

117TH CONGRESS
2D SESSION

S. 4827

To authorize the Secretary of Health and Human Services to establish a national sepsis data trust, and to fund State-based pilots and programs to establish interoperable State-based sepsis data trusts.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 13, 2022

Mr. CASSIDY (for himself and Mr. CASEY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To authorize the Secretary of Health and Human Services to establish a national sepsis data trust, and to fund State-based pilots and programs to establish interoperable State-based sepsis data trusts.

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 “National Sepsis Data
5 Trust, Outcomes, and Innovation Act” or “LuLu’s Law”.

1 **SEC. 2. TREATING AND ELIMINATING THE BURDEN OF SEP-**
2 **SIS.**

3 Part P of title III of the Public Health Service Act
4 (42 U.S.C. 280g et seq.) is amended by adding at the end
5 the following:

6 **“SEC. 399V-7. TREATING AND ELIMINATING THE BURDEN**
7 **OF SEPSIS.**

8 “(a) DEFINITION; DESIGNATION.—

9 “(1) DEFINITION OF SEPSIS.—Not later than
10 120 days after the date of enactment of the National
11 Sepsis Data Trust, Outcomes, and Innovation Act,
12 the Secretary shall issue a rule specifying a defini-
13 tion of sepsis. Such definition may specify that sep-
14 sis is a life-threatening organ dysfunction caused by
15 a dysregulated host response to infection. Such defi-
16 nition shall be standardized across departments,
17 agencies, and other entities within the Department
18 of Health of Human Services.

19 “(2) NATIONALLY NOTIFIABLE DISEASE.—The
20 Secretary, acting through the Director of the Cen-
21 ters for Disease Control and Prevention, shall take
22 such steps as may be necessary to include sepsis on
23 the list of nationally notifiable diseases published by
24 the Centers for Disease Control and Prevention.

25 “(b) NATIONAL STRATEGY.—

1 “(1) IN GENERAL.—The Secretary shall develop
2 a national strategy—

3 “(A) to treat and eliminate the burden of
4 sepsis, with the specific goals of, with respect to
5 sepsis—

6 “(i) coordinating data (including
7 through the data trust established under
8 subsection (d));

9 “(ii) spurring research; and

10 “(iii) developing diagnostic tools and
11 treatments;

12 “(B) to decrease instances of sepsis and
13 mitigate long-term health effects of sepsis; and

14 “(C) that includes specific actions to be
15 taken to treat and eliminate the burden of sep-
16 sis among at-risk populations identified pursu-
17 ant to paragraph (3).

18 “(2) COORDINATION.—In developing the strat-
19 egy under paragraph (1), the Secretary may coordi-
20 nate among agencies within the Department of
21 Health and Human Services and other Federal
22 agencies, academic institutions, and non-profit orga-
23 nizations.

24 “(3) AT-RISK POPULATIONS.—The Secretary
25 shall identify population groups the Secretary deter-

1 mines to be at a higher risk for contracting sepsis,
2 which shall include—

3 “(A) children;

4 “(B) pregnant women or women in the one
5 year postpartum period;

6 “(C) active members of the Armed Forces
7 and veterans;

8 “(D) disabled and elderly individuals;

9 “(E) individuals residing on federally-rec-
10 ognized Tribal lands; and

11 “(F) such other groups as the Secretary
12 determines to be at higher risk for contracting
13 sepsis.

14 “(c) STATE-BASED SEPSIS DATA TRUST PILOT PRO-
15 GRAMS.—

16 “(1) IN GENERAL.—Subject to the availability
17 of appropriations, the Secretary shall award grants
18 to not more than 5 States to establish pilot pro-
19 grams—

20 “(A) to collect into State-based sepsis data
21 trusts that use standardized data formats and
22 coding (as determined by the Secretary) de-
23 identified patient data concerning—

24 “(i) demographic information about
25 each case of sepsis in each such State;

1 “(ii) administrative information with
2 respect to each such case, including the
3 date of diagnosis and the source of infor-
4 mation;

5 “(iii) pathological and genetic mate-
6 rial characterizing each such case (includ-
7 ing deoxyribonucleic acids (DNA), ribo-
8 nucleic acids (RNA), single cell RNA,
9 genes, chromosomes, genotype, alleles, epi-
10 genetic alteration or modifications to DNA
11 or RNA, single nucleotide polymorphisms
12 (SNPs), uninterpreted data that results
13 from analysis of a biological sample from a
14 diagnosed sepsis patient or other source,
15 and any information extrapolated, derived,
16 or inferred therefrom);

17 “(iv) clinical information, including
18 relevant diagnoses, treatment, and patient-
19 reported outcomes of the individuals with
20 sepsis and sepsis survivors;

21 “(v) with respect to each case of sep-
22 sis in each such State, the number of staff
23 working in the relevant unit of the health
24 care provider involved;

1 “(vi) provider payments that result
2 from a sepsis diagnosis; and

3 “(vii) other elements determined ap-
4 propriate by the Secretary; and

5 “(B) to combine and connect data so col-
6 lected among such States.

