

117TH CONGRESS
1ST SESSION

S. 236

To improve activities for the gathering of data on, and the tracking of,
new variants of COVID–19.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 4, 2021

Ms. BALDWIN (for herself, Mr. BROWN, Mrs. FEINSTEIN, Mr. BLUMENTHAL,
Mr. MARKEY, Mr. PETERS, and Ms. KLOBUCHAR) introduced the fol-
lowing bill; which was read twice and referred to the Committee on
Health, Education, Labor, and Pensions

A BILL

To improve activities for the gathering of data on, and the
tracking of, new variants of COVID–19.

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 “Tracking COVID–19
5 Variants Act”.

6 **SEC. 2. FINDINGS.**

7 Congress finds that—

1 (1) new variants of SARS-CoV-2 are being
2 identified around the world and in the United
3 States;

4 (2) identifying new variants of SARS-CoV-2
5 and analyzing the epidemiology of variants are crit-
6 ical to the continued response to the COVID-19
7 pandemic and efforts to prepare for future
8 pandemics;

9 (3) national sequence-based surveillance will en-
10 able the United States to best identify new variants;
11 and

12 (4) the United States is conducting sequence-
13 based surveillance of approximately 0.3 percent of
14 COVID-19 cases, lagging far behind other nations.

15 **SEC. 3. GUIDANCE.**

16 The Secretary of Health and Human Services (re-
17 ferred to in this Act as the “Secretary”), acting through
18 the Director of the Centers for Disease Control and Pre-
19 vention, shall issue national guidance to support scientific
20 collaboration relating to viral sequencing as a key strategy
21 to the COVID-19 response activities of the United States,
22 including guidance related to the sharing of specimens ob-
23 tained from patients, the secure sharing of information
24 about such specimens necessary for an effective public

1 health response to COVID–19, and the appropriate use
2 of viral sequence data derived from such specimens.

3 **SEC. 4. FUNDING FOR GENOMIC SEQUENCING, ANALYTICS,**
4 **AND DISEASE SURVEILLANCE.**

5 (a) IN GENERAL.—The Secretary, acting through the
6 Director of the Centers for Disease Control and Preven-
7 tion, shall establish and implement a program to strength-
8 en and expand activities related to genomic sequencing,
9 analytics, and disease surveillance.

10 (b) USE OF FUNDS.—In implementing the program
11 under subsection (a), the Secretary, acting through the
12 Director of the Centers for Disease Control and Preven-
13 tion, shall—

14 (1) conduct and expand activities, including
15 supporting the Advanced Molecular Detection Pro-
16 gram, to sequence the genome of circulating strains
17 of the SARS–CoV–2 virus, to identify mutations in
18 the SARS–CoV–2 virus, and to survey the circula-
19 tion and transmission of variant strains of the
20 SARS–CoV–2 virus;

21 (2) provide technical assistance and guidance
22 and award grants or cooperative agreements to
23 State, local, Tribal, or territorial public health de-
24 partments to increase the capacity of such depart-
25 ments to sequence the genome of circulating strains

of the SARS-CoV-2 virus, to identify mutations in the SARS-CoV-2 virus, to use genomic sequencing to identify outbreaks and clusters of COVID-19 infections caused by specific variants of SARS-CoV-2, and to develop effective COVID-19 response strategies based on genetic sequencing and surveillance data; and

(3) carry out activities to both enhance the informatics capabilities of the public health workforce and expand the numbers of qualified public health informaticians available to analyze and interpret data produced through advanced molecular detection and genomic sequencing to establish, expand, or enhance capacity for conducting statistical public health research.

(c) IMPLEMENTATION.—

(1) COOPERATIVE AGREEMENTS FOR TECHNICAL ASSISTANCE.—Cooperative agreements described in subsection (b)(2) may include partnerships with academic research institutions.

(2) CAPACITY FOR SHARING AND LINKING.—The capacity referred to in subsection (b)(3) may include sharing and linking information and accessing and utilizing linked health data files in accordance with established data use agreements with data hold-

1 ers (including electronic case reporting, electronic
2 health records, and electronic test orders and re-
3 sults) with public health agencies and related sys-
4 tems, including the National Death Index, immuni-
5 zation information systems, syndromic surveillance
6 systems, laboratory information management sys-
7 tems, electronic case reporting systems, medical ex-
8 aminer case management systems, and Patient Uni-
9 fied Look-up Systems for Emergencies.

10 (d) FACILITIES.—Funds appropriated under sub-
11 section (f) may be used for grants for the construction,
12 alteration, or renovation of non-federally owned facilities
13 to improve genetic sequencing and surveillance capabilities
14 at the State and local level.

15 (e) EXPANSION OF ONGOING ACTIVITIES.—Funds
16 appropriated under subsection (f) may be used for grants
17 for the maintenance and expansion of current and ongoing
18 activities to analyze and interpret data produced through
19 advanced molecular detection and genomic sequencing, in-
20 cluding for emerging public health threats.

21 (f) AUTHORIZATION OF APPROPRIATIONS.—There is
22 authorized to be appropriated, \$2,000,000,000 for fiscal
23 year 2021 to carry out this section, to remain available
24 until expended.

