

INTRODUCTION OF THE ACCESS TO CRITICAL MEDICATIONS ACT

MR. SMITH. Mr. President, today I am introducing the Access to Critical Medications Act (ACMA), a bill that will vastly improve the coverage millions of vulnerable Medicare beneficiaries receive through the Medicare prescription drug program, known as Part D. The new drug benefit has been a tremendous success, providing access to affordable prescription drug therapies to millions of beneficiaries, some for the very first time. But many of our most vulnerable seniors, especially those suffering from serious health conditions like mental illness, HIV/AIDS or cancer, often have difficulty obtaining the vital drug therapies they need to remain functional, or in some cases, to survive. To remedy these problems, the bill I am introducing today will give the Centers for Medicare and Medicaid Services (CMS) the regulatory tools it needs to ensure that all prescription drug plans (PDP) provide unfettered access to medically essential drug therapies.

My connection to this issue began long before Medicare's new prescription drug benefit went into effect. As Chairman of the Aging Committee, I held a hearing in the spring of 2005 to explore how well CMS was preparing to transition dual-eligible beneficiaries, those who qualify for both Medicare and Medicaid, into Medicare Part D. At that hearing, advocates expressed a number of concerns with the implementation of the new drug benefit, and chief among them was guaranteeing that vulnerable beneficiaries had access to important drug therapies that either stabilized or improved their health condition. I made a personal request to then CMS Administrator Dr. Mark McClellan to work with prescription drug plans to ensure that their formularies provide access to all available drugs in certain pharmaceutical classes, including those that contain innovative treatments for mental illness, epilepsy, cancer and HIV/AIDS. The result of that conversation was the creation of the "all or substantially all" policy for six protected drug classes. CMS initially included this new policy as part of the sub-regulatory formulary guidance it issued to plans in 2005 and again in 2006.

While I was pleased with CMS providing this additional protection for the vital drug therapies in the six protected classes, its actual impact on beneficiaries gaining access to the medications they need has been uneven at best. For one, the policy was issued as sub-regulatory guidance, which limits CMS' ability to enforce it. While it is true that the annual contracts CMS develops with prescription drug plans generally include a requirement that they abide by the "all or substantially all" guidance, the agency's record of enforcing the policy has been quite poor. Instead of plans covering all drugs in the six protected classes, as CMS claims plan contracts require, beneficiaries, often the most frail and vulnerable, have had extensive access problems because their PDPs do not include their medication on its formulary. In fact, data from a study being conducted by the American Psychiatric Institute for Research and Education (APIRE) released earlier this year, showed that roughly 68 percent of surveyed beneficiaries, many of them dual eligibles, experienced some sort of problem accessing the prescription drug they needed because their PDP's formulary did not cover it. This would suggest that CMS' current approach to enforcing the "all or substantially all" policy is woefully lacking.

I should note that beneficiaries often are able to access a drug that should be covered on their plan's formulary by filing a coverage appeal. However, that process is usually long and difficult to complete, and results in the problem only being solved for one beneficiary. I appreciate the responsiveness of drug plans to specific beneficiaries' difficulties with accessing the drugs they need, but if they are not addressing the concerns raised through the appeals process on a broader scale, problems will only continue to occur. I believe we need a system-wide approach to ensuring that beneficiaries have access to the life-saving and life-improving medications they need and I believe that solution lies within the legislation I am filing today.

The Access to Critical Medications Act (ACMA) would codify, for a five-year period, the current policies in CMS existing "all or substantially all" sub-regulatory guidance. I am hopeful that providing this statutory authority will signal to plans that it is no longer an option to cover all available drugs in the six protected classes. It is a legal requirement that must be adhered to in order to participate in Medicare Part D. Accordingly, I would expect that this change will empower CMS to take a more proactive role in ensuring that prescription drug plan sponsors are not placing arbitrary barriers to accessing these critical medications covered by the "all or substantially all" policy.

During the five year period that the "all or substantially all" policy will be effective, the ACMA directs CMS to establish a process—through regulation—that would allow for this important policy to be updated and enforced in future years. None of us hold the knowledge of the pharmaceutical and medical developments of tomorrow. In a decade, there could be major breakthroughs in treating any number of debilitating illnesses, which may require the creation of or modification of pharmaceutical classes covered by this important policy. CMS needs to have the authority to update the classes and categories it covers and the process the ACMA creates will provide them the tools to do that.

In order to use those tools, the ACMA defines specific, clinically-based criteria that the Secretary must follow when evaluating whether a drug class should be added or removed from coverage under the policy. This will ensure that there is consistency in the manner by which the policy is evaluated in future years, so that the Secretary is not arbitrarily determining which medications are important enough so that all plans must provide access to them. The ACMA also makes modest changes to the appeals process, to ensure that plans and CMS resolve beneficiary complaints in a timely manner, and that access to medications is guaranteed while the appeals process runs its course.

The existing "all or substantially all" policy was a step in the right direction at the time it was created. However, as we approach the third year of Medicare's prescription drug benefit, beneficiaries' actual experience in the program provides overwhelming support that we need a more robust approach to helping vulnerable beneficiaries get the medications they need. As importantly, CMS must have a regulatory process in place that will enable it to modify the classes covered by the policy in response to changes in medical and pharmaceutical science. I believe the ACMA clearly addresses both those needs, and I hope my colleagues will agree. It is a well thought out policy that strikes a

careful balance between flexibility and enforceability. Advocacy groups such as the American Psychiatric Association, the National Alliance for Mental Illness, Mental Health America, the AIDS Institute, the HIV Medicine Association and the Epilepsy Foundation all contributed to the development of ACMA and all now support the finished product. The Senate likely will consider Medicare legislation this fall, and I have already mentioned to Chairman Baucus that I would like to see this bill advance as part of that effort.

Mr. President, I ask unanimous consent that the full text of the Access to Critical Medications Act being entered into the Record, as well as the letters of support I have received for its prompt enactment.

Thank you.

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).

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 required 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.

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