110TH CONGRESS 1ST SESSION **S. 1887**

To amend title XVIII of the Social Security Act in order to ensure access to critical medications under the Medicare part D prescription drug program.

IN THE SENATE OF THE UNITED STATES

JULY 26, 2007

Mr. SMITH (for himself and Mr. KERRY) introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

To amend title XVIII of the Social Security Act in order to ensure access to critical medications under the Medicare part D 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.

- 4 This Act may be cited as the "Medicare Access to
- 5 Critical Medications Act of 2007".

6 SEC. 2. FORMULARY REQUIREMENTS WITH RESPECT TO

7 CERTAIN CATEGORIES AND CLASSES OF
8 DRUGS.

9 (a) REQUIRED INCLUSION OF DRUGS IN CERTAIN
10 CATEGORIES AND CLASSES.—

1	(1) INITIAL LIST.—Section $1860D-4(b)(3)$ of
2	the Social Security Act (42 U.S.C. 1395w-
3	104(b)(3)) is amended—
4	(A) in subparagraph (C)(i), by striking
5	"The formulary" and inserting "Subject to sub-
6	paragraph (G), the formulary"; and
7	(B) by inserting after subparagraph (F)
8	the following new subparagraph:
9	"(G) INITIAL LIST OF REQUIRED DRUGS IN
10	CERTAIN CATEGORIES AND CLASSES.—
11	"(i) IN GENERAL.—Subject to clause
12	(iv), the formulary must include all or sub-
13	stantially all drugs in the following cat-
14	egories and classes that are available as of
15	April 30 of the year prior to the year
16	which includes the date of enactment of
17	the Medicare Access to Critical Medica-
18	tions Act of 2007:
19	"(I) Immunosuppressant.
20	"(II) Antidepressant.
21	"(III) Antipsychotic.
22	"(IV) Anticonvulsant.
23	"(V) Antiretroviral.
24	"(VI) Antineoplastic.
25	"(ii) Newly approved drugs.—

1	"(I) IN GENERAL.—In the case
2	of a drug in any of the categories and
3	classes described in subclauses (I)
4	through (VI) of clause (i) that be-
5	comes available after the April 30
6	date described in clause (i), the for-
7	mulary shall include such drug within
8	30 days of the drug becoming avail-
9	able, except that, in the case of such
10	a drug that becomes available during
11	the period beginning on such April 30
12	and ending on the date of enactment
13	of the Medicare Access to Critical
14	Medications Act of 2007, the for-
15	mulary shall include such drug within
16	30 days of such date of enactment.
17	"(II) USE OF FORMULARY MAN-
18	AGEMENT PRACTICES AND POLI-
19	CIES.—Nothing in this clause shall be
20	construed as preventing the Pharmacy
21	and Therapeutic Committee of a PDP
22	sponsor from advising such sponsor
23	on the clinical appropriateness of uti-
24	lizing formulary management prac-
25	tices and policies with respect to a

1 newly approved drug that is required 2 to be included on the formulary under 3 subclause (I). "(iii) 4 UNIQUE DOSAGES AND FORMS.—A PDP sponsor of a prescription 5 6 drug plan shall include coverage of all 7 unique dosages and forms of drugs re-8 quired to be included on the formulary 9 pursuant to clause (i) or (ii). 10 "(iv) SUNSET.—The provisions of this 11 subparagraph shall not apply after Decem-12 ber 31 of the year which includes the date 13 that is 5 years after the date of enactment 14 of the Medicare Access to Critical Medica-15 tions Act of 2007." 16 (2) REVIEW OF DRUGS COVERED UNDER THE 17 MEDICARE PART D PRESCRIPTION DRUG PRO-18 GRAM.—Section 1860D-4(b)(3) of the Social Secu-19 rity Act (42 U.S.C. 1395w-104(b)(3)), as amended 20 by paragraph (1), is amended— 21 (A) in subparagraph (C)(i), by striking

22 (H) In Susparagraph (C)(I), Sy straining
22 "subparagraph (G)" and inserting "subpara23 graphs (G) and (H)"; and

24 (B) by inserting after subparagraph (G)25 the following new subparagraph:

