

118TH CONGRESS
2D SESSION

H. R. 8412

To modernize clinical trials and remove barriers for participation in clinical trials, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 15, 2024

Mr. RUIZ (for himself and Mr. BUCSHON) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To modernize clinical trials and remove barriers for participation in clinical trials, 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 “Clinical Trial Mod-
5 ernization Act”.

6 **SEC. 2. DEFINITION.**

7 For purposes of this Act, the term “underrepresented
8 population” has the meaning given such term by the Na-
9 tional Institutes of Health for purposes of the Toolkit for

1 Patient-Focused Therapy Development (as published on
2 April 1, 2024), in addition to such populations recognized
3 by the Food and Drug Administration.

4 **SEC. 3. GRANTS TO ENCOURAGE CLINICAL TRIAL ENROLL-**
5 **MENT BY UNDERREPRESENTED POPU-**
6 **LATIONS.**

7 (a) IN GENERAL.—The Secretary may issue grants
8 to and enter into contracts with entities to support com-
9 munity education, outreach, and recruitment activities for
10 clinical trials with respect to devices and drugs, including
11 vaccines, for diseases or conditions that have a dispro-
12 tionate impact on underrepresented populations. Such ac-
13 tivities may include—

14 (1) working with community clinical trial sites,
15 including community health centers, academic health
16 centers, sites in rural communities, and other facili-
17 ties;

18 (2) training health care personnel, including po-
19 tential clinical trial investigators, with a focus on
20 significantly increasing the number of underrep-
21 resented populations of health care personnel who
22 are clinical trial investigators at the community sites
23 for ongoing clinical trials;

1 (3) engaging community stakeholders to en-
2 courage participation in clinical trials, especially in
3 underrepresented populations; and

4 (4) fostering partnerships with community-
5 based organizations serving underrepresented popu-
6 lations, including employee unions and frontline
7 health care workers.

8 (b) PRIORITY FOR GRANT AND CONTRACT
9 AWARDS.—In awarding grants and contracts under this
10 section, the Secretary shall prioritize entities that—

11 (1) develop educational, recruitment, and train-
12 ing materials in multiple languages; or

13 (2) undertake clinical trial outreach efforts in
14 communities that are traditionally underrepresented
15 in clinical trials, such as tribal areas.

16 (c) AUTHORIZATION OF APPROPRIATIONS.—There is
17 authorized to be appropriated for fiscal years 2024 and
18 2025 such sums as may be necessary to carry out this
19 section.

1 **SEC. 4. ENCOURAGEMENT OF CLINICAL TRIAL PARTICIPA-**
2 **TION BY UNDERREPRESENTED POPU-**
3 **LATIONS THROUGH PAYMENT OF STUDY PAR-**
4 **TICIPANT CLINICAL TRIAL EXPENSES AND**
5 **PROVISION OF DIGITAL HEALTH TECH-**
6 **NOLOGIES.**

7 (a) IN GENERAL.—Section 1128A(i)(6)(F) of the So-
8 cial Security Act (42 U.S.C. 1320a–7a(i)(6)(F)) is amend-
9 ed by striking “under regulations;” and inserting the fol-
10 lowing: “under regulations, including—

11 “(i) remuneration offered or trans-
12 ferred to an individual while participating
13 in a clinical trial, as defined in subsection
14 (d) of the first section 2709 of the Public
15 Health Service Act for expenses incurred
16 as part of the trial, other than patient
17 cost-sharing obligations, including without
18 limitation travel, transportation, and meal
19 expenses, so long as such remuneration is
20 made available to all study participants
21 and facilitates inclusion of patients from
22 all relevant demographic and socioeconomic
23 populations and geographies including
24 rural communities; and

1 “(ii) the free provision to an indi-
2 vidual of digital health technologies
3 where—

4 “(I) the use of the digital health
5 technologies is intended to facilitate
6 the participation of underrepresented
7 patient populations; and

8 “(II) the digital health tech-
9 nologies are necessary for participa-
10 tion in such trial;”.

11 (b) CONFORMING AMENDMENT TO THE ANTI-KICK-
12 BACK STATUTE.—Section 1128B(b)(3) of the Social Secu-
13 rity Act (42 U.S.C. 1320a–7b(b)(3)) is amended—

14 (1) by striking “and” at the end of subpara-
15 graph (K);

16 (2) by striking the period at the end of sub-
17 paragraph (L) and inserting “; and”;

18 (3) by aligning the left margin of each of sub-
19 paragraphs (J) and (K) with the left margin of sub-
20 paragraph (I); and

21 (4) by inserting after subparagraph (L) the fol-
22 lowing new subparagraphs:

23 “(M) any remuneration offered or trans-
24 ferred to an individual while participating in a
25 clinical trial (as defined in subsection (d) of the

1 first section 2709 of the Public Health Service
2 Act) for expenses incurred as part of the trial,
3 other than patient cost-sharing obligations, in-
4 cluding without limitation travel, transpor-
5 tation, and meal expenses, so long as such re-
6 munerated is made available to all study par-
7 ticipants and facilitates inclusion of patients
8 from all relevant demographic and socio-
9 economic populations and geographies, includ-
10 ing rural communities; and

11 “(N) the free provision to an individual of
12 digital health technologies where—

13 “(i) the use of the digital health tech-
14 nologies is intended to facilitate in any
15 phase of a clinical trial (as so defined) the
16 participation of underrepresented patient
17 populations; and

18 “(ii) the digital health technologies
19 are necessary to such participation.”.

