

114TH CONGRESS
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S. 2467

To reduce health care-associated infections and improve antibiotic stewardship through enhanced data collection and reporting, the implementation of State-based quality improvement efforts, and improvements in provider education in patient safety, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JANUARY 27, 2016

Mr. WHITEHOUSE introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To reduce health care-associated infections and improve antibiotic stewardship through enhanced data collection and reporting, the implementation of State-based quality improvement efforts, and improvements in provider education in patient safety, 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 “Patient Safety Im-
5 provement Act of 2016”.

6 **SEC. 2. FINDINGS.**

7 Congress finds the following:

1 (1) A 2014 prevalence survey published in the
2 New England Journal of Medicine found that ap-
3 proximately 1 in 25 hospital patients in the United
4 States has at least one health care-associated infec-
5 tion, adding up to an estimated 722,000 health care-
6 associated infections in acute care hospitals in 2011.
7 About 75,000 hospital patients with health care-as-
8 sociated infections died during their hospitalizations.

9 (2) Antibiotics are among the most commonly
10 prescribed drugs used in human medicine. Studies
11 indicate that up to 30 to 50 percent of antibiotics
12 prescribed for patients are not needed or not opti-
13 mally prescribed. This is contributing to the growth
14 in the prevalence of dangerous antibiotic-resistant
15 bacteria.

16 (3) A 2013 threat report by the Centers for
17 Disease Control and Prevention estimated that each
18 year at least 2,000,000 people in the United States
19 are infected by antibiotic-resistant bacteria, and ap-
20 proximately 23,000 die as a result.

21 (4) Estimates of the annual impact of anti-
22 biotic-resistant infections on the United States econ-
23 omy vary but range from \$20,000,000,000 to
24 \$35,000,000,000 in excess health care costs, and as

1 much as \$35,000,000,000 in lost productivity from
 2 hospitalizations and sick days.

3 (5) The prevalence of health care-associated in-
 4 fections and the rise of antibiotic resistance are seri-
 5 ous threats to human health and contribute to esca-
 6 lating health care costs. Strategies to reduce patient
 7 harm and preserve the effectiveness of existing anti-
 8 biotics are needed to combat the rise of antibiotic re-
 9 sistance that is threatening the health of Americans
 10 and people around the world.

11 **SEC. 3. IMPROVING DATA RELIABILITY AND SURVEIL-**
 12 **LANCE.**

13 (a) REDUCING THE INCIDENCE OF HEALTH CARE-
 14 ASSOCIATED INFECTIONS AND IMPROVING ANTIBIOTIC
 15 STEWARDSHIP.—

16 (1) IN GENERAL.—Subpart II of part D of title
 17 IX of the Public Health Service Act (42 U.S.C.
 18 299b–33 et seq.) is amended by adding at the end
 19 the following:

20 **“SEC. 938. HEALTH CARE-ASSOCIATED INFECTIONS AND**
 21 **ANTIBIOTIC USE.**

22 “(a) GAO STUDY ON DATA VALIDATION STRATE-
 23 GIES.—

24 “(1) IN GENERAL.—Not later than 1 year after
 25 the date of enactment of this section, the Comp-

1 troller General of the United States shall conduct an
2 independent evaluation, and submit to the appro-
3 priate committees of Congress a report, concerning
4 the action that the Centers for Disease Control and
5 Prevention and State and local departments of
6 health have taken to improve the completeness and
7 accuracy of hospital-reported National Healthcare
8 Safety Network surveillance data.

9 “(2) CONTENT.—The report submitted under
10 paragraph (1) shall review and assess—

11 “(A) the types of external and internal
12 data validation strategies that are conducted by
13 the Centers for Disease Control and Prevention,
14 State and local departments of health, and hos-
15 pitals;

16 “(B) the frequency with which the Centers
17 for Disease Control and Prevention, State and
18 local departments of health, and hospitals audit
19 data submitted to the National Healthcare
20 Safety Network; and

21 “(C) identify additional actions that the
22 Federal Government can take to support State
23 and local departments of health and hospitals
24 with such validation efforts and improvements

1 to the quality of data submitted to the National
2 Healthcare Safety Network.

