110TH CONGRESS	\mathbf{C}	
2D Session		
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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
- meeting the requirements of paragraph (3)," after
- "a State must"; and
- 16 (2) by adding at the end the following new
- 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.—

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

EXTENSION OF EFFECTIVE DATE FORSTATE LAW AMENDMENT.—In the case of a State plan under title XIX of the Social Security Act (42) U.S.C. 1396 et seq.) which the Secretary of Health and Human Services determines requires State legislation in order for the plan to meet the additional requirements imposed by the amendments made by subsection (a), the State plan shall not be regarded as failing to comply with the requirements of such title solely on the basis of its failure to meet these additional requirements before the first day of the first calendar quarter beginning after the close of the first regular session of the State legislature that begins after the date of enactment of this Act. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of the session is considered to be a separate regular 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

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

(b) Transitional Rules.—

- (1) With respect to a patent issued on or before the date of the enactment of this Act, any patent information required to be filed with the Secretary of Health and Human Services under subsection (b)(1) or (c)(2) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) to be listed on a drug to which subsection (v)(1) of such section 505 (as added by this section) applies shall be filed with the Secretary not later than 60 days after the date of the enactment of this Act.
- (2) With respect to any patent information referred to in paragraph (1) of this subsection that is filed with the Secretary within the 60-day period after the date of the enactment of this Act, the Secretary shall publish such information in the electronic version of the list referred to at section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)) as soon as it is received, but in no event later than the date that is 90 days after the enactment of this Act.
- (3) With respect to any patent information referred 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-
1415	SEC. 5. CLARIFICATION OF AUTHORITY FOR USE OF MED- ICAID INTEGRITY PROGRAM FUNDS.
15	ICAID INTEGRITY PROGRAM FUNDS.
15 16	ICAID INTEGRITY PROGRAM FUNDS. (a) CLARIFICATION OF AUTHORITY FOR USE OF
15 16 17	icaid integrity program funds. (a) Clarification of Authority for Use of Funds.—
15 16 17 18	ICAID INTEGRITY PROGRAM FUNDS. (a) CLARIFICATION OF AUTHORITY FOR USE OF FUNDS.— (1) IN GENERAL.—Section 1936 of the Social
15 16 17 18 19	ICAID 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—
15 16 17 18 19 20	ICAID 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 "Edu-
15 16 17 18 19 20 21	ICAID 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,"
15 16 17 18 19 20 21 22	ICAID 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

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 (42
9	U.S.C. 1395iii(b)(1)) is amended by striking

10 "\$2,220,000,000" and inserting "\$2,290,000,000".