1	"(H) REQUIRED INCLUSION OF DRUGS IN
2	CERTAIN CATEGORIES AND CLASSES.—
3	"(i) Required inclusion of drugs
4	IN CERTAIN CATEGORIES AND CLASSES.—
5	"(I) IN GENERAL.—Beginning
6	January 1 of the year after the year
7	which includes the date that is 5 years
8	after the date of enactment of the
9	Medicare Access to Critical Medica-
10	tions Act of 2007, PDP sponsors of-
11	fering prescription drug plans shall be
12	required to include all unique dosages
13	and forms of all or substantially all
14	drugs in certain categories and class-
15	es, including the categories and class-
16	es described in subclauses (I) through
17	(VI) of subparagraph (G)(i), on the
18	formulary of such plans within 30
19	days of the drug becoming available.
20	"(II) REGULATIONS.—Not later
21	than January 1 of the year after the
22	year which includes the date that is 4
23	years after the date of enactment of
24	the Medicare Access to Critical Medi-
25	cations Act of 2007, the Secretary

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1	shall issue regulations to carry out
2	this clause.
3	"(ii) Periodic review.—The Sec-
4	retary shall establish procedures to provide
5	for periodic review of the drugs required to
6	be included on the formulary under clause
7	(i).
8	"(iii) UPDATING.—
9	"(I) IN GENERAL.—The Sec-
10	retary may update the list of drugs
11	required to be included on the for-
12	mulary under clause (i) if the Sec-
13	retary determines, in accordance with
14	this clause, that updating such list is
15	appropriate.
16	"(II) ADDING CATEGORIES OR
17	CLASSES.—In issuing the regulations
18	under clause (i) and updating the list
19	in order to add a drug in a category
20	or class to the list of drugs required
21	to be included on the formulary under
22	such clause, the Secretary shall con-
23	sider factors that justify requiring
24	coverage of drugs in a certain cat-
25	egory or class, including the following:

1	"(aa) Whether the drugs in
2	a category or class are used to
3	treat a disease or disorder that
4	can cause significant negative
5	clinical outcomes to individuals in
6	a short timeframe.
7	"(bb) Whether there are
8	special or unique benefits with
9	respect to the majority of drugs
10	in a given category or class.
11	"(cc) High predicted drug
12	and medical costs for the dis-
13	eases or disorders treated by the
14	drugs in a given category or
15	class.
16	"(dd) Whether restricted ac-
17	cess to the drugs in the category
18	or class has major clinical con-
19	sequences for individuals enrolled
20	in a prescription drug plan who
21	have a disease or disorder treated
22	by the drugs in such category or
23	class.
24	"(ee) The potential for the
25	development of discriminatory

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1	formulary policies based on the
2	clinical or functional characteris-
3	tics of such individuals and the
4	high cost of certain drugs in a
5	category or class.
6	"(ff) The need for access to
7	multiple drugs within a category
8	or class due to the unique chem-
9	ical action and pharmacological
10	effects of drugs within the cat-
11	egory or class and any variation
12	in clinical response based on dif-
13	ferences in such individuals' me-
14	tabolism, age, gender, ethnicity,
15	comorbidities, drug-resistance,
16	and severity of disease.
17	"(gg) Any applicable revi-
18	sions that have been made to
19	widely-accepted clinical practice
20	guidelines endorsed by pertinent
21	medical specialty organizations.
22	"(III) REMOVAL OF CATEGORIES
23	OR CLASSES.—In updating the list in
24	order to remove a drug in a category
25	or class from the list of drugs re-

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quired to be included on the formulary
under clause (i), the Secretary may
remove a drug from such list in the
case where the Secretary determines
that widely-accepted clinical practice
guidelines endorsed by pertinent na-
tional medical specialty organizations
indicate that, for substantially all
drugs in the category or class, re-
stricting access to such drugs is un-
likely to result in adverse clinical con-
sequences for individuals with condi-
tions for which the drugs are clinically
indicated.".
(b) LIMITATION OF UTILIZATION MANAGEMENT
Tools for Drugs in Certain Categories and Class-
ES.—Section 1860D–4(c) of the Social Security Act (42)
U.S.C. 1395w–104(c)) is amended—
(1) in paragraph (1)(A), by striking "A cost-ef-
fective" and inserting "Subject to paragraph (3), a
cost-effective"; and
(2) by adding at the end the following new
paragraph:

1	"(3) LIMITATION OF UTILIZATION MANAGE-
2	MENT TOOLS FOR DRUGS IN CERTAIN CATEGORIES
3	AND CLASSES.—
4	"(A) IN GENERAL.—A PDP sponsor of a
5	prescription drug plan may not apply a utiliza-
6	tion management tool, such as prior authoriza-
7	tion or step therapy, to the following:
8	"(i) During the period beginning on
9	the date of enactment of this paragraph
10	and ending on December 31 of the year
11	which includes the date that is 5 years
12	after such date of enactment—
13	"(I) a drug in a category or class
14	described in subsection
15	(b)(3)(G)(i)(V); and
16	"(II) a drug in a category or
17	class described in subclause (I), (II),
18	(III), (IV), or (VI) of subsection
19	(b)(3)(G)(i) in the case where an en-
20	rollee was engaged in a treatment reg-
21	imen using such drug in the 90-day
22	period prior to the date on which such
23	tool would be applied to the drug with
24	respect to the enrollee under the plan
25	or the PDP sponsor is unable to de-

1 termine if the enrollee was engaged in 2 such a treatment regimen prior to 3 such date. "(ii) Beginning January 1 of the year 4 5 after the year which includes the date that 6 is 5 years after the date of enactment of 7 this paragraph— "(I) a drug in a category or class 8 9 in described subsection 10 (b)(3)(G)(i)(V), if such drug is re-11 quired to be included on the formulary 12 under subsection (b)(3)(H); and "(II) a drug in any other cat-13 14 egory or class required to be included 15 on the formulary under subsection 16 (b)(3)(H) in the case where an en-17 rollee was engaged in a treatment reg-18 imen using such drug in the 90-day 19 period prior to the date on which such 20 tool would be applied to the drug with 21 respect to the enrollee under the plan 22 or the PDP sponsor is unable to de-23 termine if the enrollee was engaged in 24 such a treatment regimen prior to 25 such date.

1 "(B) STATEMENT OF EVIDENCE BASE FOR 2 APPLICATION OF UTILIZATION MANAGEMENT 3 TOOL.—In the case where a utilization manage-4 ment tool is applied to a drug in a category or 5 class required to be included on a plan for-6 mulary under subparagraph (G) or (H) of sub-7 section (b)(3), the PDP sponsor of such plan 8 shall provide a statement of the evidence base 9 substantiating the clinical appropriateness of 10 the application of such tool.".

11 (c) RULE OF CONSTRUCTION.—Nothing in the provi-12 sions of this section, or the amendments made by this sec-13 tion, shall be construed as prohibiting the Secretary of Health and Human Services from issuing guidance or reg-14 15 ulations to establish formulary or utilization management requirements under section 1860D–4 of the Social Secu-16 rity Act (42 U.S.C. 1395w–104) as long as they do not 17 18 conflict with such provisions and amendments.

19 (d) EFFECTIVE DATE.—The amendments made by20 this section shall apply to contract years beginning on or21 after January 1, 2008.

22 SEC. 3. APPEALS REQUIREMENTS FOR CERTAIN CAT-23 EGORIES AND CLASSES OF DRUGS.

24 (a) COVERAGE DETERMINATIONS AND RECONSIDER25 ATION.—Section 1860D–4(g) of the Social Security Act

1 (42 U.S.C. 1395w-104(g)) is amended by adding at the
2 end the following new paragraph:

3 "(3) REQUEST FOR A DETERMINATION OR RE4 CONSIDERATION FOR THE TREATMENT OF DRUGS IN
5 CERTAIN CATEGORIES AND CLASSES.—

6 "(A) IN GENERAL.—In the case where an 7 individual enrolled in a prescription drug plan 8 disputes a utilization management requirement, 9 an adverse coverage determination, a reconsid-10 eration by a PDP sponsor of a prescription 11 drug plan, or an adverse reconsideration by an 12 Independent Review Entity with respect to a 13 covered part D drug in the categories and class-14 es required to be included on the formulary 15 under subparagraph (G) of subsection (b)(3) or 16 under the regulations issued under subpara-17 graph (H) of such subsection, the PDP sponsor 18 shall continue to cover such prescription drug 19 until the date that is not less that 60 days after 20 the latest of the following has occurred:

21 "(i) The enrollee has received written
22 notice of an adverse reconsideration by a
23 PDP sponsor.