3 “(b) DATA RELIABILITY FRAMEWORK.—

4 “(1) IN GENERAL.—Following the submission
5 of the report under subsection (a), the Director of
6 the Centers for Disease Control and Prevention, in
7 collaboration with the Administrator of the Agency
8 for Healthcare Research and Quality and relevant
9 stakeholders, shall develop a framework to improve
10 the consistency and reliability of hospital data on
11 health care-associated infections that is submitted to
12 the National Healthcare Safety Network.

13 “(2) REQUIREMENTS.—The framework devel-
14 oped under paragraph (1) shall—

15 “(A) address issues identified in the find-
16 ings of the study conducted under subsection
17 (a);

18 “(B) propose data validation and reliability
19 methodologies; and

20 “(C) assess the effectiveness and the cost
21 to implement proposed methodologies.

22 “(c) DATA COLLECTION PILOT PROGRAM.—

23 “(1) IN GENERAL.—The Administrator of the
24 Agency for Healthcare Research and Quality, in col-
25 laboration with the Director of the Centers for Dis-

1 ease Control and Prevention, shall convene a meet-
2 ing with relevant stakeholders to identify best prac-
3 tices and approaches for the collection and reporting
4 of data on the incidence of health care-associated in-
5 fections to the National Healthcare Safety Network
6 by long-term care facilities, ambulatory surgical cen-
7 ters, and dialysis facilities.

8 “(2) PILOT PROGRAM.—After conducting the
9 meeting under paragraph (1), the Administrator of
10 the Agency shall establish and implement a pilot
11 program to test best practices and approaches for
12 the collection and reporting of data on the incidence
13 of health care-associated infections by long-term care
14 facilities, ambulatory surgical centers, and dialysis
15 facilities. Such pilot program should incorporate ap-
16 plicable data validation methodologies and other rec-
17 ommendations described in the framework developed
18 under subsection (b).

19 “(3) REPORT.—Not later than 1 year after the
20 completion of the pilot program under paragraph
21 (2), the Administrator shall submit to the Secretary
22 and the appropriate committees of Congress a report
23 on the best practices identified through the pilot
24 program under paragraph (1), including the lessons
25 learned and challenges encountered with respect to

1 data collection and reporting in long-term care set-
2 tings, ambulatory surgical centers, and dialysis fa-
3 cilities as well as recommended data validation
4 methods for those settings.

5 “(4) AUTHORIZATION OF APPROPRIATIONS.—

6 There is authorized to be appropriated, such sums
7 as may be necessary to carry out this subsection.

8 Amounts appropriated under the preceding sentence
9 may be used for the purchase of software and tech-
10 nology that supports data collection and reporting.”.

11 **SEC. 4. ALIGNING QUALITY MEASURES.**

12 Not later than 1 year after the date of enactment
13 of this Act, the Secretary of Health and Human Services
14 shall solicit input from the Administrator of the Centers
15 for Medicare & Medicaid Services, the Director of the Cen-
16 ters for Disease Control and Prevention, an entity with
17 the contract under section 1890(a) of the Social Security
18 Act (42 U.S.C. 1395aaa), and relevant stakeholders (in-
19 cluding accreditation bodies) concerning which definitions
20 for health care-associated infections measures used in
21 Federal and State quality reporting and payment pro-
22 grams for hospitals, long-term care facilities, ambulatory
23 surgical centers, and dialysis centers should be aligned.
24 Using such input, the Secretary shall submit a report to
25 Congress that identifies the following:

1 (1) Priorities for measure alignment.

2 (2) Programs in which the priority measures
3 identified under paragraph (1) are utilized.

4 (3) Recommendations on how to implement the
5 alignment of such measures.

