

PUBLIC LAW 111–255—OCT. 5, 2010

IMPROVING ACCESS TO CLINICAL TRIALS
ACT OF 2009

Public Law 111–255
111th Congress

An Act

Oct. 5, 2010
[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.

Improving Access
to Clinical Trials
Act of 2009.
42 USC 1305
note.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the “Improving Access to Clinical Trials Act of 2009”.

42 USC 1382a
note.

SEC. 2. FINDINGS.

Congress finds the following:

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

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

(3) In accordance with ethical standards established by the National Institutes of Health, sponsors of clinical research may provide payments to trial participants for out-of-pocket costs associated with trial enrollment and for the time and commitment demanded by those who participate in a study. When offering compensation, clinical trial sponsors are required to provide such payments to all participants.

(4) The offer of payment for research participation may pose a barrier to trial enrollment when such payments threaten the eligibility of clinical trial participants for Supplemental Security Income and Medicaid benefits.

(5) With a small number of potential trial participants and the possible loss of Supplemental Security Income and Medicaid benefits for many who wish to participate, clinical trial research for rare diseases and conditions becomes exceptionally difficult and may hinder research on new treatments and potential cures for these rare diseases and conditions.

SEC. 3. EXCLUSION FOR COMPENSATION FOR PARTICIPATION IN CLINICAL TRIALS FOR RARE DISEASES OR CONDITIONS.

(a) **EXCLUSION FROM INCOME.**—Section 1612(b) of the Social Security Act (42 U.S.C. 1382a(b)) is amended—

- (1) by striking “and” at the end of paragraph (24);
- (2) by striking the period at the end of paragraph (25) and inserting “; and”; and
- (3) by adding at the end the following:

“(26) the first \$2,000 received during a calendar year by such individual (or such spouse) as compensation for participation in a clinical trial involving research and testing of treatments for a rare disease or condition (as defined in section 5(b)(2) of the Orphan Drug Act), but only if the clinical trial—

“(A) has been reviewed and approved by an institutional review board that is established—

“(i) to protect the rights and welfare of human subjects participating in scientific research; and

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

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

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

- (1) by striking “and” at the end of paragraph (15);
- (2) by striking the period at the end of paragraph (16) and inserting “; and”; and
- (3) by inserting after paragraph (16) the following:

“(17) any amount received by such individual (or such spouse) which is excluded from income under section 1612(b)(26) (relating to compensation for participation in a clinical trial involving research and testing of treatments for a rare disease or condition).”.

(c) **MEDICAID EXCLUSION.**—

(1) **IN GENERAL.**—Section 1902(e) of the Social Security Act (42 U.S.C. 1396a(e)), is amended by adding at the end the following:

“(14) **EXCLUSION OF COMPENSATION FOR PARTICIPATION IN A CLINICAL TRIAL FOR TESTING OF TREATMENTS FOR A RARE DISEASE OR CONDITION.**—The first \$2,000 received by an individual (who has attained 19 years of age) as compensation for participation in a clinical trial meeting the requirements of section 1612(b)(26) shall be disregarded for purposes of determining the income eligibility of such individual for medical assistance under the State plan or any waiver of such plan.”.

(2) **CONFORMING AMENDMENT.**—Section 1902(a)(17) of such Act (42 U.S.C. 1396a(a)(17)) is amended by inserting “(e)(14),” before “(1)(3)”.

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

- (1) the effective date of final regulations promulgated by the Commissioner of Social Security to carry out this section and such amendments; or
- (2) 180 days after the date of enactment of this Act.

(e) **SUNSET PROVISION.**—This Act and the amendments made by this Act are repealed on the date that is 5 years after the date of the enactment of this Act.

42 USC 1382a
note.

Regulations.

42 USC 1382a
note, 1305 note,
1382a, 1382b,
1396a.

SEC. 4. STUDY AND REPORT.

(a) **STUDY.**—Not later than 36 months after the effective date of this Act, the Comptroller General of the United States shall conduct a study to evaluate the impact of this Act on enrollment of individuals who receive Supplemental Security Income benefits under title XVI of the Social Security Act (referred to in this section as “SSI beneficiaries”) in clinical trials for rare diseases or conditions. Such study shall include an analysis of the following:

(1) The percentage of enrollees in clinical trials for rare diseases or conditions who were SSI beneficiaries during the 3-year period prior to the effective date of this Act as compared to such percentage during the 3-year period after the effective date of this Act.

(2) The range and average amount of compensation provided to SSI beneficiaries who participated in clinical trials for rare diseases or conditions.

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

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

(b) **REPORT.**—Not later than 12 months after completion of the study conducted under subsection (a), the Comptroller General shall submit to Congress a report containing the results of such study, together with recommendations for such legislation and administrative action as the Comptroller General determines appropriate.

Approved October 5, 2010.

LEGISLATIVE HISTORY—S. 1674:

CONGRESSIONAL RECORD, Vol. 156 (2010):

Aug. 5, considered and passed Senate.

Sept. 23, considered and passed House.

