

110TH CONGRESS
2D SESSION

S. _____

To amend title XIX of the Social Security to provide additional funds for the qualifying individual (QI) program, and for other purposes.

IN THE SENATE OF THE UNITED STATES

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

A BILL

To amend title XIX of the Social Security to provide additional funds for the qualifying individual (QI) program, and for other purposes.

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 “QI Program Supple-
5 mental Funding Act of 2008”.

6 **SEC. 2. FUNDING FOR THE QUALIFYING INDIVIDUAL (QI)**
7 **PROGRAM.**

8 Section 1933(g)(2) of the Social Security Act (42
9 U.S.C. 1396u–3(g)(2)), as amended by section 111(b) of

1 the Medicare Improvements for Patients and Providers
2 Act of 2008 (Public Law 110–275), is amended—

3 (1) in subparagraph (I), by striking
4 “\$300,000,000” and inserting “\$315,000,000”; and

5 (2) in subparagraph (J), by striking
6 “\$100,000,000” and inserting “\$130,000,000”.

7 **SEC. 3. MANDATORY USE OF STATE PUBLIC ASSISTANCE**
8 **REPORTING INFORMATION SYSTEM (PARIS)**
9 **PROJECT.**

10 (a) **IN GENERAL.**—Section 1903(r) of the Social Se-
11 curity Act (42 U.S.C. 1396b(r)) is amended—

12 (1) in paragraph (1), in the matter preceding
13 subparagraph (A), by inserting “, in addition to
14 meeting the requirements of paragraph (3),” after
15 “a State must”; and

16 (2) by adding at the end the following new
17 paragraph:

18 “(3) In order to meet the requirements of this para-
19 graph, a State must have in operation an eligibility deter-
20 mination system which provides for data matching
21 through the Public Assistance Reporting Information Sys-
22 tem (PARIS) facilitated by the Secretary (or any suc-
23 cessor system), including matching with medical assist-
24 ance programs operated by other States.”.

25 (b) **EFFECTIVE DATE.**—

1 (1) IN GENERAL.—Except as provided in para-
2 graph (2), the amendments made by subsection (a)
3 take effect on October 1, 2009.

4 (2) EXTENSION OF EFFECTIVE DATE FOR
5 STATE LAW AMENDMENT.—In the case of a State
6 plan under title XIX of the Social Security Act (42
7 U.S.C. 1396 et seq.) which the Secretary of Health
8 and Human Services determines requires State legis-
9 lation in order for the plan to meet the additional
10 requirements imposed by the amendments made by
11 subsection (a), the State plan shall not be regarded
12 as failing to comply with the requirements of such
13 title solely on the basis of its failure to meet these
14 additional requirements before the first day of the
15 first calendar quarter beginning after the close of
16 the first regular session of the State legislature that
17 begins after the date of enactment of this Act. For
18 purposes of the previous sentence, in the case of a
19 State that has a 2-year legislative session, each year
20 of the session is considered to be a separate regular
21 session of the State legislature.

1 **SEC. 4. INCENTIVES FOR THE DEVELOPMENT OF, AND AC-**
2 **CESS TO, CERTAIN ANTIBIOTICS.**

3 (a) IN GENERAL.—Section 505 of the Federal Food,
4 Drug, and Cosmetic Act (21 U.S.C. 355) is amended by
5 adding at the end the following:

6 “(v) ANTIBIOTIC DRUGS SUBMITTED BEFORE NO-
7 VEMBER 21, 1997.—

8 “(1) ANTIBIOTIC DRUGS APPROVED BEFORE
9 NOVEMBER 21, 1997.—

10 “(A) IN GENERAL.—Notwithstanding any
11 provision of the Food and Drug Administration
12 Modernization Act of 1997 or any other provi-
13 sion of law, a sponsor of a drug that is the sub-
14 ject of an application described in subparagraph
15 (B)(i) shall be eligible for, with respect to the
16 drug, the 3-year exclusivity period referred to
17 under clauses (iii) and (iv) of subsection
18 (c)(3)(E) and under clauses (iii) and (iv) of
19 subsection (j)(5)(F), subject to the require-
20 ments of such clauses, as applicable.