6 **SEC. 5. REDUCING THE INCIDENCE OF HEALTH CARE-ASSO-**
7 **CIATED INFECTIONS.**

8 (a) IN GENERAL.—Part B of title III of the Public
9 Health Service Act (42 U.S.C. 243 et seq.) is amended
10 by adding at the end the following:

11 **“SEC. 320B. EFFORTS TO REDUCE HEALTH CARE-ASSOCI-**
12 **ATED INFECTIONS.**

13 “(a) GRANT PROGRAM TO REDUCE HEALTH CARE-
14 ASSOCIATED INFECTIONS.—

15 “(1) IN GENERAL.—The Secretary shall award
16 competitive grants to eligible entities to support
17 State-based collaboratives in implementing evidence-
18 based, regional approaches to infection prevention,
19 control, and surveillance.

20 “(2) PURPOSE.—Amounts awarded under
21 grants under paragraph (1) may be used to support
22 the following activities:

23 “(A) Inter-professional and inter-facility
24 learning activities.

1 “(B) Building Statewide learning
2 collaboratives.

3 “(C) Assisting with the implementation of
4 the transition-of-care documentation required in
5 section 5 of the Patient Safety Improvement
6 Act of 2016.

7 “(D) Conducting a needs assessment to
8 identify gaps in health care-associated infection
9 prevention and reporting in a State or region.

10 “(E) Other activities determined appro-
11 priate by the Secretary.

12 “(3) ELIGIBILITY.—To be eligible to receive a
13 grant under this subsection, an entity shall be a
14 public or private nonprofit entity that submits to the
15 Secretary an application at such time, in such man-
16 ner, and containing such information as the Sec-
17 retary may require, including—

18 “(A) a description of the activities to be
19 carried out under the grant, including the par-
20 ticipants in any collaborative established to
21 carry out such activities;

22 “(B) goals for the reduction in regional or
23 Statewide rates of health care-associated infec-
24 tions;

1 “(C) an assurance that the entity will pub-
 2 licly report performance on a set of quality and
 3 outcomes measures determined by the Sec-
 4 retary; and

5 “(D) any other information determined ap-
 6 propriate by the Secretary.

7 “(4) PRIORITY.—In awarding grants under this
 8 subsection, the Secretary shall prioritize applicants
 9 that collaborate with multiple stakeholders across a
 10 region or State.

11 “(5) AUTHORIZATION OF APPROPRIATIONS.—
 12 There is authorized to be appropriated, such sums
 13 as may be necessary to carry out this subsection.”.

14 (b) IMPROVING COMMUNICATION OF PATIENT INFECTION
 15 TIONS IN MEDICARE AND MEDICAID.—

16 (1) MEDICARE.—Section 1866(a) of the Social
 17 Security Act (42 U.S.C. 1395cc(a)) is amended—

18 (A) in paragraph (1)—

19 (i) in subparagraph (X), by striking
 20 “and” at the end;

21 (ii) in subparagraph (Y), by striking
 22 the period at the end and inserting “,
 23 and”; and

24 (iii) by inserting after subparagraph
 25 (Y) the following new subparagraph:

1 “(Z) to comply with the requirement of
2 paragraph (4) (relating to the transmission of
3 information regarding infections).”; and

4 (B) by adding at the end the following new
5 paragraph:

6 “(4)(A) For purposes of paragraph (1)(Z), the
7 requirement of this paragraph is that a hospital
8 transmit information about infections or coloniza-
9 tions that present in an individual receiving treat-
10 ment not later than 24 hours upon receipt of the
11 culture to—

12 “(i) the individual;

13 “(ii) in the case of an individual who is
14 being transferred to another provider, the re-
15 ceiving provider; and

16 “(iii) the individual’s primary care pro-
17 vider, if identified.

18 “(B) The information described in subpara-
19 graph (A) shall contain the information fields in-
20 cluded in the Centers for Disease Control and Pre-
21 vention’s Inter-facility Infection Control Transfer
22 Form and any other information the Secretary de-
23 termines appropriate.

24 “(C) When transmitting information to a re-
25 ceiving provider under subparagraph (A)(ii), a pro-

1 vider shall, where practical, transmit such informa-
 2 tion electronically.”.