24 "(ii) In the case where an enrollee has
25 requested reconsideration by an Inde-

1	pendent Review Entity, such Entity has
2	issued an adverse reconsideration.
3	"(iii) In the case where an appeal of
4	such adverse reconsideration has been filed
5	by the individual, an administrative law
6	judge has decided or dismissed the appeal.
7	"(B) DEFINITION OF INDEPENDENT RE-
8	VIEW ENTITY.—In this paragraph, the term
9	'Independent Review Entity' means the inde-
10	pendent, outside entity the Secretary contracts
11	with under section $1852(g)(4)$, including such
12	an entity that the Secretary contracts with in
13	order to meet the requirements of such section
14	under section 1860D–4(h)(1).".
15	(b) APPEALS.—Section 1860D–4(h) of the Social Se-
16	curity Act (42 U.S.C. 1395w–104(h)) is amended—
17	(1) in paragraph (2), by striking "A part D"
18	and inserting "Subject to paragraph (4), a part D";
19	and
20	(2) by adding at the end the following new
21	paragraph:
22	"(4) TREATMENT OF APPEALS FOR DRUGS IN
23	CERTAIN CATEGORIES AND CLASSES.—
24	"(A) IN GENERAL.—A part D eligible indi-
25	vidual who is enrolled in a prescription drug

1	plan offered by a PDP sponsor may appeal
2	under paragraph (1) a determination by such
3	sponsor not to provide coverage of a covered
4	part D drug in a category or class required to
5	be included on the formulary under subpara-
6	graph (G) of subsection $(b)(3)$ or under the reg-
7	ulations issued under subparagraph (H) of such
8	subsection at any time after such determination
9	by requesting a reconsideration by an Inde-
10	pendent Review Entity.
11	"(B) DEFINITION OF INDEPENDENT RE-
12	VIEW ENTITY.—In this paragraph, the term
13	'Independent Review Entity' has the meaning
14	given such term in subsection $(g)(3)(B)$.".
15	(c) EFFECTIVE DATE.—The amendments made by
16	this section shall apply to contract years beginning on or
17	after January 1, 2008.
18	SEC. 4. DATA REPORTING REQUIREMENTS FOR CERTAIN
19	CATEGORIES AND CLASSES OF DRUGS
20	UNDER THE MEDICARE PART D PRESCRIP-
21	TION DRUG PROGRAM.
22	(a) IN GENERAL.—Section 1860D–4 of the Social
23	Security Act (42 U.S.C. 1395w–104) is amended by add-
24	ing at the end the following new subsection:

1	"(1) DATA REPORTING FOR CERTAIN CATEGORIES
2	AND CLASSES OF DRUGS.—
3	"(1) IN GENERAL.—A PDP sponsor offering a
4	prescription drug plan shall disclose to the Secretary
5	(in a manner specified by the Secretary) data at the
6	plan level on the number of—
7	"(A) favorable and adverse decisions made
8	with respect to exceptions requested to for-
9	mulary policies—
10	"(i) during the period beginning on
11	the date of enactment of this subsection
12	and ending on December 31 of the year
13	which includes the date that is 5 years
14	after such date of enactment, for each of
15	the categories and classes of drugs de-
16	scribed in subclauses (I) through (VI) of
17	subsection $(b)(3)(G)(i)$; and
18	"(ii) beginning January 1 of the year
19	after the year which includes the date that
20	is 5 years after such date of enactment, for
21	each of the categories and classes of drugs
22	required to be included on the formulary
23	under the regulations issued under sub-
24	section $(b)(3)(H);$

1	"(B) favorable and advance coverage datas
1	"(B) favorable and adverse coverage deter-
2	minations made with respect to each of such
3	categories and classes during the applicable pe-
4	riod;
5	"(C) favorable and adverse reconsider-
6	ations made by a PDP sponsor with respect to
7	each of such categories and classes during the
8	applicable period;
9	"(D) favorable and adverse reconsider-
10	ations made by an Independent Review Entity
11	(as defined in subsection $(g)(3)(B)$) with re-
12	spect to each of such categories and classes
13	during the applicable period; and
14	"(E) appeals made to an administrative
15	law judge and the decisions made on such ap-
16	peals with respect to each of such categories
17	and classes during the applicable period.
18	"(2) ANNUAL REPORT.—The Secretary shall—
19	"(A) submit an annual report to Congress
20	containing the data disclosed to the Secretary
21	under paragraph (1) ; and
22	"(B) publish such report in the Federal
23	Register.".

(b) EFFECTIVE DATE.—The amendment made by
 subsection (a) shall apply to contract years beginning on
 or after January 1, 2008.