Medicare & Medicaid Services, for the purpose of ensuring that individuals have adequate access to impartial advice and assistance in enrolling in the prescription drug program under part D of title XVIII of the Social Security Act.

(b) USE OF FUNDS.—Amounts provided under subsection (a) shall be used for the following purposes:

(1) GRANTS TO STATE HEALTH INSURANCE ASSISTANCE PROGRAMS.—To provide additional grants to State health insurance counseling programs (receiving assistance under section 4360 of the Omnibus Reconciliation Act of 1990) to broaden their capacity to—

(A) provide personal and impartial assistance to individuals seeking to enroll in a prescription drug plan or an MA–PD plan under such program;

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

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

(2) GRANTS FOR INNOVATIVE PROGRAMS.—To provide grants to eligible States to conduct innovative programs that provide any of the services described in subparagraphs (A), (B), and (C) of paragraph (1). A State is eligible for a grant under this paragraph if the level of enrollment in the State in the prescription drug program under such part is below the national average.

(3) PROMOTION.—To widely promote and disseminate information about the existence of, and services provided by, State health insurance counseling programs.

(c) PRIORITY.—In awarding grants under paragraphs (1) and (2) of subsection (b), priority shall be given to States, and State health insurance counseling programs located in States, with the lowest percentage of part D eligible individuals enrolled in such prescription drug program.

(d) AVAILABILITY.—Amounts provided under subsection (a) shall remain available until December 31, 2010.

TITLE II—BENEFICIARY PROTECTION IMPROVEMENTS

SEC. 201. IMPROVED PLAN INFORMATION.

(a) COMPARATIVE INFORMATION PROVIDED BY THE SECRETARY.—

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

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

''(vi) COST AND UTILIZATION MANAGEMENT TOOLS.—A clear and prominent display of the cost and utilization management tools used under the plan to impose a restriction or limitation on the coverage of a drug on the formulary of the plan.''; and

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

''(C) REQUIREMENTS.—In disseminating comparative information under paragraph (2)(A), the Secretary shall—

"(i) ensure that such information clearly distinguishes between—

"(I) plans that offer only basic prescription drug coverage and plans that offer supplemental prescription drug coverage;

"(II) plans that offer coinsurance and plans that offer flat copayments; and

"(III) plans that cover all covered part D drugs and plans that cover less than all such drugs;

"(ii) to the extent that comparative information is linked on the Internet to an Internet website of a prescription drug plan or an MA–PD plan, ensure that the information, including information relating to the formulary of the plan, is directly linked to the relevant page of the plan Internet website and not the homepage of such website; and

"(iii) use the standardized definitions, nomenclature, language, and format developed under sections 1860D–2(f)(4) and 1860D–4(l).".

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

(b) INFORMATION PROVIDED BY PLANS.—

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

(A) in subparagraph (A), by striking ''subparagraph (B)'' and inserting ''subparagraphs (B), (C), (D), and (E)'';

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

''(ii) How any formulary used by the sponsor functions, including, using the standard definitions developed under subsection (l), how any cost and utilization management tools used to impose a restriction or limitation on the coverage of a drug on the formulary (such as through the application of the tools described in such subsection) functions.

''(iii) Beneficiary cost-sharing requirements, including the tiered or other copay-

ment level applicable for each drug (or class of drugs).''; and

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

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

''(D) CONTACT INFORMATION.—The information described in this subparagraph is the plan's toll-free customer call line and Internet website and the name, address, and phone number of the plan administrator.

''(E) SPECIFIC INFORMATION.—The information described in this subparagraph is a description of—

''(i) the specific information, including the information described in paragraph (2)(A), an enrollee can request of the PDP sponsor under the mechanism described in paragraph (3)(A); and

"(ii) how the enrollee can make such a request.".

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

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

"(A) information similar (as determined by the Secretary) to the information described in subparagraphs (A) and (C) of section 1852(c)(2); and

"(B) information disclosed to enrollees under paragraphs (1) and (5).".

(3) STANDARDIZED FORMAT FOR INFORMATION.—Section 1860D–4(a) of the Social Security Act (42 U.S.C. 1395w–104(a)), as amended by section 111(b), is amended by adding at the end the following new paragraph:

"(6) STANDARDIZED INFORMATION.—

"(A) IN GENERAL.—The Secretary shall 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:

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

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

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

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

''(B) drugs not included on the formulary under the plan.''.

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

SEC. 203. STANDARDIZED ENROLLEE NOTICE REGARDING COVERAGE DETERMINATIONS.

