

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.

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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

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## 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).

4 “(iii) UNIQUE DOSAGES AND  
 5 FORMS.—A PDP sponsor of a prescription  
 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 “subparagraph (G)” and inserting “subpara-  
 23 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

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

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-

1                   quired to be included on the formulary  
2                   under clause (i), the Secretary may  
3                   remove a drug from such list in the  
4                   case where the Secretary determines  
5                   that widely-accepted clinical practice  
6                   guidelines endorsed by pertinent na-  
7                   tional medical specialty organizations  
8                   indicate that, for substantially all  
9                   drugs in the category or class, re-  
10                  stricting access to such drugs is un-  
11                  likely to result in adverse clinical con-  
12                  sequences for individuals with condi-  
13                  tions for which the drugs are clinically  
14                  indicated.”.

15           (b) LIMITATION OF UTILIZATION MANAGEMENT  
16 TOOLS FOR DRUGS IN CERTAIN CATEGORIES AND CLASS-  
17 ES.—Section 1860D–4(c) of the Social Security Act (42  
18 U.S.C. 1395w–104(c)) is amended—

19                   (1) in paragraph (1)(A), by striking “A cost-ef-  
20                  fective” and inserting “Subject to paragraph (3), a  
21                  cost-effective”; and

22                   (2) by adding at the end the following new  
23                  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.

4           “(ii) Beginning January 1 of the year  
5           after the year which includes the date that  
6           is 5 years after the date of enactment of  
7           this paragraph—

8                   “(I) a drug in a category or class  
9                   described           in           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

13                   “(II) a drug in any other cat-  
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  
14          Health and Human Services from issuing guidance or reg-  
15          ulations to establish formulary or utilization management  
16          requirements under section 1860D–4 of the Social Secu-  
17          rity Act (42 U.S.C. 1395w–104) as long as they do not  
18          conflict with such provisions and amendments.

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

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

24          (a) COVERAGE DETERMINATIONS AND RECONSIDER-  
25          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 RE-  
4           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 than 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 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.”.

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

○