

111TH CONGRESS
1ST SESSION

H. R. 1421

To amend title XIX of the Social Security Act to provide Medicaid coverage of drugs prescribed for certain research study child participants.

IN THE HOUSE OF REPRESENTATIVES

MARCH 10, 2009

Mr. SHUSTER introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend title XIX of the Social Security Act to provide Medicaid coverage of drugs prescribed for certain research study child participants.

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 “Nino’s Act”.

5 **SEC. 2. MEDICAID COVERAGE OF DRUGS PRESCRIBED FOR**
6 **RESEARCH STUDY CHILD PARTICIPANTS.**

7 (a) MANDATORY COVERAGE IF STATE PROVIDES
8 DRUG COVERAGE.—

1 (1) STATE PLAN REQUIREMENT.—Section
2 1902(a) of the Social Security Act (42 U.S.C.
3 1396a(a)) is amended—

4 (A) in paragraph (72), by striking “and”
5 at the end;

6 (B) in paragraph (73), by striking the pe-
7 riod at the end and inserting “; and”; and

8 (C) by inserting after paragraph (73) the
9 following new paragraph:

10 “(74) in the case of a State plan that provides
11 medical assistance for prescribed drugs under sec-
12 tion 1905(a)(12), provide for such medical assist-
13 ance to include coverage for any drug, biological
14 product, or insulin prescribed for a child (including
15 any such drug, product, or insulin that is self-ad-
16 ministered) who—

17 “(A) is eligible for medical assistance
18 under the State plan (including a child who is
19 eligible only on the basis of paragraph
20 (10)(A)(i)(VIII));

21 “(B) is a current or former participant in
22 a research study conducted or funded (in whole
23 or in part) by the National Institutes of Health;
24 and

1 “(C) satisfies the requirements of subpara-
2 graphs (B), (C), and (D) of subsection
3 (gg)(1).”.

4 (2) MANDATORY COVERAGE OF DRUGS OF RE-
5 SEARCH STUDY CHILD PARTICIPANTS WHO ARE NOT
6 OTHERWISE ELIGIBLE FOR MEDICAID IF THE STATE
7 OFFERS DRUG COVERAGE.—

8 (A) IN GENERAL.—Section
9 1902(a)(10)(A)(i) of the Social Security Act
10 (42 U.S.C. 1396b(a)(10)(A)(i)) is amended—

11 (i) in subclause (VI), by striking “or”
12 at the end;

13 (ii) in subclause (VII), by adding “or”
14 at the end; and

15 (iii) by adding at the end the fol-
16 lowing new subclause:

17 “(VIII) who are research study
18 child participants described in sub-
19 section (gg)(1), but only if the med-
20 ical assistance made available by the
21 State includes prescribed drugs under
22 section 1905(a)(12),”.

23 (B) GROUP DESCRIBED.—Section 1902 of
24 the Social Security Act (42 U.S.C. 1396a) is

1 amended by adding at the end the following
2 new subsection:

3 “(gg)(1) Research study child participants described
4 in this subsection are individuals who—

5 “(A) are not otherwise eligible for medical
6 assistance under the State plan;

7 “(B) have not attained age 19;

8 “(C) have been certified by a physician
9 participating in a research study conducted or
10 funded (in whole or in part) by the National In-
11 stitutes of Health to be current or former par-
12 ticipants in such trial or study who have a spe-
13 cific disease or condition that—

14 “(i) is or has been successfully treated
15 under such trial or study with a prescribed
16 use of a drug, biological product, or insulin
17 that is not approved under the Federal
18 Food, Drug, and Cosmetic Act; and

19 “(ii) is likely to continue to be suc-
20 cessfully treated with such drug, product,
21 or insulin; and

22 “(D) do not have other health coverage for
23 such drug, product, or insulin.

24 “(2) A State shall redetermine not less than every
25 2 years the eligibility of an individual for medical assist-

1 ance who is eligible solely on the basis of subsection
2 (a)(10)(A)(i)(VIII).

3 “(3) For purposes of this subsection and paragraphs
4 (10)(A)(i)(VIII) and (74) of subsection (a), the term ‘re-
5 search study’ means a clinical study, including an observa-
6 tional (or natural history) study, or a clinical trial, to test
7 an experimental therapy.”.

