

110TH CONGRESS  
2D SESSION

# H. R. 5468

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

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## IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 14, 2008

Mr. SHUSTER (for himself and Mr. PLATTS) introduced the following bill;  
which was referred to the Committee on Energy and Commerce

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## 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 (69), by striking “and”  
5       at the end;

6                   (B) in paragraph (70), by striking the pe-  
7       riod at the end and inserting “; and”; and

8                   (C) by inserting after paragraph (70) the  
9       following new paragraph:

10           “(71) 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 (dd)(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 (dd)(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           “(dd)(1) Research study child participants described  
4 in this subsection are individuals who—

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

7                 “(B) have not attained age 19;

8                 “(C) have been certified by a physician partici-  
9           pating in a research study conducted or funded (in  
10          whole or in part) by the National Institutes of  
11          Health to be current or former participants in such  
12          trial or study who have a specific disease or condi-  
13          tion that—

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

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

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

23           “(2) A State shall redetermine not less than every  
24 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 (71) 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 (dd)(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 the Social Security Act (42 U.S.C. 1396r–1b) is amend-  
 12 ed—

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

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

1 graphs (B), (C), and (D) of section 1902(dd)(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(dd)(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 (71) 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 2008 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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