

119TH CONGRESS
2D SESSION

S. _____

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

IN THE SENATE OF THE UNITED STATES

Mr. SCOTT of South Carolina (for himself and Mr. WARNER) introduced the following bill; which was read twice and referred to the Committee on

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
10 Patient-Focused Therapy Development (as published on

1 April 1, 2024), in addition to such populations recognized
2 by the Food and Drug Administration.

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

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

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

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

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

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

5 (b) **PRIORITY FOR GRANT AND CONTRACT**
6 **AWARDS.**—In awarding grants and contracts under this
7 section, the Secretary shall prioritize entities that—

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

10 (2) undertake clinical trial outreach efforts in
11 communities that are traditionally underrepresented
12 in clinical trials, such as tribal areas.

13 (c) **AUTHORIZATION OF APPROPRIATIONS.**—There is
14 authorized to be appropriated for fiscal years 2027 and
15 2028 such sums as may be necessary to carry out this
16 section.

17 **SEC. 4. ENCOURAGEMENT OF CLINICAL TRIAL PARTICIPA-**
18 **TION BY UNDERREPRESENTED POPU-**
19 **LATIONS THROUGH PAYMENT OF STUDY PAR-**
20 **TICIPANT CLINICAL TRIAL EXPENSES AND**
21 **PROVISION OF DIGITAL HEALTH TECH-**
22 **NOLOGIES.**

23 (a) **IN GENERAL.**—Section 1128A(i)(6)(F) of the So-
24 cial Security Act (42 U.S.C. 1320a–7a(i)(6)(F)) is amend-

1 ed by striking “under regulations);” and inserting the fol-
2 lowing: “under regulations, including—

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

17 “(ii) the free provision to an indi-
18 vidual of digital health technologies
19 where—

20 “(I) the use of the digital health
21 technologies is intended to facilitate
22 the participation of underrepresented
23 patient populations; and

1 “(II) the digital health tech-
2 nologies are necessary for partici-
3 pation in such trial;”.

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

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

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

11 (3) by aligning the left margin of each of sub-
12 paragraphs (J) and (K) with the left margin of sub-
13 paragraph (I); and

14 (4) by inserting after subparagraph (L) the fol-
15 lowing new subparagraphs:

16 “(M) any remuneration offered or trans-
17 ferred to an individual while participating in a
18 clinical trial (as defined in subsection (d) of the
19 first section 2709 of the Public Health Service
20 Act) for expenses incurred as part of the trial,
21 other than patient cost-sharing obligations, in-
22 cluding without limitation travel, transpor-
23 tation, and meal expenses, so long as such re-
24 muneration is made available to all study par-
25 ticipants and facilitates inclusion of patients

1 from all relevant demographic and socio-
2 economic populations and geographies, includ-
3 ing rural communities; and

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

6 “(i) the use of the digital health tech-
7 nologies is intended to facilitate in any
8 phase of a clinical trial (as so defined) the
9 participation of underrepresented patient
10 populations; and

11 “(ii) the digital health technologies
12 are necessary to such participation.”.

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

16 **SEC. 5. ENCOURAGEMENT OF CLINICAL TRIAL ACCESSI-**
17 **BILITY THROUGH SUPPORT OF CLINICAL**
18 **TRIAL COST-SHARING.**

19 The payment of patient cost-sharing obligations asso-
20 ciated with participation in a clinical trial (as defined in
21 subsection (d) of the first section 2709 of the Public
22 Health Service Act) or for which a diversity action plan
23 is required pursuant to sections 505(z) or 520(g)(9) of
24 the Federal Food, Drug, and Cosmetic Act by drug or de-
25 vice manufacturers or their agents for their clinical trial

1 participants shall not be considered a violation of section
2 1128A of the Social Security Act (42 U.S.C. 1320a–7a)
3 (commonly known as the “Civil Monetary Penalties
4 Law”), section 1128B of the Social Security Act (42
5 U.S.C. 1320a–7b), or sections 3729 through 3733 of title
6 31, United States Code (commonly known as the “False
7 Claims Act”), provided that the following requirements
8 are met:

9 (1) The trial and any coverage of items or serv-
10 ices provided in the trial is consistent with all appli-
11 cable coverage rules by any Federal health care pro-
12 grams providing coverage and reimbursement for
13 beneficiaries participating in the trial as study sub-
14 jects, including but not limited to, any existing trial
15 qualification requirements imposed by the Centers
16 for Medicare & Medicaid Services for Medicare cov-
17 erage of the trial.

18 (2) The proposed arrangement for the payment
19 of patient cost-sharing obligations is a reasonable
20 means of facilitating enrollment of an underrep-
21 resented set of subjects or reducing the likelihood of
22 attrition in the trial by removing a potential finan-
23 cial barrier to participation in the trial.

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

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

7 (5) Any sponsor payments of participating pa-
8 tient cost-sharing obligations will not be provided in
9 excess of the patient's cost-sharing obligations under
10 relevant Federal health care programs.

11 (6) A participating patient receiving cost-shar-
12 ing assistance from a sponsor will be required to
13 agree not to accept other financial assistance to
14 cover the patient's cost-sharing obligations.

15 (7) Any sponsor payments of participating pa-
16 tient cost-sharing obligations will cease upon the pa-
17 tient's disenrollment from the clinical trial or the
18 conclusion of the clinical trial, whichever is first.

19 (8) The proposed arrangement for the payment
20 of patient cost-sharing obligations includes the fol-
21 lowing elements to protect against improper in-
22 creased costs or inappropriate utilization of items
23 and services reimbursed in whole or in part under
24 Federal health care programs:

1 (A) The availability of cost-sharing sub-
2 sidies will not be advertised, but may be dis-
3 closed as required or permitted by law in the in-
4 formed consent forms, protocol, or other docu-
5 mentation associated with the study.

6 (B) Participating Federal health care pro-
7 gram beneficiaries must satisfy formal, objec-
8 tive, and predetermined enrollment criteria and
9 execute an informed consent document.

10 (C) The sponsor must enter into a written
11 agreement with investigators that requires the
12 investigators to comply with the written pro-
13 tocol for the study and to be subject to over-
14 sight and monitoring by an institutional review
15 board or other similar body providing inde-
16 pendent oversight for the trial.

17 (D) Total enrollment for the trial is
18 capped.

19 **SEC. 6. EXCLUSION FROM GROSS INCOME FOR REMUNERA-**
20 **TION PROVIDED BY SPONSORS OF APPROVED**
21 **CLINICAL TRIALS TO PARTICIPANTS.**

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

1 **“SEC. 139J. REMUNERATION PROVIDED BY SPONSORS OF**
2 **APPROVED CLINICAL TRIALS TO PARTICI-**
3 **PANTS.**

4 “(a) IN GENERAL.—Gross income shall not include
5 the value of any payment received by an individual from
6 participation in an approved clinical trial (as defined in
7 subsection (d) of the first section 2709 of the Public
8 Health Service Act).

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

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

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

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

19 **SEC. 7. RULE OF CONSTRUCTION.**

20 Nothing in section 4 or section 5 of this Act shall
21 be construed to limit or narrow in any way any other pro-
22 tections from liability under section 1128A or 1128B of
23 the Social Security Act (42 U.S.C. 1320a-7a; 1320a-7b)
24 or sections 3729 through 3733 of title 31, United States

1 Code, whether such other protections are set forth in stat-
2 ute, regulation, or any form of guidance, that may apply
3 to any practice or arrangement encouraging participation
4 in or accessibility of clinical trials.