8 (C) MEDICAL ASSISTANCE LIMITED TO
9 COVERAGE OF THE RESEARCH OR OBSERVA-
10 TIONAL TRIAL DRUGS, BIOLOGICAL PRODUCT,
11 OR INSULIN.—Section 1902(a)(10) of the Social
12 Security Act (42 U.S.C. 1396a(a)(10)) is
13 amended in the matter following subparagraph
14 (G)—

15 (i) by striking “and (XIV)” and in-
16 serting “(XIV)”; and

17 (ii) by inserting “, and (XV) the med-
18 ical assistance made available to a research
19 study child participant described in sub-
20 section (gg)(1) who is eligible for medical
21 assistance solely on the basis of subpara-
22 graph (A)(10)(i)(VIII) shall be limited to
23 medical assistance for a drug, biological
24 product, or insulin that is prescribed for
25 the participant as a result of participation

1 in such trial or study (including any such
2 drug, product, or insulin that is self-ad-
3 ministered)” before the semicolon.

4 (D) CONFORMING AMENDMENT.—Section
5 1903(f)(4) of such Act (42 U.S.C.
6 1396b)(f)(4)) is amended in the matter pre-
7 ceding subparagraph (A) by inserting
8 “1902(a)(10)(A)(i)(VIII),” after
9 “1902(a)(10)(A)(i)(VII),”.

10 (b) PRESUMPTIVE ELIGIBILITY.—Section 1920B of
11 such Act (42 U.S.C. 1396r–1b) is amended—

12 (1) in the section heading, by inserting “OR RE-
13 SEARCH STUDY CHILD PARTICIPANTS” after “PA-
14 TIENTS”;

15 (2) in subsection (a), by inserting “or a child
16 who is eligible for medical assistance under the State
17 plan (including a child who is eligible only on the
18 basis of section 1902(a)(10)(A)(i)(VIII) but subject
19 to the limitation on medical assistance for such a
20 child under clause (XV) of the matter following sec-
21 tion 1902(a)(10)(G)), is a current or former partici-
22 pant in a research study conducted or funded (in
23 whole or in part) by the National Institutes of
24 Health, and satisfies the requirements of subpara-

1 graphs (B), (C), and (D) of section 1902(gg)(1)”
2 after “patients”;

3 (3) in subsection (b)(1)(A), by inserting “or
4 subsection (a)” after “1902(aa)”;

5 (4) in subsection (d), in the flush language fol-
6 lowing paragraph (2), by striking “for purposes of
7 clause (4) of the first sentence of section 1905(b)”
8 and inserting “for purposes of the first sentence of
9 section 1905(b) (and, in the case of medical assist-
10 ance furnished to an individual described in section
11 1902(aa), for purposes of clause (4) of such sen-
12 tence)”.

13 (c) NOTICE OF MEDICAID COVERAGE FOR RESEARCH
14 STUDY CHILD PARTICIPANTS.—

15 (1) IN GENERAL.—Not later than 90 days after
16 the date of enactment of this Act, the Secretary of
17 Health and Human Services, in consultation with
18 the Director of the Institutes of Health and State
19 Medicaid Directors, shall—

20 (A) develop a written notice for child par-
21 ticipants in research studies (as defined in sec-
22 tion 1902(gg)(3) of the Social Security Act, as
23 added by subsection (a)(2)(B)) conducted or
24 funded (in whole or in part) by the National In-
25 stitutes of Health who are likely to eligible for

1 medical assistance for a drug, biological prod-
2 uct, or insulin prescribed for such participants
3 as a result of participation in such a study (in-
4 cluding any such drug, product, or insulin that
5 is self-administered) in accordance with para-
6 graph (10)(A)(i)(VIII) or (74) of section
7 1902(a) of the Social Security Act (42 U.S.C.
8 1396a(a)) (as added by subsection (a)), of the
9 availability of such assistance; and

10 (B) establish procedures for making such
11 notice available to the child participants
12 through physicians participating in such re-
13 search studies or such other means as the Sec-
14 retary determines appropriate.

15 (2) AUTHORIZATION OF APPROPRIATIONS.—

16 There is authorized to be appropriated for fiscal
17 year 2010 and each fiscal year thereafter such sums
18 as may be necessary to carry out this subsection.

19 (d) EFFECTIVE DATE.—The amendments made by
20 this section apply to medical assistance for items and serv-
21 ices furnished on or after the date of enactment of this
22 Act, without regard to whether final regulations to carry
23 out such amendments have been promulgated.

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