

117TH CONGRESS
1ST SESSION

S. _____

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

_____ introduced the following bill; which was read twice
and referred to the Committee on _____

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—

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

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

6 (3) national sequence-based surveillance will en-
7 able the United States to best identify new variants;
8 and

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

12 **SEC. 3. GUIDANCE.**

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

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

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

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

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

19 (2) provide technical assistance and guidance
20 and award grants or cooperative agreements to
21 State, local, Tribal, or territorial public health depart-
22 ments to increase the capacity of such departments
23 to sequence the genome of circulating strains of the
24 SARS-CoV-2 virus, to identify mutations in the
25 SARS-CoV-2 virus, to use genomic sequencing to
26 identify outbreaks and clusters of COVID-19 infec-

1 tions caused by specific variants of SARS–CoV–2,
2 and to develop effective COVID–19 response strate-
3 gies based on genetic sequencing and surveillance
4 data; and

5 (3) carry out activities to both enhance the
6 informatics capabilities of the public health work-
7 force and expand the numbers of qualified public
8 health informaticians available to analyze and inter-
9 pret data produced through advanced molecular de-
10 tection and genomic sequencing to establish, expand,
11 or enhance capacity for conducting statistical public
12 health research.

13 (c) IMPLEMENTATION.—

14 (1) COOPERATIVE AGREEMENTS FOR TECH-
15 NICAL ASSISTANCE.—Cooperative agreements de-
16 scribed in subsection (b)(2) may include partner-
17 ships with academic research institutions.

18 (2) CAPACITY FOR SHARING AND LINKING.—
19 The capacity referred to in subsection (b)(3) may in-
20 clude sharing and linking information and accessing
21 and utilizing linked health data files in accordance
22 with established data use agreements with data hold-
23 ers (including electronic case reporting, electronic
24 health records, and electronic test orders and re-
25 sults) with public health agencies and related sys-

1 tems, including the National Death Index, immuni-
2 zation information systems, syndromic surveillance
3 systems, laboratory information management sys-
4 tems, electronic case reporting systems, medical ex-
5 aminer case management systems, and Patient Uni-
6 fied Look-up Systems for Emergencies.

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

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

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

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

23 (a) IN GENERAL.—The Secretary, acting through the
24 Director of the National Center for Health Statistics, shall
25 carry out a demonstration program to expand the data

1 linkage program of the Department of Health and Human
2 Services, consisting of Federal statistical and pro-
3 grammatic datasets from specified Federal entities, as au-
4 thorized by subchapter III of chapter 35 of title 44,
5 United States Code, for the purpose of facilitating statis-
6 tical public health research on trends and patterns across
7 specifically defined, statistically relevant populations, with
8 a particular focus on linking social determinants of health
9 data, including with respect to—

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

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

- 21 (1) assessing the availability of identified and
22 deidentified data sets held by Federal, State, local,
23 and non-Federal entities that may be useful for re-
24 search described in subsection (a); and

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

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

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

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

15 (3) exclusively for the purpose described in sub-
16 section (a).

17 (d) PROCESS FOR MAKING DATA AVAILABLE.—

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

22 (2) REQUIREMENTS.—Prior to making any
23 data available under the demonstration program
24 under this section, by an entity described in sub-

1 section (b)(1) to another entity described in sub-
2 section (b)(1)—

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

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

11 (e) RULEMAKING.—

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

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

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

20 (2) PROMULGATION.—The Secretary shall—

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

23 (B) specify in such regulations the allowed
24 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 demonstration
6 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 nonFederal 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.