

117TH CONGRESS
2^D SESSION

H. R. 8865

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 HOUSE OF REPRESENTATIVES

SEPTEMBER 15, 2022

Ms. SHERRILL introduced the following bill; which was referred to the Committee on Energy and Commerce

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 Research, Outcomes, and Innovation Act” or “LuLu’s
6 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 the enactment of the Na-
11 tional Sepsis Data Research, Outcomes, and Innova-
12 tion Act, the Secretary shall issue a rule specifying
13 a definition of sepsis. Such definition may specify
14 that sepsis is a life-threatening organ dysfunction
15 caused by a dysregulated host response to infection.
16 Such definition shall be standardized across depart-
17 ments, agencies, and other entities within the De-
18 partment 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 Council of State and Territorial Epidemiologists
25 and the Centers for Disease Control and Prevention.

26 “(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.—The Secretary may, in de-
19 veloping the strategy under paragraph (1), 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 servicemembers and veterans;

7 “(D) disabled and elderly individuals; and

8 “(E) individuals residing on federally rec-
9 ognized tribal lands.

10 “(c) STATE-BASED SEPSIS DATA TRUST PILOT PRO-
11 GRAMS.—

12 “(1) IN GENERAL.—Subject to the availability
13 of appropriations, the Secretary shall award grants
14 to not more than 5 States to establish pilot pro-
15 grams—

16 “(A) to collect into State-based sepsis data
17 trusts that use standardized data formats and
18 coding (as determined by the Secretary) de-
19 identified patient data concerning—

20 “(i) demographic information about
21 each case of sepsis in each such State;

22 “(ii) administrative information with
23 respect to each such case, including the
24 date of diagnosis and the source of infor-
25 mation;

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

13 “(iv) clinical information, including
14 relevant diagnoses, treatment, and patient-
15 reported outcomes of the individuals with
16 sepsis and sepsis survivors;

17 “(v) with respect to each case of sep-
18 sis in each such State, the number of staff
19 working in the relevant unit of the health
20 care provider involved;

21 “(vi) provider payments that result
22 from a sepsis diagnosis; and

23 “(vii) other elements determined ap-
24 propriate by the Secretary; and

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

3 “(2) DATA TRUST GUIDELINES.—

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

12 “(B) DATA SHARING.—The guidelines es-
13 tablished under subparagraph (A) shall specify
14 that—

15 “(i) no entity participating in the data
16 trust may share patient data with any en-
17 tity not participating in the data trust; and

18 “(ii) an entity shall agree, as a condi-
19 tion on participation in the data trust to
20 not share any patient data with any entity
21 not participating in the data trust.

22 “(3) SELECTION CRITERIA.—In reviewing appli-
23 cations submitted by States for grants under this
24 section, the Secretary shall take into consideration
25 whether the States submitting such applications

1 demonstrate established partnerships with a range of
2 public and private stakeholders. The Secretary shall,
3 of the States that demonstrate such partnerships,
4 select—

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

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

13 “(C) a diverse array of other States in
14 such a manner as to ensure diversity of popu-
15 lation density, geographic location, and general
16 healthcare access and infrastructure; and

17 “(D) other States in such a manner as to
18 ensure geographic and population diversity.

19 “(4) ALTERNATIVE CRITERIA.—If no State
20 meeting the criteria specified in paragraph (3) estab-
21 lishes a pilot program in coordination with the Sec-
22 retary within 36 months after the date of the enact-
23 ment of this section, the Secretary may identify al-
24 ternative requirements for such States.

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

9 “(A) the process by which the State estab-
10 lished the data trust;

11 “(B) the process by which data was col-
12 lected, de-identified, and standardized across
13 multiple data systems;

14 “(C) implementation barriers experienced
15 and the course of corrective action taken to ad-
16 dress these barriers; and

17 “(D) lessons learned through the establish-
18 ment of the data trust.

19 “(6) AUTHORIZATION OF APPROPRIATIONS.—
20 There are authorized to be appropriated to carry out
21 this subsection \$5,000,000 for each of fiscal years
22 2023 through 2028.

