109TH CONGRESS 2D SESSION	S.
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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) in-
	troduced the following bill; which was read twice and referred to the Com-
	mittee on

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 SIMPLIFICA-

TION AND IMPROVEMENT

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	"(1) 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-

1	ary of the Centers for Medicare & Med-
2	icaid Services.
3	"(ii) Assuring equivalent unsub-
4	SIDIZED VALUE OF COVERAGE.—The un-
5	subsidized value of the coverage is equal to
6	the unsubsidized value of standard pre-
7	scription drug coverage, as estimated by
8	the Chief Actuary of the Centers for Medi-
9	care & Medicaid Services. For purposes of
10	this subparagraph, the unsubsidized value
11	of coverage is the amount by which the ac-
12	tuarial value of the coverage exceeds the
13	actuarial value of the subsidy payments
14	under section 1860D–15 with respect to
15	such coverage.
16	"(iii) Assuring standard payment
17	FOR COSTS AT INITIAL COVERAGE LIMIT.—
18	The coverage is designed, based upon an
19	actuarially representative pattern of utili-
20	zation, to provide for the payment, with re-
21	spect to costs incurred that are equal to
22	the initial coverage limit under subsection
23	(b)(3) for the year, of an amount equal to
24	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 of
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

1	(as determined by the Secretary) if the PDF
2	sponsor of the prescription drug plan or the
3	Medicare Advantage organization offering the
4	MA-PD plan has an exceptions process under
5	subsection (g) with respect to the 4th tier or
6	level.
7	"(5) Balancing of objectives.—In estab
8	lishing the benefit packages under paragraph (2)
9	the Secretary shall balance the objectives of—
10	"(A) simplifying the benefit structures to
11	facilitate comparisons among plans;
12	"(B) avoiding adverse selection;
13	"(C) ensuring meaningful differences be
14	tween benefit packages;
15	"(D) providing program stability; and
16	"(E) promoting competition among plans
17	"(6) Standardized Language, nomen
18	CLATURE, DEFINITIONS, AND FORMAT.—
19	"(A) In GENERAL.—In establishing the
20	benefit packages under paragraph (2), the Sec
21	retary shall develop—
22	"(i) standardized language, nomen
23	clature, and definitions to be used by the
24	Secretary and PDP sponsors and MA-PI

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.".

Subtitle B—Formulary 1 Requirements and Improvements 2 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-

1	er cost-sharing for a beneficiary) other
2	than the date on which PDP sponsors may
3	begin marketing their plans with respect to
4	the immediately succeeding plan year, as
5	determined by the Secretary.
6	"(ii) Exceptions to limitation on
7	REMOVAL.—Subject to clause (iii), clause
8	(i) shall not apply with respect to a cov-
9	ered part D drug that—
10	"(I) is a brand name drug for
11	which there is a generic drug ap-
12	proved under section 505(j) of the
13	Food and Drug Cosmetic Act that is
14	placed on the market during the pe-
15	riod in which there are limitations on
16	removal or change in the formulary
17	under clause (i);
18	"(II) is a drug for which the
19	Commissioner of Food and Drugs
20	issues a safety warning that would im-
21	pose a restriction on the drug or re-
22	quire a drug label warning during the
23	plan year;
24	"(III) is a drug that the Phar-
25	macy 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 adding
5	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	(1) in subparagraph (C)(i), by striking "The
2	formulary" and inserting "Subject to subparagraph
3	(G), the formulary"; and
4	(2) by inserting after subparagraph (F) the fol-
5	lowing new subparagraph:
6	"(G) REQUIRED INCLUSION OF DRUGS IN
7	CERTAIN CATEGORIES AND CLASSES.—
8	"(i) For 2007 and 2008.—For 2007
9	and 2008, the formulary must include all
10	or substantially all drugs in the following
11	6 categories that are available as of June
12	1 of the prior year:
13	"(I) Immunosuppressant.
14	"(II) Antidepressant.
15	"(III) Antipsychotic.
16	"(IV) Anticonvulsant.
17	"(V) Antiretroviral.
18	"(VI) Antineoplastic.
19	A PDP sponsor of a prescription drug plan
20	may not apply a utilization management
21	tool, such as prior authorization or step
22	therapy, to a drug required to be included
23	on the formulary pursuant to the preceding
24	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	plification 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."

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Subtitle C—Funding Certain Costs for Administrative Improvements SEC. 121. ADDITIONAL FUNDING FOR ENROLLMENT ASSISTANCE.

- 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 prescription 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:
 - (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—
- 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 ar
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	"(11) 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(e)(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

1 information by PDP sponsors of a prescription 2 drug plan to enrollees pursuant to this sub-3 section, including the covered part D drugs covered under the plan's formulary and the cost 4 5 and utilization management tools used under 6 the plan. 7 "(B) Written and electronic infor-8 MATION.—Such standardized format shall apply 9 to information presented in writing and elec-10 tronically.". 11 (4) Effective date.—The amendments made 12 by this subsection shall apply with respect to infor-13 mation provided with respect to plan years beginning 14 on or after January 1, 2007. 15 SEC. 202. STANDARDIZED DEFINITION FOR COST AND UTI-16 LIZATION MANAGEMENT TOOLS AND NOMEN-17 CLATURE FOR DISTINGUISHING BETWEEN 18 EXCLUDED AND NONFORMULARY DRUGS. 19 (a) In General.—Section 1860D-4 of the Social 20 Security Act (42 U.S.C. 1395w–104) is amended by add-21 ing at the end the following new subsection: 22 "(1) STANDARDIZED DEFINITIONS AND NOMEN-23 CLATURE.—The Secretary shall develop, and require PDP sponsors offering a prescription drug plan to use, the fol-25 lowing:

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. "(3) State authority to enforce stand-20 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-

24

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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. "(C) STATE REPORTING OF VIOLATIONS 16 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-

mit an annual report to Congress on the en-

forcement of such standardized marketing re-

1	quirements, together with such recommenda-
2	tions as the Secretary determines appropriate.
3	Such report shall include—
4	"(i) a list of any alleged violations of
5	such requirements reported to the Sec-
6	retary by a State, a PDP sponsor, or a
7	Medicare Advantage organization; and
8	"(ii) the disposition of such reported
9	violations.".
10	(2) Required compliance with standard-
11	IZED MARKETING REQUIREMENTS FOR PRESCRIP-
12	TION DRUG PLANS AND MA-PD PLANS.—
13	(A) Prescription drug plans.—Section
14	1860D–12(b) of the Social Security Act (42
15	U.S.C. 1395w-112(b)) is amended by adding at
16	the end the following new paragraph:
17	"(4) Standardized marketing require-
18	MENTS.—With respect to plan years beginning on or
19	after January 1, 2008, each contract entered into
20	with a PDP sponsor under this section with respect
21	to a prescription drug plan offered by such sponsor
22	shall provide that the plan (or agents of such plan)
23	shall comply with the standardized marketing re-
24	quirements 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 section 1860D-13(b)(8)" before the period at the end. 16 17 (c) Effective Date.—The amendments made by 18 this section shall take effect on the date of enactment of 19 this Act. 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 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.

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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

plan as of September 1 of the year prior

to the plan year for which the information

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	(e) 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.