7 “(2) DATA TRUST GUIDELINES.—

8 “(A) IN GENERAL.—The Secretary shall
9 establish governance guidelines, data access re-
10 quirements, privacy and security protocols, and
11 other such standards as may be required to
12 support the establishment of interoperable
13 State-based sepsis data trusts for purposes of
14 the national sepsis data trust to be established
15 under subsection (d).

16 “(B) DATA SHARING.—The guidelines es-
17 tablished under subparagraph (A) shall specify
18 that—

19 “(i) no entity participating in the data
20 trust may share patient data with any en-
21 tity not participating in the data trust; and

22 “(ii) an entity shall agree, as a condi-
23 tion on participation in the data trust to
24 not share any patient data with any entity
25 not participating in the data trust.

1 “(3) SELECTION CRITERIA.—In reviewing appli-
2 cations submitted by States for grants under this
3 section, the Secretary shall consider whether the
4 States submitting such applications demonstrate es-
5 tablished partnerships with a range of public and
6 private stakeholders. Of the States that demonstrate
7 such partnerships, the Secretary shall select—

8 “(A) at least one State that has a death
9 rate from septicemia of greater than 15 people
10 per 100,000 people per year and 1,500 deaths
11 per year for the 5 calendar years preceding the
12 declaration of the public health emergency with
13 respect to COVID–19;

14 “(B) at least one rural State with above
15 average sepsis mortality rate;

16 “(C) a selection of other States in such a
17 manner as to ensure diversity of population
18 density, geographic location, and general health
19 care access and infrastructure; and

20 “(D) other States in such a matter as to
21 ensure geographic and population diversity.

22 “(4) ALTERNATIVE CRITERIA.—If no State
23 meeting the criteria specified in paragraph (3) estab-
24 lishes a pilot program in coordination with the Sec-
25 retary within 3 years of the date of enactment of the

1 National Sepsis Data Trust, Outcomes, and Innova-
 2 tion Act, the Secretary may identify alternative re-
 3 quirements for such States.

4 “(5) REPORTING.—Not later than 18 months
 5 after the date on which a State successfully (as de-
 6 termined by the Secretary) establishes a State-based
 7 sepsis data trust using funds received through a
 8 grant under this subsection, the State shall submit
 9 to the Secretary a report. Such report shall include,
 10 with respect to the State-based sepsis data trust in-
 11 volved—

12 “(A) the process by which the State estab-
 13 lished the data trust, including governance and
 14 data access rules;

15 “(B) the process by which data was col-
 16 lected, de-identified, and standardized across
 17 multiple data systems;

18 “(C) implementation barriers experienced
 19 and the course of corrective action taken to ad-
 20 dress these barriers; and

21 “(D) lessons learned through the establish-
 22 ment of the data trust.

23 “(6) AUTHORIZATION OF APPROPRIATIONS.—

24 There are authorized to be appropriated to carry out

1 this subsection \$5,000,000 for each of fiscal years
2 2023 through 2028.

3 “(d) NATIONAL SEPSIS DATA TRUST.—

4 “(1) IN GENERAL.—The Secretary shall estab-
5 lish a national sepsis data trust to improve research,
6 outcomes, and innovation in support of the national
7 strategy developed under subsection (b) (including
8 the actions to be taken pursuant to paragraph
9 (1)(C) of such subsection). Such national sepsis data
10 trust shall—

11 “(A) accelerate innovation that seeks to
12 improve sepsis prevention, diagnosis, treatment,
13 outcomes, and survivor support, including
14 through—

15 “(i) advancing the pace of academic
16 research; and

17 “(ii) catalyzing more investment in
18 mechanisms that provide promise in the
19 early recognition and expeditious treatment
20 of sepsis;

21 “(B) support public health efforts to im-
22 prove sepsis care, particularly in underserved
23 geographic areas and among at-risk and under-
24 served communities;

1 “(C) improve the targeting of antimicrobial
2 drugs and other substances for the treatment of
3 sepsis, promoting both better care and improved
4 antimicrobial stewardship;

