118TH CONGRESS
2D SESSION

H. R. 8078

To authorize Federal support of States in piloting interoperable State-based repositories of sepsis cases, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 18, 2024

Ms. SHERRILL (for herself and Mr. BUCSHON) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To authorize Federal support of States in piloting interoperable State-based repositories of sepsis cases, and for other purposes.

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 "Sepsis Harm and Cost
5 Reduction Act" or the "LuLu's Law".

6 **SEC. 2. FINDINGS.**

7 Congress finds the following:

8 (1) Sepsis affects 1.7 million people in the
9 United States each year, and results in 350,000
10 adult deaths annually.

1 (2) Sepsis is a leading cause of maternal mor-
2 tality in the United States.
3 (3) Sepsis is a leading cause of rising newborn
4 mortality in the United States.
5 (4) Nearly 7,000 children die from sepsis annu-
6 ally in the United States.
7 (5) Many survivors face life-long after-effects of
8 sepsis, including 14,000 annually who receive ampu-
9 tations.
10 (6) Each hour a septic patient goes untreated
11 increases the risk of death by as much as 8 percent.
12 (7) Sepsis is the leading cause of death in
13 United States hospitals, and the leading cause of
14 hospital readmissions.
15 (8) Sepsis hospitalizations cost Medicare $41.8
16 billion in 2019.
17 (9) Sepsis is responsible for $62 billion in hos-
18 pitalization costs annually.
19 (10) Additional information about sepsis could
20 help improve timely diagnosis and treatment, reduc-
21 ing loss of life, harm and costs due to sepsis.

22 **SEC. 3. REDUCING THE BURDEN OF SEPSIS.**

23 Part P of title III of the Public Health Service Act
24 (42 U.S.C. 280g et seq.) is amended by adding at the end
25 the following:

"SEC. 399V–8. REDUCING THE BURDEN OF SEPSIS.

''(a) DEFINITION OF SEPSIS.—Not later than 120 days after the date of the enactment of the Sepsis Harm and Cost Reduction Act, the Secretary shall issue a rule specifying a definition of sepsis. Such definition may specify that sepsis is a life-threatening organ dysfunction caused by a dysregulated host response to infection. Such definition shall be standardized across departments, agencies, and other entities within the Department of Health of Human Services.

''(b) STATE-BASED SEPSIS REPOSITORY PILOT PROGRAMS.—

''(1) IN GENERAL.—Subject to the availability of appropriations for a fiscal year, the Secretary shall award grants to not more than 5 States each fiscal year to establish pilot statewide sepsis repositories.

''(2) APPLICATION.—A State seeking a grant under paragraph (1) shall submit to the Secretary an application at such time, in such manner, and containing—

''(A) a certification that the State has established a sepsis advisory committee, in accordance with paragraph (3); and

''(B) such other information as the Secretary may require.

1 “(3) SEPSIS ADVISORY COMMITTEE.—
2 “(A) DUTIES.—A State sepsis advisory
3 committee referred to in paragraph (2)(A)
4 shall—
5 “(i) advise the State in the design, de-
6 velopment, and operation of the statewide
7 sepsis repository;
8 “(ii) ensure that all information in-
9 cluded in the sepsis repository is de-identi-
10 fied and privacy protected; and
11 “(iii) assist in securing voluntary par-
12 ticipation in, and contributions of informa-
13 tion to, the sepsis repository by organiza-
14 tions and entities in the State.
15 “(B) COMPOSITION.—A State sepsis advi-
16 sory committee referred to in paragraph (2)(A)
17 shall be composed of multidisciplinary and di-
18 verse membership that represents a variety of
19 stakeholders, including clinical specialties, pub-
20 lic health officials, epidemiologists, statisticians,
21 data scientists, payers, patient safety advocates,
22 and individuals or organizations that represent
23 sepsis survivors, family members of sepsis pa-
24 tients, and populations that are most affected

1 by sepsis or experience the greatest disparities
2 in sepsis outcomes.
3 "(4) SELECTION CRITERIA.—In selecting States
4 to receive a grant under this subsection, the Sec-
5 retary shall select, from among the States submit-
6 ting an application for such a grant that meets the
7 requirements of paragraph (2)—
8 "(A) at least 1 State that has a death rate
9 from sepsis of greater than 15 people per
10 100,000 people per year and 1,500 deaths per
11 year for the 5 calendar years preceding the dec-
12 laration of the public health emergency with re-
13 spect to COVID–19;
14 "(B) at least 1 rural State with an above
15 average sepsis mortality rate;
16 "(C) a diverse array of other States in
17 such a manner as to ensure diversity of popu-
18 lation density, geographic location, and general
19 healthcare access and infrastructure; and
20 "(D) other States in such a manner as to
21 ensure geographic and population diversity.
22 "(5) ALTERNATIVE CRITERIA.—If no State
23 meeting the criteria specified in paragraph (4) estab-
24 lishes a pilot program in coordination with the Sec-
25 retary within 36 months after the date of enactment

1 of this section, the Secretary may identify alter-
2 native requirements for such States.

3 ''(6) SEPSIS REPOSITORY ACTIVITIES.—A State
4 receiving a grant under this subsection shall use
5 funds received through the grant to, in consultation
6 with the applicable State sepsis advisory committee
7 established pursuant to paragraph (2), establish a
8 statewide sepsis repository that integrates—

9 ''(A) demographic information about each
10 case of sepsis in such State;

11 ''(B) administrative information with re-
12 spect to each such case;

13 ''(C) characterizations of each such case,
14 including pathological analysis and
15 uninterpreted data;

16 ''(D) clinical information, including rel-
17 evant diagnoses, treatment, and patient-re-
18 ported outcomes of the individuals with sepsis
19 and sepsis survivors; and

20 ''(E) provider payments that result from a
21 sepsis diagnosis.

