

111TH CONGRESS
1ST SESSION

S. 1674

To provide for an exclusion under the Supplemental Security Income program and the Medicaid program for compensation provided to individuals who participate in clinical trials for rare diseases or conditions.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 15, 2009

Mr. WYDEN (for himself, Mr. DODD, Mr. SHELBY, and Mr. INHOFE) introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

To provide for an exclusion under the Supplemental Security Income program and the Medicaid program for compensation provided to individuals who participate in clinical trials for rare diseases or conditions.

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 “Improving Access to
5 Clinical Trials Act of 2009”.

6 **SEC. 2. FINDINGS.**

7 Congress finds the following:

1 (1) Advances in medicine depend on clinical
2 trial research conducted at public and private re-
3 search institutions across the United States.

4 (2) The challenges associated with enrolling
5 participants in clinical research studies are especially
6 difficult for studies that evaluate treatments for rare
7 diseases and conditions (defined by the Orphan
8 Drug Act as a disease or condition affecting fewer
9 than 200,000 Americans), where the available num-
10 ber of willing and able research participants may be
11 very small.

12 (3) In accordance with ethical standards estab-
13 lished by the National Institutes of Health, sponsors
14 of clinical research may provide payments to trial
15 participants for out-of-pocket costs associated with
16 trial enrollment and for the time and commitment
17 demanded by those who participate in a study. When
18 offering compensation, clinical trial sponsors are re-
19 quired to provide such payments to all participants.

20 (4) The offer of payment for research participa-
21 tion may pose a barrier to trial enrollment when
22 such payments threaten the eligibility of clinical trial
23 participants for Supplemental Security Income and
24 Medicaid benefits.

1 (5) With a small number of potential trial par-
 2 ticipants and the possible loss of Supplemental Secu-
 3 rity Income and Medicaid benefits for many who
 4 wish to participate, clinical trial research for rare
 5 diseases and conditions becomes exceptionally dif-
 6 ficult and may hinder research on new treatments
 7 and potential cures for these rare diseases and con-
 8 ditions.

9 **SEC. 3. EXCLUSION FOR COMPENSATION FOR PARTICIPA-**
 10 **TION IN CLINICAL TRIALS FOR RARE DIS-**
 11 **EASES OR CONDITIONS.**

12 (a) EXCLUSION FROM INCOME.—Section 1612(b) of
 13 the Social Security Act (42 U.S.C. 1382a(b)) is amend-
 14 ed—

15 (1) by striking “and” at the end of paragraph
 16 (24);

17 (2) by striking the period at the end of para-
 18 graph (25) and inserting “; and”; and

19 (3) by adding at the end the following:

20 “(26) the first \$2,000 received during a cal-
 21 endar year by such individual (or such spouse) as
 22 compensation for participation in a clinical trial in-
 23 volving research and testing of treatments for a rare
 24 disease or condition (as defined in section 5(b)(2) of

1 the Orphan Drug Act), but only if the clinical
 2 trial—

3 “(A) has been reviewed and approved by
 4 an institutional review board that is estab-
 5 lished—

6 “(i) to protect the rights and welfare
 7 of human subjects participating in sci-
 8 entific research; and

9 “(ii) in accord with the requirements
 10 under part 46 of title 45, Code of Federal
 11 Regulations; and

12 “(B) meets the standards for protection of
 13 human subjects as provided under part 46 of
 14 title 45, Code of Federal Regulations.”.

15 (b) EXCLUSION FROM RESOURCES.—Section
 16 1613(a) of the Social Security Act (42 U.S.C. 1382b(a))
 17 is amended—

18 (1) by striking “and” at the end of paragraph
 19 (15);

20 (2) by striking the period at the end of para-
 21 graph (16) and inserting “; and”; and

22 (3) by inserting after paragraph (16) the fol-
 23 lowing:

24 “(17) any amount received by such individual
 25 (or such spouse) which is excluded from income

1 under section 1612(b)(26) (relating to compensation
 2 for participation in a clinical trial involving research
 3 and testing of treatments for a rare disease or con-
 4 dition).”.

5 (c) MEDICAID EXCLUSION.—

6 (1) IN GENERAL.—Section 1902(e) of the So-
 7 cial Security Act (42 U.S.C. 1396a(e)), is amended
 8 by adding at the end the following:

9 “(14) EXCLUSION OF COMPENSATION FOR PAR-
 10 TICIPATION IN A CLINICAL TRIAL FOR TESTING OF
 11 TREATMENTS FOR A RARE DISEASE OR CONDI-
 12 TION.—The first \$2,000 received by an individual
 13 (who has attained 19 years of age) as compensation
 14 for participation in a clinical trial meeting the re-
 15 quirements of section 1612(b)(26) shall be dis-
 16 regarded for purposes of determining the income eli-
 17 gibility of such individual for medical assistance
 18 under the State plan or any waiver of such plan.”.

19 (2) CONFORMING AMENDMENT.—Section
 20 1902(a)(17) of such Act (42 U.S.C. 1396a(a)(17))
 21 is amended by inserting “(e)(14),” before “(l)(3)”.

22 (d) EFFECTIVE DATE.—The amendments made by
 23 this section shall take effect on the date that is the earlier
 24 of—

1 (1) the effective date of final regulations pro-
2 mulgated by the Commissioner of Social Security to
3 carry out this section and such amendments; or

4 (2) 180 days after the date of enactment of this
5 Act.

6 (e) SUNSET PROVISION.—This Act and the amend-
7 ments made by this Act are repealed on the date that is
8 5 years after the date of the enactment of this Act.

9 **SEC. 4. STUDY AND REPORT.**

10 (a) STUDY.—Not later than 36 months after the ef-
11 fective date of this Act, the Comptroller General of the
12 United States shall conduct a study to evaluate the impact
13 of this Act on enrollment of individuals who receive Sup-
14 plemental Security Income benefits under title XVI of the
15 Social Security Act (referred to in this section as “SSI
16 beneficiaries”) in clinical trials for rare diseases or condi-
17 tions. Such study shall include an analysis of the following:

18 (1) The percentage of enrollees in clinical trials
19 for rare diseases or conditions who were SSI bene-
20 ficiaries during the 3-year period prior to the effec-
21 tive date of this Act as compared to such percentage
22 during the 3-year period after the effective date of
23 this Act.

24 (2) The range and average amount of com-
25 pensation provided to SSI beneficiaries who partici-

1 pated in clinical trials for rare diseases or condi-
2 tions.

3 (3) The overall ability of SSI beneficiaries to
4 participate in clinical trials.

5 (4) Any additional related matters that the
6 Comptroller General determines appropriate.

7 (b) REPORT.—Not later than 12 months after com-
8 pletion of the study conducted under subsection (a), the
9 Comptroller General shall submit to Congress a report
10 containing the results of such study, together with rec-
11 ommendations for such legislation and administrative ac-
12 tion as the Comptroller General determines appropriate.

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