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

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

''(m) STANDARDIZED ENROLLEE NOTICE.—

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

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

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

''(2) REQUIREMENT FOR NOTICE.—The standard notice required under paragraph (1) shall include—

''(A) an explanation of the coverage decision;

''(B) information on how to request a reconsideration and an exception under subsection

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

''(C) the contact name, address, and phone number for the PDP sponsor of the plan or the Medicare Advantage organization offering the plan.

''(3) REQUIRED INFORMATION TO PHARMACIES.—A PDP sponsor of a prescription drug plan shall have in place procedures to provide pharmacies with the information necessary for the pharmacy to distribute the appropriate notice required under paragraph (1).

''(4) REIMBURSEMENT OF PHARMACY COSTS.—A PDP sponsor of a prescription drug plan shall provide appropriate reimbursement to pharmacies for the costs of the pharmacy in distributing the appropriate notice required under paragraph (1)''.

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

SEC. 204. STANDARDIZED AND SIMPLIFIED PROCESSES FOR RECONSIDERATIONS, EXCEPTIONS, AND APPEALS.

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

''(n) STANDARDIZED FORMS AND PROCESSES FOR RECONSIDERATIONS AND EXCEPTIONS.—

''(1) STANDARDIZED FORMS.—

''(A) IN GENERAL.—The Secretary shall develop standardized forms to be used under a prescription drug plan to request a reconsideration or an exception under subsection (g), with the goal of making such reconsideration and exceptions process more simple, transparent, and efficient for enrollees and providers.

''(B) REQUIRED USE BY PLANS.—If a PDP sponsor of a prescription drug plan requires a request for a reconsideration or an exception to be in writing, the sponsor shall use the standardized forms developed under subparagraph (A).

''(2) STANDARDIZED PROCESSES FOR RECONSIDERATIONS AND EXCEPTIONS.—

''(A) IN GENERAL.—The Secretary shall develop, and require PDP sponsors of prescription drug plans to use, a standardized process for reconsiderations and exceptions under subsection (g).

''(B) REQUIREMENT.—The process developed in subparagraph (A)—

''(i) shall require that determinations regarding medical necessity are based on professional medical judgement, the medical condition of the enrollee, the treating provider's recommendation, and other medical evidence; and

''(ii) may not require an enrollee or a provider to submit extraneous information beyond the standardized form described in paragraph (1) as a condition for the plan to make a reconsideration or exception but shall permit the enrollee or provider to provide additional information to the request if they so choose.''.

(b) IMPROVED APPEALS PROCESS FOR NONFORMULARY DRUGS.—Section 1860D–4(h)(2) of the Social Security Act (42 U.S.C. 1395w–104(h)(2)) is amended by striking ''only if'' and all that follows through the period

and inserting the following: ''only if the prescribing physician determines at least one of the following applies:

''(A) That all covered part D drugs on any tier of the formulary for treatment of the same condition would not be as effective for the individual.

''(B) That all covered part D drugs on any tier of the formulary for treatment of the same condition would have adverse effects for the individual.

''(C) That the covered part D drug that is not on the formulary under the plan is the most effective drug for the individual and that the individual would destabilize if coverage of the drug is not provided.''.

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

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

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

(a) STANDARDIZED MARKETING REQUIREMENTS.—

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

(A) in subsection (b)(1)(B)(vi), by striking ''Section'' and inserting ''Subject to subsection (d), section''; and

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

''(d) STANDARDIZED MARKETING REQUIREMENTS.—

''(1) DEVELOPMENT BY THE NAIC.—

''(A) REQUIREMENTS.—The Secretary shall request the National Association of Insurance Commissioners (in this subsection referred to as the 'NAIC') to—

''(i) develop standardized marketing requirements for prescription drug plans and MA–PD plans; and

''(ii) submit a report on such requirements to the Secretary by not later than April 1, 2007.

''(B) PROHIBITED ACTIVITIES.—Such requirements shall prohibit the following:

''(i) Cross-selling of non-Medicare products or services with products or services offered by a prescription drug plan under this part or an MA–PD plan under part C.

''(ii) Up-selling from prescription drug plans to MA–PD plans.

''(iii) Telemarketing (including cold calling) conducted by a prescription drug plan or MA–PD plan (or agent of such plan).

''(C) OTHER ACTIVITIES TO ADDRESS.—Such requirements shall address the conduct of agents engaged in on-site promotion at a facility of an organization with which the PDP sponsor or Medicare Advantage organization has a cobranding relationship and any other marketing practices that are determined to be inappropriate for the eligible part D individual population.

''(2) IMPLEMENTATION OF REQUIREMENTS.—

''(A) REQUIREMENTS BASED ON NAIC RECOMMENDATIONS.—If the NAIC develops standardized marketing requirements and submits the report pursuant to paragraph (1), the Sec-

retary shall promulgate regulations for standardized marketing requirements for prescription drug plans and MA–PD plans that are based on the NAIC recommendations contained in such report. The Secretary shall ensure that such regulations take effect not later than July 31, 2007.

