

110TH CONGRESS  
2D SESSION

# S. 3549

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

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## IN THE SENATE OF THE UNITED STATES

SEPTEMBER 23 (legislative day, SEPTEMBER 17), 2008

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

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## A BILL

To amend title XIX of the Social Security Act 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

“(II) the 5-year exclusivity period referred to under clause (ii) of subsection (c)(3)(E) and under clause (ii) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable; or

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

“(B) APPLICATION; ANTIBIOTIC DRUG DESCRIBED.—

“(i) APPLICATION.—An application described in this clause is an application for marketing submitted under this section after the date of the enactment of this subsection in which the drug that is the subject of the application contains an antibiotic drug described in clause (ii).

“(ii) ANTIBIOTIC DRUG.—An antibiotic drug described in this clause is an antibiotic drug that was the subject of 1 or more applications received by the Secretary under section 507 of this Act (as in effect 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.”.

1           (2) EFFECTIVE DATE.—The amendment made  
 2       by paragraph (1) shall apply to conferences con-  
 3       ducted under the authority of section 1936(b)(4) of  
 4       the Social Security Act (42 U.S.C. 1396u–6(b)(4))  
 5       after the date of enactment of this Act.

6 **SEC. 6. FUNDING FOR THE MEDICARE IMPROVEMENT**  
 7 **FUND.**

8       Section 1898(b)(1) of the Social Security Act, as  
 9       added by section 7002(a) of the Supplemental Appropria-  
 10      tions Act, 2008 (Public Law 110–252) and amended by  
 11      section 188(a)(2) of the Medicare Improvements for Pa-  
 12      tients and Providers Act of 2008 (Public Law 110–275),  
 13      is amended to read as follows:

14           “(1) IN GENERAL.—There shall be available to  
 15      the Fund, for expenditures from the Fund for serv-  
 16      ices furnished during—

17                   “(A) fiscal year 2014, \$2,290,000,000;  
 18                   and

19                   “(B) fiscal years 2014 through 2017,  
 20                   \$19,900,000,000.”.

○