117TH CONGRESS
1ST SESSION

S. 2706

To improve diversity in clinical trials and data collection for COVID–19 and future public health threats to address social determinants of health.

IN THE SENATE OF THE UNITED STATES

AUGUST 10, 2021

Mr. MENENDEZ (for himself and Mr. SCOTT of South Carolina) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To improve diversity in clinical trials and data collection for COVID–19 and future public health threats to address social determinants of health.

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 ''Diversifying Investigations Via Equitable Research Studies for Everyone Trials Act'' or the ''DIVERSE Trials Act''.

SEC. 2. GUIDANCE ON DECENTRALIZED CLINICAL TRIALS.

(a) DEFINITIONS.—In this section, the term ''decentralized clinical trials'' includes clinical trials that are exe-

cuted through a broad spectrum of options, such as telemedicine or other mobile or digital technologies, to allow for the remote collection and assessment of clinical trial data from participants, including in the home or office setting.

(b) GUIDANCE.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this Act as the ''Secretary''), acting through the Commissioner of Food and Drugs (referred to in this Act as the ''Commissioner''), shall issue a draft guidance that addresses how to conduct decentralized clinical trials with meaningful demographic diversity, including racial, ethnic, age, gender, and geographic diversity in patient engagement, enrollment, and participation, including how to appropriately use digital health technologies or other remote assessment options, such as telemedicine, to support such trials. Not later than 6 months after the date the public comment period for the draft guidance ends, the Secretary shall issue a final guidance.

(c) CONTENT OF GUIDANCE.—The guidance under subsection (b) shall address the following:

(1) Strategies to engage with prospective clinical trial participants and community partners, such as patient advocacy groups with diverse representa-

tion, to incorporate input of such patients and partners into the design of decentralized clinical trials.

(2) Recommendations for—

(A) protocol design approaches;

(B) appropriate clinical endpoints;

(C) institutional review board composition and ensuring that such boards include members with expertise in decentralized clinical trials;

(D) delegation of clinical research organization responsibilities and suitable proxies for clinical research organizations; and

(E) simplifying informed consent.

(3) Recommendations for how digital health technology or other remote assessment options, such as telemedicine, could support decentralized clinical trials, including guidance on appropriate technological platforms and mediums, data collection and use, data integrity, and communication to study participants through digital technology.

(4) Recommendations for appropriate methods of patient recruitment and retention, including institutional review board oversight, patient communication, and the role of study participants and community partners as advocates to facilitate clinical trial

recruitment, particularly with respect to underrepresented populations.

(5) Information regarding when and how a study sponsor may solicit a meeting with the Secretary regarding the issues described in paragraphs (1) through (4).

(d) INTERNATIONAL HARMONIZATION.—After issuing the final guidance under subsection (b), the Secretary, acting through the Commissioner, may work with foreign regulators pursuant to existing memoranda of understanding governing exchange of information to facilitate international harmonization of the regulation of decentralized clinical trials and use of digital health technology or other remote assessment options.

SEC. 3. ENCOURAGEMENT OF CLINICAL TRIAL ENROLLMENT BY RACIALLY AND ETHNICALLY DIVERSE POPULATIONS.

(a) NO COST PROVISION OF DIGITAL HEALTH TECHNOLOGIES.—The free provision of digital health technologies by drug or device manufacturers to their clinical trial participants shall not be considered a violation of section 1128A of the Social Security Act (commonly known as the ''Civil Monetary Penalties Law'') (42 U.S.C. 1320a–7a), section 1128B of the Social Security Act (42 U.S.C. 1320a–7b), or sections 3729 through 3733 of title

31, United States Code, (commonly known as the ''False Claims Act''), provided that—

(1) the use of digital health technologies will facilitate in any phase of clinical development the inclusion of diversity of patient populations, such as underrepresented racial and ethnic minorities, low-income populations, and the elderly;

(2) the digital health technologies will facilitate individuals participation, or are necessary to such participation;

(3) all features of the digital health technologies that are unrelated to use in the clinical trial are disabled or only allowed to remain activated to model real-world usage of the digital technology; and

(4) the clinical trial sponsor requires participants to return, purchase, or disable the digital health technologies by the conclusion of the trial.

(b) GRANTS AND CONTRACTS.—

(1) IN GENERAL.—The Secretary may issue grants to and enter into contracts with entities to support community education, outreach, and recruitment activities for clinical trials with respect to drugs, including vaccines for diseases or conditions which have a disproportionate impact on underrepresented populations (including on racial and ethnic

minority populations), including for the diagnosis, prevention, or treatment of COVID–19. Such activities may include—

(A) working with community clinical trial sites, including community health centers, academic health centers, and other facilities;

(B) training health care personnel including potential clinical trial investigators, with a focus on significantly increasing the number of underrepresented racial and ethnic minority healthcare personnel who are clinical trial investigators at the community sites for ongoing clinical trials;

(C) engaging community stakeholders to encourage participation in clinical trials, especially in underrepresented racial and ethnic minority communities; and

(D) fostering partnerships with community-based organizations serving underrepresented racial and ethnical minority populations, including employee unions and frontline health care workers.