23 “(d) NATIONAL SEPSIS DATA TRUST.—

24 “(1) IN GENERAL.—The Secretary shall estab-
25 lish a national sepsis data trust to improve research,

1 outcomes, and innovation in support of the national
2 strategy developed under subsection (b) (including
3 the actions to be taken pursuant to paragraph
4 (1)(C) of such subsection). Such national sepsis data
5 trust shall—

6 “(A) accelerate innovation that seeks to
7 improve sepsis prevention, diagnosis, treatment,
8 outcomes, and survivor support, including
9 through—

10 “(i) advancing the pace of academic
11 research; and

12 “(ii) catalyzing more investment in
13 mechanisms that provide promise in the
14 early recognition and expeditious treatment
15 of sepsis;

16 “(B) support public health efforts to im-
17 prove sepsis care, particularly in underserved
18 geographic areas and among at-risk and under-
19 served communities;

20 “(C) improve the targeting of antimicrobial
21 drugs and other substances for the treatment of
22 sepsis, promoting both better care and improved
23 antimicrobial stewardship;

24 “(D) coordinate and integrate the develop-
25 ment of State-based sepsis data trusts, includ-

1 ing by defining data elements to be included in
2 State-based sepsis data trusts, including self-re-
3 ported data on age, race, ethnicity, primary lan-
4 guage, membership in a federally recognized
5 tribe, status as a member of the armed services,
6 status as a veteran, status as pregnant or re-
7 cently pregnant, and any other data determined
8 to be appropriate by the Secretary; and

9 “(E) provide for appropriate privacy and
10 security of de-identified data in the data trust
11 by—

12 “(i) prohibiting any entity partici-
13 pating in the data trust from sharing pa-
14 tient data with any entity not participating
15 in the data trust; and

16 “(ii) ensuring that an entity agrees,
17 as a condition on participation in the data
18 trust to not share any patient data with
19 any entity not participating in the data
20 trust; and

21 “(F) allow access to data de-identified data
22 in the data trust by health care providers and
23 other entities participating in the data trust.

24 “(2) STATE GRANTS.—

1 “(A) IN GENERAL.—In addition to award-
2 ing grants under subsection (c), the Secretary
3 may make grants directly to States to support
4 the development and operation of State-based
5 sepsis data trusts (or make grants, or enter
6 into contracts with academic or nonprofit orga-
7 nizations designated by a State to operate the
8 State-based sepsis data trust involved) to com-
9 bine and connect data collected by the State
10 concerning—

11 “(i) demographic information about
12 each case of sepsis in each such State;

13 “(ii) administrative information with
14 respect to each such case, including the
15 date of diagnosis and the source of infor-
16 mation;

17 “(iii) pathological and genetic data
18 characterizing each such case;

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

23 “(v) other elements determined appro-
24 priate by the Secretary.

1 “(B) MATCHING FUNDS.—The Secretary
2 may make a grant under paragraph (1) only if
3 the State involved (or the academic or nonprofit
4 private organization designated by a State to
5 operate the State-based sepsis data trust in-
6 volved) agrees, with respect to the costs of the
7 program to be funded through the grant, to
8 make available (directly or through donations
9 from public or private entities) non-Federal
10 contributions toward such costs in an amount
11 that is not less than 25 percent of such costs.

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

22 “(3) REPORT ON GOVERNMENT SEPSIS DATA
23 ACTIVITIES AND RESOURCES.—Not later than 180
24 days after the date of the enactment of this section,
25 the Secretary shall submit to the Committee on En-

1 ergy and Commerce of the House of Representatives
2 and the Committee on Health, Education, Labor
3 and Pensions of the Senate a report containing the
4 following:

5 “(A) An outline of existing Federal efforts
6 to collect and make available data on sepsis and
7 its associated conditions, including existing
8 Federal repositories of sepsis-relevant de-identi-
9 fied patient data.

10 “(B) A summary of the use of these sepsis
11 data by third parties, including public health
12 professionals, physicians and nurses, and re-
13 searchers.

14 “(C) A description of Federal efforts to
15 improve care related to sepsis and infection in
16 underserved populations and communities that
17 experience disproportionately poor health out-
18 comes.

19 “(e) DEFINITIONS.—In this section:

20 “(1) DE-IDENTIFIED.—The term ‘de-identified’
21 means, with respect to data in a data trust estab-
22 lished under or pursuant to this section, information
23 that has been de-identified (and remains de-identi-
24 fied) in accordance with the applicable requirements

1 of section 164.514 of title 45, Code of Federal Reg-
2 ulations (or any successor regulation).

3 “(2) NATIONAL SEPSIS DATA TRUST.—The
4 term ‘national sepsis data trust’ means an interoper-
5 able, de-identified, privacy-protected collection sys-
6 tem that contains de-identified data from a variety
7 of sources established by individual States.”.

○