5 “(D) coordinate and integrate the develop-
6 ment of State-based sepsis data trusts, includ-
7 ing by defining data elements to be included in
8 State-based sepsis data trusts, including self-re-
9 ported data on age, race, ethnicity, primary lan-
10 guage, membership in a federally-recognized
11 Tribe, status as a member of the Armed
12 Forces, status as a veteran, status as pregnant
13 or recently pregnant, and any other data the
14 Secretary determines appropriate;

15 “(E) provide for appropriate privacy and
16 security of de-identified data in the data trust
17 by—

18 “(i) prohibiting any entity partici-
19 pating in the data trust from sharing pa-
20 tient data with any entity not participating
21 in the data trust; and

22 “(ii) ensuring that an entity agrees,
23 as a condition on participation in the data
24 trust to not share any patient data with

1 any entity not participating in the data
2 trust; and

3 “(F) allow access to data de-identified data
4 in the data trust by health care providers and
5 other entities participating in the data trust.

6 “(2) STATE GRANTS AND CONTRACTS.—

7 “(A) IN GENERAL.—In addition to award-
8 ing grants under subsection (c), the Secretary
9 may award grants directly to States to support
10 the development and operation of State-based
11 sepsis data trusts (or award grants or contracts
12 to academic or nonprofit organizations des-
13 ignated by a State to operate the State-based
14 sepsis data trust involved) to combine and con-
15 nect data collected by the State concerning—

16 “(i) demographic information about
17 each case of sepsis in each such State;

18 “(ii) administrative information with
19 respect to each such case, including the
20 date of diagnosis and the source of infor-
21 mation;

22 “(iii) pathological and genetic data
23 characterizing each such case;

24 “(iv) clinical information, including
25 relevant diagnoses, treatment, and patient-

1 reported outcomes of the individuals with
2 sepsis and sepsis survivors; and

3 “(v) other elements, as the Secretary
4 determines appropriate.

5 “(B) MATCHING FUNDS.—The Secretary
6 may award a grant or contract under para-
7 graph (2) only if the State involved (or the aca-
8 demic or nonprofit private organization des-
9 ignated by a State to operate the State-based
10 sepsis data trust involved) agrees, with respect
11 to the costs of the program to be funded
12 through the award, to make available (directly
13 or through donations from public or private en-
14 tities) non-Federal contributions toward such
15 costs in an amount that is not less than 25 per-
16 cent of such costs.

17 “(C) DATA TRUST GUIDELINES.—The
18 guidelines developed under subsection (c)(2)
19 shall apply with respect to State-based sepsis
20 data trusts established under this paragraph in
21 the same manner and to the same extent as
22 such guidelines apply with respect to State-
23 based sepsis data trusts established under sub-
24 section (c) (including the data sharing limita-

1 tions specified in paragraph (2)(B) of such sub-
2 section).

3 “(3) REPORT ON GOVERNMENT SEPSIS DATA
4 ACTIVITIES AND RESOURCES.—Not later than 180
5 days after the date of enactment of the National
6 Sepsis Data Trust, Outcomes, and Innovation Act,
7 the Secretary shall submit to the Committee on
8 Health, Education, Labor, and Pensions of the Sen-
9 ate and the Committee on Energy and Commerce of
10 the House of Representatives a report containing the
11 following:

12 “(A) An outline of existing Federal efforts
13 to collect and make available data on sepsis and
14 its associated conditions, including existing
15 Federal repositories of sepsis-relevant de-identi-
16 fied patient data.

17 “(B) A summary of the use of these sepsis
18 data by third parties, including public health
19 professionals, physicians and nurses, and re-
20 searchers.

21 “(C) A description of Federal efforts to
22 improve care related to sepsis and infection in
23 underserved populations and communities that
24 experience disproportionately poor health out-
25 comes.

1 “(e) DEFINITIONS.—In this section:

2 “(1) DE-IDENTIFIED.—The term ‘de-identified’
3 means, with respect to data in a data trust estab-
4 lished under or pursuant to this section, information
5 that has been de-identified (and remains de-identi-
6 fied) in accordance with the applicable requirements
7 of section 164.514 of title 45, Code of Federal Reg-
8 ulations (or any successor regulation).

9 “(2) NATIONAL SEPSIS DATA TRUST.—The
10 term ‘national sepsis data trust’ means an interoper-
11 able, de-identified, privacy-protected collection,
12 curation, and storage system that contains de-identi-
13 fied data from a variety of sources established by in-
14 dividual States, with data made available to entities
15 and individuals approved by the Secretary.”.

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