21 “(B) APPLICATION; ANTIBIOTIC DRUG DE-
22 SCRIBED.—

23 “(i) APPLICATION.—An application
24 described in this clause is an application
25 for marketing submitted under this section
26 after the date of the enactment of this sub-

1 section in which the drug that is the sub-
2 ject of the application contains an anti-
3 biotic drug described in clause (ii).

4 “(ii) ANTIBIOTIC DRUG.—An anti-
5 biotic drug described in this clause is an
6 antibiotic drug that was the subject of an
7 application approved by the Secretary
8 under section 507 of this Act (as in effect
9 before November 21, 1997).

10 “(2) ANTIBIOTIC DRUGS SUBMITTED BEFORE
11 NOVEMBER 21, 1997, BUT NOT APPROVED.—

12 “(A) IN GENERAL.—Notwithstanding any
13 provision of the Food and Drug Administration
14 Modernization Act of 1997 or any other provi-
15 sion of law, a sponsor of a drug that is the sub-
16 ject of an application described in subparagraph
17 (B)(i) may elect to be eligible for, with respect
18 to the drug—

19 “(i)(I) the 3-year exclusivity period re-
20 ferred to under clauses (iii) and (iv) of
21 subsection (c)(3)(E) and under clauses (iii)
22 and (iv) of subsection (j)(5)(F), subject to
23 the requirements of such clauses, as appli-
24 cable; and

1 “(II) the 5-year exclusivity period re-
2 ferred to under clause (ii) of subsection
3 (c)(3)(E) and under clause (ii) of sub-
4 section (j)(5)(F), subject to the require-
5 ments of such clauses, as applicable; or

6 “(ii) a patent term extension under
7 section 156 of title 35, United States
8 Code, subject to the requirements of such
9 section.

10 “(B) APPLICATION; ANTIBIOTIC DRUG DE-
11 SCRIBED.—

12 “(i) APPLICATION.—An application
13 described in this clause is an application
14 for marketing submitted under this section
15 after the date of the enactment of this sub-
16 section in which the drug that is the sub-
17 ject of the application contains an anti-
18 biotic drug described in clause (ii).

19 “(ii) ANTIBIOTIC DRUG.—An anti-
20 biotic drug described in this clause is an
21 antibiotic drug that was the subject of 1 or
22 more applications received by the Secretary
23 under section 507 of this Act (as in effect
24 before November 21, 1997), none of which

1 was approved by the Secretary under such
2 section.

3 “(3) LIMITATIONS.—

4 “(A) EXCLUSIVITIES AND EXTENSIONS.—

5 Paragraphs (1)(A) and (2)(A) shall not be con-
6 strued to entitle a drug that is the subject of
7 an approved application described in subpara-
8 graphs (1)(B)(i) or (2)(B)(i), as applicable, to
9 any market exclusivities or patent extensions
10 other than those exclusivities or extensions de-
11 scribed in paragraph (1)(A) or (2)(A).

12 “(B) CONDITIONS OF USE.—Paragraphs
13 (1)(A) and (2)(A)(i) shall not apply to any con-
14 dition of use for which the drug referred to in
15 subparagraph (1)(B)(i) or (2)(B)(i), as applica-
16 ble, was approved before the date of the enact-
17 ment of this subsection.

18 “(4) APPLICATION OF CERTAIN PROVISIONS.—

19 Notwithstanding section 125, or any other provision,
20 of the Food and Drug Administration Modernization
21 Act of 1997, or any other provision of law, and sub-
22 ject to the limitations in paragraphs (1), (2), and
23 (3), the provisions of the Drug Price Competition
24 and Patent Term Restoration Act of 1984 shall
25 apply to any drug subject to paragraph (1) or any

1 drug with respect to which an election is made under
2 paragraph (2)(A).”.

3 (b) TRANSITIONAL RULES.—

4 (1) With respect to a patent issued on or before
5 the date of the enactment of this Act, any patent in-
6 formation required to be filed with the Secretary of
7 Health and Human Services under subsection (b)(1)
8 or (c)(2) of section 505 of the Federal Food, Drug,
9 and Cosmetic Act (21 U.S.C. 355) to be listed on a
10 drug to which subsection (v)(1) of such section 505
11 (as added by this section) applies shall be filed with
12 the Secretary not later than 60 days after the date
13 of the enactment of this Act.