''(B) REQUIREMENTS IF NAIC DOES NOT SUBMIT REPORT.—If the NAIC does not develop standardized marketing requirements and submit the report pursuant to paragraph (1), the Secretary shall promulgate regulations for standardized marketing requirements for prescription drug plans and MA–PD plans. Such regulations shall prohibit the conduct described in paragraph (1)(B) and address the conduct described in paragraph (1)(C). The Secretary shall ensure that such regulations take effect not later than July 31, 2007.

''(3) STATE AUTHORITY TO ENFORCE STANDARDIZED MARKETING REQUIREMENTS.—

''(A) STATE ENFORCEMENT AGAINST AGENTS OF PRESCRIPTION DRUG PLANS.—Notwithstanding any other provision of law, if a State provides for the adoption of the standard-

ized marketing requirements under the regulations under subparagraph (A) or (B) of paragraph (2), the State may provide for the enforcement of such requirements with respect to agents of prescription drug plans or MA–PD plans that are licensed within the State.

''(B) MEMORANDUM OF UNDERSTANDING PROVIDING ENFORCEMENT AGAINST PRESCRIPTION DRUG PLANS.—Notwithstanding any other provision of law, the Secretary may enter into a memorandum of understanding with a State that provides for State enforcement of such standardized marketing requirements with respect to prescription drug plans and MA–PD plans that are licensed within the State.

''(C) STATE REPORTING OF VIOLATIONS OF STANDARDIZED MARKETING REQUIREMENTS.—The Secretary shall request that States report any violations of such standardized marketing requirements to national and regional offices of the Centers for Medicare & Medicaid Services.

''(D) REPORT.—The Secretary shall submit an annual report to Congress on the enforcement 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).''.

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

''(3) INCORPORATION OF PRESCRIPTION DRUG PLAN CONTRACT REQUIREMENT REGARDING MARKETING.—The provisions of section 1860D–12(b)(4) shall apply to a contract with a Medicare Advantage organization offering an MA–PD plan in the same manner as they apply to a contract with a PDP sponsor offering a prescription drug plan under part D.''.

(b) STATE CERTIFICATION PRIOR TO WAIVER OF LICENSURE REQUIREMENTS.—

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

(A) in paragraph (1)(A), by striking ''In the case'' and inserting ''Subject to paragraph (5), in the case''; and

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

''(5) STATE CERTIFICATION REQUIRED.—

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

the Secretary has received a certification from the State insurance commissioner that the prescription drug plan has a substantially complete application pending in the State.

''(B) REVOCATION OF WAIVER UPON FINDING OF FRAUD AND ABUSE.—The Secretary shall revoke a waiver granted under paragraph (1)(A) if the State insurance commissioner submits a certification to the Secretary that the recipient of such a waiver has—

''(i) committed fraud or abuse with respect to such waiver;

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

''(iii) was determined ineligible for licensure by the State''.

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

SEC. 206. AUTHORITY TO WAIVE LATE ENROLLMENT PENALTY IN CERTAIN CIRCUMSTANCES.

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

''(8) AUTHORITY TO WAIVE PENALTY.—If the Secretary finds that a part D eligible individual's nonenrollment in a prescription drug plan, an MA–PD plan, or another plan with creditable prescription drug coverage is based on exceptional circumstances, such as an individual receiving erroneous information regarding the program under this part, the Secretary may waive the application of this subsection with respect to the individual (or a category of individuals) as may be necessary to eliminate the effects of such nonenrollment.''.

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

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

SEC. 207. INTEGRATED APPLICATION AND ENROLLMENT PROCESS FOR CERTAIN SUBSIDY-ELIGIBLE INDIVIDUALS.

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

amended by adding at the end the following new subparagraph:

"(G) INTEGRATED APPLICATION AND ENROLLMENT PROCESS.—The Secretary, jointly with the Commissioner of Social Security, shall work to integrate processes and beneficiary information for applying for a subsidy under this section and enrolling in a prescription drug plan or an MA–PD plan under section 1860D–1(b) in order to simplify steps for part D eligible individuals who wish to participate in both.".

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

SEC. 208. GAO STUDY AND REPORT ON COST AND UTILIZATION MANAGEMENT TOOLS USED UNDER PRESCRIPTION DRUG PLANS AND MA–PD PLANS.

(a) STUDY.—

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

part C of such title to impose a restriction or limitation on the coverage of a drug on the formulary (such as through the application of a preferred status or tiered formulary structure, usage restriction, step therapy, prior authorization, or quantity limitation).