1 **SEC. 5. EVIDENCE-BUILDING DEMONSTRATION PROGRAM.**

2 (a) IN GENERAL.—The Secretary, acting through the
 3 Director of the National Center for Health Statistics, shall
 4 carry out a demonstration program to expand the data
 5 linkage program of the Department of Health and Human
 6 Services, consisting of Federal statistical and pro-
 7 grammatic datasets from specified Federal entities, as au-
 8 thorized by subchapter III of chapter 35 of title 44,
 9 United States Code, for the purpose of facilitating statis-
 10 tical public health research on trends and patterns across
 11 specifically defined, statistically relevant populations, with
 12 a particular focus on linking social determinants of health
 13 data, including with respect to—

- 14 (1) food insecurity;
- 15 (2) housing instability;
- 16 (3) transportation access;
- 17 (4) safety;
- 18 (5) social connection and isolation;
- 19 (6) financial resource strain;
- 20 (7) stress;
- 21 (8) race and ethnicity; and
- 22 (9) sexual orientation and gender identity.

23 (b) ACTIVITIES.—Activities carried out under the
 24 demonstration program under this section shall include—

- 25 (1) assessing the availability of identified and
- 26 deidentified data sets held by Federal, State, local,

1 and non-Federal entities that may be useful for re-
2 search described in subsection (a); and

3 (2) using existing authorities and linkages of
4 data in accordance with subchapter III of chapter 35
5 of title 44, United States Code, when relevant to re-
6 quest the submission of datasets to the National
7 Center for Health Statistics for linking.

8 (c) LIMITATION.—The Secretary shall limit access to
9 data under the demonstration program under this sec-
10 tion—

11 (1) to Federal statistical agencies and qualified
12 public and private researchers, as determined by the
13 Director of the National Center for Health Statis-
14 tics;

15 (2) for a period to be specified by the Sec-
16 retary; and

17 (3) exclusively for the purpose described in sub-
18 section (a).

19 (d) PROCESS FOR MAKING DATA AVAILABLE.—

20 (1) IN GENERAL.—Consistent with paragraph
21 (2), the Secretary shall establish a rigorous process
22 for making data available and usable under the dem-
23 onstration program under this section.

24 (2) REQUIREMENTS.—Prior to making any
25 data available under the demonstration program

1 under this section, by an entity described in sub-
 2 section (b)(1) to another entity described in sub-
 3 section (b)(1)—

4 (A) the receiving entity shall submit to the
 5 Director of the National Center for Health Sta-
 6 tistics an application for data for the purpose
 7 described in subsection (a); and

8 (B) the Director shall approve or deny
 9 such request in writing, including in the case of
 10 a denial an explanation of the reasons for the
 11 denial.

12 (e) RULEMAKING.—

13 (1) NO DELAY ON IMPLEMENTATION.—The
 14 Secretary—

15 (A) shall begin the implementation of the
 16 demonstration program under this section upon
 17 the date of enactment of this Act; and

18 (B) shall not delay such implementation
 19 for purposes of promulgating the regulations re-
 20 quired by paragraph (2).

21 (2) PROMULGATION.—The Secretary shall—

22 (A) promulgate regulations for carrying
 23 out this section; and

24 (B) specify in such regulations the allowed
 25 and disallowed purposes for sharing and linking

1 data through the program, including areas of
2 potential research.

3 (f) WEBSITE.—The Secretary shall maintain a pub-
4 licly accessible website—

5 (1) providing information about the demonstra-
6 tion program under this section;

7 (2) facilitating stakeholder participation in such
8 demonstration program;

9 (3) facilitating oversight of such demonstration
10 program;

11 (4) providing lists of datasets from Federal and
12 non-Federal entities;

13 (5) providing lists of identified and deidentified
14 datasets;

15 (6) identifying linked datasets;

16 (7) delineating a process to protect privacy and
17 confidentiality;

18 (8) identifying sources of the datasets; and

19 (9) delineating categories of personal data.

20 (g) PROGRAM REQUIREMENTS.—The demonstration
21 program under this section shall be designed to—

22 (1) support data matching services for agencies
23 and researchers using the National Death Index;
24 and

1 (2) facilitate collaboration with States and pri-
2 vate entities to examine, update, and modernize the
3 fee structure of the National Death Index to support
4 a broad range of data queries.

5 (h) CONTRACTED ENTITIES.—

6 (1) IN GENERAL.—Subject to the availability of
7 appropriations, the Secretary may enter into con-
8 tracts with eligible entities, as appropriate, for infra-
9 structure and support services in carrying out the
10 demonstration program under this section.

11 (2) ELIGIBILITY.—To be eligible for a contract
12 under paragraph (1), an entity shall—

13 (A) demonstrate core capabilities for data
14 sharing, data linkage, and compliance with sub-
15 chapter III of chapter 35 of title 44, United
16 States Code; and

17 (B) adhere to security standards in accord-
18 ance with the Federal Risk and Authorization
19 Management Program (or any successor pro-
20 gram).

21 (i) RULE OF CONSTRUCTION.—Nothing in this sec-
22 tion shall be construed to authorize the availability or use
23 of data for—

24 (1) law enforcement; or

1 (2) any determination of the eligibility of an in-
2 dividual for any direct or indirect payment, benefit,
3 or service.

4 (j) REPORT TO CONGRESS.—Not later than 1 year
5 after the date of enactment of this Act, and annually
6 thereafter, the Secretary shall submit a report to the Con-
7 gress on the implementation of this section, including—

8 (1) identification of best State practices for—

9 (A) sharing data with, and reporting data
10 to, the National Death Index; and

11 (B) ensuring the quality of such data; and

12 (2) recommendations to improve—

13 (A) such sharing and reporting; and

14 (B) access to the National Death Index by
15 researchers.

16 (k) AUTHORIZATION OF APPROPRIATIONS.—There is
17 authorized to be appropriated to carry out this section,
18 \$10,000,000 for fiscal year 2021, to remain available until
19 expended.

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