(2) PRIORITY FOR GRANT AND CONTRACT AWARDS.—In awarding grants and contracts under

this subsection, the Secretary shall prioritize entities that—

(A) develop educational, recruitment, and training materials in multiple languages; or

(B) undertake clinical trial outreach efforts in more diverse racial and ethnic communities that are traditionally underrepresented in clinical trials, such as tribal areas.

(3) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated for fiscal years 2020 and 2021 such sums as may be necessary to carry out this subsection.

SEC. 4. ENHANCEMENT OF COVID–19 DATA COLLECTION TO ADDRESS DEMOGRAPHIC DATA GAPS AND SOCIAL DETERMINANTS OF HEALTH.

(a) DATA COLLECTION TO ADDRESS DEMOGRAPHIC DATA GAPS.—

(1) IN GENERAL.—The Secretary shall require laboratories that are subject to the reporting requirements under section 18115(a) of the Coronavirus Aid, Relief, and Economic Security Act (Public Law 116–136), to include with reports made under such section 18115(a) information to enhance such existing COVID–19 data collection activities and to advance policies to address social deter-

minants of health, including additional identifiers, such as those identified by the Commissioner, including building on guidance existing on the date of enactment of this Act, for the collection of race and ethnicity data in clinical trials, as determined appropriate by the Secretary.

(2) ADDITIONAL USE OF DATA.—The data collected under paragraph (1) may be used to inform—

(A) clinical trial recruitment;

(B) resource allocations;

(C) treatment strategies; and

(D) other public health activities.

(3) COLLECTION VIA GRANTS OR CONTRACTS.—

(A) IN GENERAL.—The Secretary may issue grants to, and enter into contracts with, States, local public health departments, or other entities supplying data to the Secretary as required under this subsection, to support the activities under this subsection.

(B) GUIDANCE FOR USE OF FUNDS.—In issuing grants or contracts under subparagraph (A), the Secretary may issue guidance regarding best practices for collecting data pursuant to paragraph (1) and track the performance of entities receiving grants or contracts.

(4) USE AND DISCLOSURE FOR PUBLIC HEALTH ACTIVITIES.—The submission and use of data collected pursuant to this subsection shall be considered a permitted disclosure and use for public health activities as set forth in section 164.512(b)(1)(i) of 45, Code of Federal Regulations (or any successor regulations).

(b) DATA COLLECTION REGARDING ENHANCED RISK FOR COVID–19.—The Secretary shall—

(1) conduct a study on best practices for laboratories that are subject to the reporting requirements under section 18115(a) of the Coronavirus Aid, Relief, and Economic Security Act (Public Law 116–136) to aid such laboratories in collecting data elements related to enhanced risk for COVID–19, such as data, with respect to a patient, regarding income, education, employment, disability, community resources, and social support;

(2) consider which governmental entities (including Federal, State, and local governmental entities) would be best suited to aiding in collecting such data elements in coordination with such laboratories; and

(3) issue guidance on such best practices.

SEC. 5. CLARIFICATION THAT CERTAIN REMUNERATION RELATED TO PARTICIPATION IN CLINICAL TRIALS DOES NOT CONSTITUTE REMUNERATION UNDER THE FEDERAL CIVIL MONEY PENALTIES LAW.

(a) IN GENERAL.—Section 1128A(i)(6)(F) of the Social Security Act (42 U.S.C. 1320a–7a(i)(6)(F)) is amended by inserting ''(including remuneration offered or transferred to an individual to promote the participation in an approved clinical trial, as defined in subsection (d) of the first section 2709 of the Public Health Service Act, that is registered with the database of clinical trials maintained by the National Library of Medicine (or any successor database), so long as such remuneration facilitates equitable inclusion of patients from all relevant demographic and socioeconomic populations and is related to patient participation in the approved clinical trial)'' after ''promotes access to care''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to remuneration provided on or after the date of the enactment of this Act.

SEC. 6. NATIONAL ACADEMY OF MEDICINE STUDY.

(a) IN GENERAL.—The Secretary shall enter into an arrangement with the National Academy of Medicine under which the National Academy agrees to study and propose a design for a national interoperable data plat-

form to improve access to health data, and other relevant data needs, during public health emergencies.

(b) REPORT.—The arrangement under subsection (a) shall provide for submission by the National Academy of Medicine to the Secretary and Congress, not later than 120 days after the date of enactment of this Act, of a report on the results of the study under subsection (a) and the design proposed based on such study.

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