

110TH CONGRESS
2D SESSION

S. 3560

AN ACT

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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “QI Program Supple-
3 mental Funding Act of 2008”.

4 **SEC. 2. FUNDING FOR THE QUALIFYING INDIVIDUAL (QI)**
5 **PROGRAM.**

6 Section 1933(g)(2) of the Social Security Act (42
7 U.S.C. 1396u–3(g)(2)), as amended by section 111(b) of
8 the Medicare Improvements for Patients and Providers
9 Act of 2008 (Public Law 110–275), is amended—

- 10 (1) in subparagraph (I), by striking
11 “\$300,000,000” and inserting “\$315,000,000”; and
12 (2) in subparagraph (J), by striking
13 “\$100,000,000” and inserting “\$130,000,000”.

14 **SEC. 3. MANDATORY USE OF STATE PUBLIC ASSISTANCE**
15 **REPORTING INFORMATION SYSTEM (PARIS)**
16 **PROJECT.**

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

- 19 (1) in paragraph (1), in the matter preceding
20 subparagraph (A), by inserting “, in addition to
21 meeting the requirements of paragraph (3),” after
22 “a State must”; and

- 23 (2) by adding at the end the following new
24 paragraph:

25 “(3) In order to meet the requirements of this para-
26 graph, a State must have in operation an eligibility deter-

1 mination system which provides for data matching
 2 through the Public Assistance Reporting Information Sys-
 3 tem (PARIS) facilitated by the Secretary (or any suc-
 4 cessor system), including matching with medical assist-
 5 ance programs operated by other States.”.

6 (b) EFFECTIVE DATE.—

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

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

1 of the session is considered to be a separate regular
 2 session of the State legislature.

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

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

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

10 “(1) ANTIBIOTIC DRUGS APPROVED BEFORE
 11 NOVEMBER 21, 1997.—

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) shall be eligible for, with respect to the
 18 drug, the 3-year exclusivity period referred to
 19 under clauses (iii) and (iv) of subsection
 20 (c)(3)(E) and under clauses (iii) and (iv) of
 21 subsection (j)(5)(F), subject to the require-
 22 ments of such clauses, as applicable.

23 “(B) APPLICATION; ANTIBIOTIC DRUG DE-
 24 SCRIBED.—

1 “(i) APPLICATION.—An application
2 described in this clause is an application
3 for marketing submitted under this section
4 after the date of the enactment of this sub-
5 section in which the drug that is the sub-
6 ject of the application contains an anti-
7 biotic drug described in clause (ii).

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

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

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

23 “(i)(I) the 3-year exclusivity period re-
24 ferred to under clauses (iii) and (iv) of
25 subsection (c)(3)(E) and under clauses (iii)

1 and (iv) of subsection (j)(5)(F), subject to
2 the requirements of such clauses, as appli-
3 cable; and

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

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

13 “(B) APPLICATION; ANTIBIOTIC DRUG DE-
14 SCRIBED.—

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

22 “(ii) ANTIBIOTIC DRUG.—An anti-
23 biotic drug described in this clause is an
24 antibiotic drug that was the subject of 1 or
25 more applications received by the Secretary

1 under section 507 of this Act (as in effect
2 before November 21, 1997), none of which
3 was approved by the Secretary under such
4 section.

5 “(3) LIMITATIONS.—

6 “(A) EXCLUSIVITIES AND EXTENSIONS.—

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

14 “(B) CONDITIONS OF USE.—Paragraphs

15 (1)(A) and (2)(A)(i) shall not apply to any con-
16 dition of use for which the drug referred to in
17 subparagraph (1)(B)(i) or (2)(B)(i), as applica-
18 ble, was approved before the date of the enact-
19 ment of this subsection.

20 “(4) APPLICATION OF CERTAIN PROVISIONS.—

21 Notwithstanding section 125, or any other provision,
22 of the Food and Drug Administration Modernization
23 Act of 1997, or any other provision of law, and sub-
24 ject to the limitations in paragraphs (1), (2), and
25 (3), the provisions of the Drug Price Competition

1 and Patent Term Restoration Act of 1984 shall
2 apply to any drug subject to paragraph (1) or any
3 drug with respect to which an election is made under
4 paragraph (2)(A).”.

5 (b) TRANSITIONAL RULES.—

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

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

(3) With respect to any patent information referred to in paragraph (1) that is filed with the Secretary within the 60-day period after the date of enactment of this Act, each applicant that, not later than 120 days after the date of the enactment of this Act, amends an application that is, on or before the date of the enactment of this Act, a substantially complete application (as defined in paragraph (5)(B)(iv) of section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j))) to contain a certification described in paragraph (2)(A)(vii)(IV) of such section 505(j) with respect to that patent shall be deemed to be a first applicant (as defined in paragraph (5)(B)(iv) of such section 505(j)).

SEC. 5. CLARIFICATION OF AUTHORITY FOR USE OF MEDICAID INTEGRITY PROGRAM FUNDS.

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

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

(A) in subsection (b)(4), by striking “Education of” and inserting “Education or training, including at such national, State, or regional conferences as the Secretary may establish, of

1 State or local officers, employees, or inde-
2 pendent contractors responsible for the adminis-
3 tration or the supervision of the administration
4 of the State plan under this title,”; and

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

7 “(2) AVAILABILITY; AUTHORITY FOR USE OF
8 FUNDS.—

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

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

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

1 education, training, or consultative activi-
2 ties conducted under the authority of that
3 subsection.”.

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

9 (b) PUBLIC DISCLOSURE.—

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

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

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

22 “(II) the amount of funds ex-
23 pended for each such conference that
24 were for transportation and for travel
25 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 (42
9 U.S.C. 1395iii(b)(1)) is amended by striking
10 “\$2,220,000,000” and inserting “\$2,290,000,000”.

Passed the Senate September 25 (legislative day,
September 17), 2008.

Attest:

Secretary.

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