14 (2) With respect to any patent information re-
15 ferred to in paragraph (1) of this subsection that is
16 filed with the Secretary within the 60-day period
17 after the date of the enactment of this Act, the Sec-
18 retary shall publish such information in the elec-
19 tronic version of the list referred to at section
20 505(j)(7) of the Federal Food, Drug, and Cosmetic
21 Act (21 U.S.C. 355(j)(7)) as soon as it is received,
22 but in no event later than the date that is 90 days
23 after the enactment of this Act.

24 (3) With respect to any patent information re-
25 ferred to in paragraph (1) that is filed with the Sec-

1 retary within the 60-day period after the date of en-
2 actment of this Act, each applicant that, not later
3 than 120 days after the date of the enactment of
4 this Act, amends an application that is, on or before
5 the date of the enactment of this Act, a substantially
6 complete application (as defined in paragraph
7 (5)(B)(iv) of section 505(j) of the Federal Food,
8 Drug, and Cosmetic Act (21 U.S.C. 355(j))) to con-
9 tain a certification described in paragraph
10 (2)(A)(vii)(IV) of such section 505(j) with respect to
11 that patent shall be deemed to be a first applicant
12 (as defined in paragraph (5)(B)(iv) of such section
13 505(j)).

14 **SEC. 5. CLARIFICATION OF AUTHORITY FOR USE OF MED-**
15 **ICAID INTEGRITY PROGRAM FUNDS.**

16 (a) CLARIFICATION OF AUTHORITY FOR USE OF
17 FUNDS.—

18 (1) IN GENERAL.—Section 1936 of the Social
19 Security Act (42 U.S.C. 1396u–6) is amended—

20 (A) in subsection (b)(4), by striking “Edu-
21 cation of” and inserting “Education or training,
22 including at such national, State, or regional
23 conferences as the Secretary may establish, of
24 State or local officers, employees, or inde-
25 pendent contractors responsible for the adminis-

1 tration or the supervision of the administration
2 of the State plan under this title,”; and

3 (B) in subsection (e), by striking para-
4 graph (2) and inserting the following:

5 “(2) AVAILABILITY; AUTHORITY FOR USE OF
6 FUNDS.—

7 “(A) AVAILABILITY.—Amounts appro-
8 priated pursuant to paragraph (1) shall remain
9 available until expended.

10 “(B) AUTHORITY FOR USE OF FUNDS FOR
11 TRANSPORTATION AND TRAVEL EXPENSES FOR
12 ATTENDEES AT EDUCATION, TRAINING, OR CON-
13 SULTATIVE ACTIVITIES.—

14 “(i) IN GENERAL.—The Secretary
15 may use amounts appropriated pursuant to
16 paragraph (1) to pay for transportation
17 and the travel expenses, including per diem
18 in lieu of subsistence, at rates authorized
19 for employees of agencies under subchapter
20 I of chapter 57 of title 5, United States
21 Code, while away from their homes or reg-
22 ular places of business, of individuals de-
23 scribed in subsection (b)(4) who attend
24 education, training, or consultative activi-

1 ties conducted under the authority of that
2 subsection.”.

3 (2) EFFECTIVE DATE.—The amendments made
4 by paragraph (1) shall take effect as if included in
5 the enactment of section 1936 of the Social Security
6 Act, as added by section 6034(a) of the Deficit Re-
7 duction Act of 2005 (Public Law 109–171).

8 (b) PUBLIC DISCLOSURE.—

9 (1) IN GENERAL.—Section 1936(e)(2)(B) of
10 such Act (42 U.S.C. 1396u–6(e)(2)(B)), as added by
11 subsection (a) of this section, is amended by adding
12 at the end the following:

13 “(ii) PUBLIC DISCLOSURE.—The Sec-
14 retary shall make available on a website of
15 the Centers for Medicare & Medicaid Serv-
16 ices that is accessible to the public—

17 “(I) the total amount of funds
18 expended for each conference con-
19 ducted under the authority of sub-
20 section (b)(4); and

21 “(II) the amount of funds ex-
22 pended for each such conference that
23 were for transportation and for travel
24 expenses.”.