22 ''(7) GUIDELINES.—The Secretary shall estab-
23 lish governance guidelines, information access re-
24 quirements, privacy and security protocols, and
25 other such standards as may be necessary to support

1 the establishment of interoperable statewide sepsis
2 repositories.
3 "(8) STATE REPORTING.—Not later than 18
4 months after the date on which a State successfully
5 establishes a statewide sepsis repository using funds
6 received through a grant under this subsection, the
7 State shall submit to the Secretary a report. Such
8 report shall include, with respect to the repository—
9 "(A) the process by which the State estab-
10 lished the repository;
11 "(B) the process by which information re-
12 garding sepsis was collected, de-identified, and
13 standardized across multiple contributing sys-
14 tems;
15 "(C) implementation barriers experienced
16 and the State's response to address such bar-
17 riers; and
18 "(D) lessons learned through the establish-
19 ment of the repository.
20 "(9) BEST PRACTICES RELATING TO THE IM-
21 PLEMENTATION OF STATEWIDE SEPSIS REPOSI-
22 TORIES.—The Secretary, acting through the Direc-
23 tor of the Centers for Disease Control and Preven-
24 tion, shall collect from the recipients of grants
25 awarded under this subsection, and disseminate, not

1 later than 18 months after receiving data from grant
2 recipients, and at least once each fiscal year there-
3 after—

4 ‘‘(A) lessons learned and best practices in
5 the design, development, implementation, and
6 operation of statewide sepsis repositories; and

7 ‘‘(B) lessons learned and best practices on
8 identifying and decreasing sepsis-related events
9 through the implementation and operation of
10 statewide sepsis repositories.

11 ‘‘(10) AUTHORIZATION OF APPROPRIATIONS.—
12 There are authorized to be appropriated to carry out
13 this subsection $5,000,000 for each of fiscal years
14 2025 through 2030.

15 ‘‘(c) NATIONAL SEPSIS REPOSITORY.—

16 ‘‘(1) IN GENERAL.—The Secretary, acting
17 through the Director of the Centers for Disease
18 Control and Prevention, shall establish a national
19 sepsis repository to improve research, outcomes, and
20 innovation in support of the national strategy devel-
21 oped under subsection (d). Such national sepsis re-
22 pository shall—

23 ‘‘(A) accelerate innovation that seeks to
24 improve sepsis prevention, diagnosis, treatment,
25 outcomes, and survivor support, including

1 through advancing the pace of academic re-
2 search and catalyzing more investment in mech-
3 anisms that provide promise in the early rec-
4 ognition and expeditious treatment of sepsis;
5 "(B) support public health efforts to im-
6 prove sepsis care, particularly in underserved
7 geographic areas and among at-risk and under-
8 served communities;
9 "(C) improve the targeting of antimicrobial
10 drugs and other substances for the treatment of
11 sepsis, promoting both better care and improved
12 antimicrobial stewardship;
13 "(D) coordinate with States and State sep-
14 sis advisory committees in the development of
15 statewide sepsis repositories, including by defin-
16 ing data elements to be included in statewide
17 sepsis repositories; and
18 "(E) provide for appropriate privacy and
19 security of de-identified information in the re-
20 pository.
21 "(2) RULE OF CONSTRUCTION.—Nothing in
22 paragraph (1) shall be construed as requiring a
23 State to provide data to the national sepsis reposi-
24 tory established under such paragraph.

1 “(d) NATIONAL SEPSIS ACTION PLAN.—The Sec-
2 retary shall develop a national action plan to reduce the
3 incidence of sepsis, improve outcomes, and reduce the clin-
4 ical and economic burden of sepsis.

5 “(1) IN GENERAL.—The Secretary shall create
6 a sepsis advisory committee to advise the Secretary
7 in the development of a sepsis action plan. The sep-
8 sis advisory committee shall include a multidisci-
9 plinary and diverse membership that represents a
10 variety of stakeholders, including clinical specialtists,
11 public health officials, epidemiologists, payors, pa-
12 tient safety advocates, and individuals or organiza-
13 tions that represent sepsis survivors, family mem-
14 bers of sepsis patients, and populations that are
15 most affected by sepsis or experience the greatest
16 disparities in sepsis outcomes.

17 “(2) ELEMENTS OF SEPSIS ACTION PLAN.—The
18 sepsis action plan developed under paragraph (1)
19 may include—

20 “(A) increasing research;

21 “(B) spurring innovation;

22 “(C) incentivizing development of diag-
23 nostic tools and treatments;

24 “(D) coordinating among agencies within
25 the Department of Health and Human Services

1 and other Federal agencies, academic institutions, and non-profit organizations;

3 "(E) coordinating information assembled through the statewide sepsis repositories;

5 "(F) identifying populations that are at higher risk for contracting sepsis or for disparate sepsis outcomes; and

8 "(G) detailing specific actions to be taken to address and eliminate the burden of sepsis, including among at-risk populations.

11 "(e) DEFINITIONS.—In this section:

12 "(1) DE-IDENTIFIED.—The term 'de-identified' means, with respect to data in a data trust established under or pursuant to this section, information that has been de-identified (and remains de-identified) in accordance with the applicable requirements of section 164.514 of title 45, Code of Federal Regulations (or any successor regulation).

19 "(2) SEPSIS REPOSITORY.—The term 'sepsis repository' means an interoperable, de-identified, privacy-protected collection system that contains de-identified data from a variety of sources established by individual States.".

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