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

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

(B) a comparison of cost and utilization management tools used under such plans with the cost and utilization tools used by private insurance plans in the commercial market and by plans under the Federal Employees Health Benefits Program under chapter 89 of title 5, United States Code;

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

(i) enrollee access to recommended medications;

(ii) enrollee health;

(iii) providers; and

(iv) pharmacists;

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

(E) an assessment of the feasibility, advantages, and disadvantages of implementing standardized cost and utilization management tools under such plans and standardized criteria for the use of such tools.

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

TITLE III—PERFORMANCE AND QUALITY

SEC. 301. REQUIREMENTS FOR COMPARATIVE INFORMATION REGARDING PERFORMANCE OF PLANS UNDER MEDICARE PART D.

(a) IN GENERAL.—Section 1860D–1(c)(3) of the Social Security Act (42 U.S.C. 1395w–101(c)(3)), as amended by section 201(a), is amended—

(1) in subparagraph (A), in the matter preceding clause (i), by striking ''subparagraph (B)'' and inserting ''subparagraphs (B) and (D)''; and

(2) by adding at the end the following new subparagraph:

''(D) REQUIREMENTS FOR COMPARATIVE INFORMATION REGARDING PERFORMANCE UNDER THE PLAN.—The comparative information regarding performance under the plan under subparagraph (A)(iii) shall include a comparison of the following:

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

"(ii) The percentage of all drugs dispensed under the plan that were generic drugs.

"(iii) The total number of grievances received under the plan.

"(iv) The total number of appeals received under the plan and the percentage of such appeals in which the appeal was successful.

"(v) The total number of calls received at customer service call centers.

"(vi) The average time on hold at customer service call centers under the plan.

"(vii) The percentage of drugs dispensed under the plan that required prior authorization.

"(viii) The percentage of drugs dispensed under the plan that required step therapy.

"(ix) Any additional information regarding performance under the plan determined appropriate by the Secretary.

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

specify the time period to be used for compiling the information.''.

(b) REQUIREMENT THAT ENROLLMENT AND APPEALS INFORMATION BE INCLUDED IN COMPARATIVE INFORMATION BEGINNING WITH THE SECOND PLAN YEAR.—Section 1860D–1(c)(3)(B)(ii) of the Social Security Act (42 U.S.C. 1395w–101(c)(3)(B)(ii)) is amended by striking ''for'' and inserting ''except with respect to the comparative information under clauses (i), (v), (vi), (vii), and (viii) of subparagraph (D), for''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to comparative information disseminated with respect to plan years beginning on or after January 1, 2007.

SEC. 302. REQUIRED QUALITY FOR APPROVAL OF PLAN.

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

''(E) QUALITY PERFORMANCE.—

''(i) IN GENERAL.—With respect to plan years beginning on or after January 1, 2007, the plan and the PDP sponsor demonstrate satisfactory quality of performance, as determined by the Secretary.

''(ii) DETERMINATION.—In making the determination under clause (i), the Secretary shall consider—

''(I) indicators of consumer service (including grievances and appeals, calls to customer service call centers, errors in transition plans, and errors in charges to enrollees) in the prior year;

''(II) indicators of compliance with pharmacy service (including delays in payment) in the prior year;

''(III) incorporation by the plan of reports on treatment effectiveness developed by the Agency for Healthcare Research and Quality;

''(IV) adverse consequences to the health of enrollees as a consequence of formulary, utilization management, or transition policies in the prior year;

''(V) indicators resulting from the study conducted under section 303 of the Medicare Prescription Drug Simplification Act of 2006;

''(VI) the negligent provision to the Secretary of inaccurate formulary information for inclusion in the comparative information disseminated under section 1860D–1(c); and

''(VII) clinical quality indicators determined appropriate by the Secretary.''.

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

(a) STUDY.—The Medicare Payment Advisory Commission shall conduct a study on the establishment and implementation of a value-based purchasing program under the Medicare program under title XVIII of the Social Security Act with respect to the provision of prescription drug coverage under part D of such title under prescription drug plans and fallback prescription drug plans under such part D, under Medicare Advantage plans under part C of such title, and under reasonable cost contracts under section 1876(h) of such Act (42 U.S.C. 1395mm). Such study shall include an analysis of potential clinical quality indicators and options for aligning payments to such plans with performance with respect to the

provision of prescription drug coverage under such part D.

(b) REPORT.—Not later than June 1, 2007, the Commission shall submit a report to Congress and the Secretary on the study conducted under subsection (a) together with recommendations for such legislation and administrative actions as the Commission considers appropriate.