20 (c) EFFECTIVE DATE.—The amendments made by
21 this section shall apply to remuneration provided on or
22 after the date of enactment of this Act.

1 **SEC. 5. ENCOURAGEMENT OF CLINICAL TRIAL ACCESSI-**
2 **BILITY THROUGH SUPPORT OF CLINICAL**
3 **TRIAL COST-SHARING.**

4 The payment of patient cost-sharing obligations asso-
5 ciated with participation in a clinical trial (as defined in
6 subsection (d) of the first section 2709 of the Public
7 Health Service Act) or for which a diversity action plan
8 is required pursuant to sections 505(z) or 520(g)(9) of
9 the Federal Food, Drug, and Cosmetic Act by drug or de-
10 vice manufacturers or their agents for their clinical trial
11 participants shall not be considered a violation of section
12 1128A of the Social Security Act (42 U.S.C. 1320a–7a)
13 (commonly known as the “Civil Monetary Penalties
14 Law”), section 1128B of the Social Security Act (42
15 U.S.C. 1320a–7b), or sections 3729 through 3733 of title
16 31, United States Code (commonly known as the “False
17 Claims Act”), provided that the following requirements
18 are met:

19 (1) The trial and any coverage of items or serv-
20 ices provided in the trial is consistent with all appli-
21 cable coverage rules by any Federal health care pro-
22 grams providing coverage and reimbursement for
23 beneficiaries participating in the trial as study sub-
24 jects, including but not limited to, any existing trial
25 qualification requirements imposed by the Centers

1 for Medicare & Medicaid Services for Medicare cov-
2 erage of the trial.

3 (2) The proposed arrangement for the payment
4 of patient cost-sharing obligations is a reasonable
5 means of facilitating enrollment of an underrep-
6 resented set of subjects or reducing the likelihood of
7 attrition in the trial by removing a potential finan-
8 cial barrier to participation in the trial.

9 (3) Any sponsor payments of participating pa-
10 tient cost-sharing obligations must be available
11 throughout the entirety of the clinical trial.

12 (4) Any sponsor payments of participating pa-
13 tient cost-sharing obligations are not contingent on
14 the future use or purchase of any product or service.

15 (5) Any sponsor payments of participating pa-
16 tient cost-sharing obligations will not be provided in
17 excess of the patient's cost-sharing obligations under
18 relevant Federal health care programs.

19 (6) A participating patient receiving cost-shar-
20 ing assistance from a sponsor will be required to
21 agree not to accept other financial assistance to
22 cover the patient's cost-sharing obligations.

23 (7) Any sponsor payments of participating pa-
24 tient cost-sharing obligations will cease upon the pa-

1 tient’s disenrollment from the clinical trial or the
2 conclusion of the clinical trial, whichever is first.

3 (8) The proposed arrangement for the payment
4 of patient cost-sharing obligations includes the fol-
5 lowing elements to protect against improper in-
6 creased costs or inappropriate utilization of items
7 and services reimbursed in whole or in part under
8 Federal health care programs:

9 (A) The availability of cost-sharing sub-
10 sidies will not be advertised, but may be dis-
11 closed as required or permitted by law in the in-
12 formed consent forms, protocol, or other docu-
13 mentation associated with the study.

14 (B) Participating Federal health care pro-
15 gram beneficiaries must satisfy formal, objec-
16 tive, and predetermined enrollment criteria and
17 execute an informed consent document.

18 (C) The sponsor must enter into a written
19 agreement with investigators that requires the
20 investigators to comply with the written pro-
21 tocol for the study and to be subject to over-
22 sight and monitoring by an institutional review
23 board or other similar body providing inde-
24 pendent oversight for the trial.

1 (D) Total enrollment for the trial is
2 capped.

3 **SEC. 6. EXCLUSION FROM GROSS INCOME FOR REMUNERA-**
4 **TION PROVIDED BY SPONSORS OF APPROVED**
5 **CLINICAL TRIALS TO PARTICIPANTS.**

6 (a) IN GENERAL.—Part III of subchapter B of chap-
7 ter 1 of the Internal Revenue Code of 1986 is amended
8 by inserting before section 140 the following new section:

9 **“SEC. 139J. REMUNERATION PROVIDED BY SPONSORS OF**
10 **APPROVED CLINICAL TRIALS TO PARTICI-**
11 **PANTS.**

12 “(a) IN GENERAL.—Gross income shall not include
13 the value of any payment received by an individual from
14 participation in an approved clinical trial (as defined in
15 subsection (d) of the first section 2709 of the Public
16 Health Service Act).

17 “(b) LIMITATION.—The amount excluded from gross
18 income under subsection (a) for any taxable year shall not
19 exceed \$2,000.”.

20 (b) CLERICAL AMENDMENT.—The table of sections
21 for part III of subchapter B of chapter 1 of the Internal
22 Revenue Code of 1986 is amended by inserting before the
23 item relating to section 140 the following new item:

“Sec. 139J. Remuneration provided by sponsors of approved clinical trials to participants.”.

1 (c) EFFECTIVE DATE.—The amendments made by
2 this section shall apply to taxable years beginning after
3 the date of enactment of this Act.

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