3 (2) MEDICAID.—Section 1902(a) of the Social
 4 Security Act (42 U.S.C. 1396a(a)) is amended—

5 (A) in paragraph (80), by striking “and”
 6 at the end;

7 (B) in paragraph (81), by striking the pe-
 8 riod at the end and inserting “; and”; and

9 (C) by inserting after paragraph (81) the
 10 following new paragraph:

11 “(82) in the case of any hospital (as defined in
 12 section 1861(e)) that is a participating provider
 13 under the State plan, provide that such hospital
 14 meet the requirements of subparagraph (Z) of sec-
 15 tion 1866(a)(1).”.

16 (c) STANDARDIZED FORM.—Not later than 6 months
 17 after the date of the enactment of this Act, the Secretary
 18 of Health and Human Services, acting through the Direc-
 19 tor of the Centers for Disease Control and Prevention,
 20 shall issue a standardized electronic version of the form
 21 for use by providers in transmitting information as re-
 22 quired by the amendments made by subsection (b).

23 (d) EFFECTIVE DATE.—

24 (1) MEDICARE.—In the case of the require-
 25 ments imposed by the amendments made by sub-

1 section (b)(1), such requirements shall apply to
2 agreements entered into or renewed on or after the
3 date that is 180 days after the date of the issuance
4 of the guidance described in subsection (c).

5 (2) MEDICAID.—

6 (A) IN GENERAL.—Except as provided in
7 subparagraph (B), the requirements imposed by
8 the amendments made by subsection (b)(2)
9 shall take effect on the date that is 180 days
10 after the date of the issuance of the guidance
11 described in subsection (c).

12 (B) DELAY PERMITTED IF STATE LEGISLA-
13 TION REQUIRED.—In the case of a State plan
14 for medical assistance under title XIX of the
15 Social Security Act which the Secretary of
16 Health and Human Services determines re-
17 quires State legislation (other than legislation
18 appropriating funds) in order for the plan to
19 meet the additional requirements imposed by
20 subsection (b)(2), the State plan shall not be
21 regarded as failing to comply with the require-
22 ments of such title solely on the basis of its fail-
23 ure to meet these additional requirements be-
24 fore the first day of the first calendar quarter
25 beginning after the close of the first regular

1 session of the State legislature that begins after
2 the date described in clause (i). For purposes of
3 the previous sentence, in the case of a State
4 that has a 2-year legislative session, each year
5 of such session shall be deemed to be a separate
6 regular session of the State legislature.

7 **SEC. 6. STRENGTHENING ANTIBIOTIC STEWARDSHIP.**

8 (a) IN GENERAL.—Section 320B of the Public
9 Health Service Act, as added by section 5(a), is amended
10 by adding at the end the following:

11 “(b) GRANT PROGRAM FOR STATE ANTIBIOTIC
12 STEWARDSHIP ACTION PLANS.—

13 “(1) IN GENERAL.—The Secretary, acting
14 through the Director of the Centers for Disease
15 Control and Prevention, shall award grants to States
16 for the development of State plans to promote anti-
17 biotic stewardship and prevent the spread of anti-
18 microbial-resistant bacteria across health care set-
19 tings.

20 “(2) ELIGIBILITY.—To be eligible to receive a
21 grant under this subsection, a State shall submit to
22 the Secretary an application at such time, in such
23 manner, and containing such information as the Sec-
24 retary may require, including—

1 “(A) an assurance that development of the
 2 plan under the grant will be led by an infec-
 3 tious-disease trained physician or a pharmacist
 4 with expertise in infectious disease; and

5 “(B) an assurance that the plan will focus
 6 on collaboration across acute and ambulatory
 7 care settings and include a summary of re-
 8 source gaps and challenges.

9 “(3) AUTHORIZATION OF APPROPRIATIONS.—
 10 There is authorized to be appropriated, such sums
 11 as may be necessary to carry out this subsection.”.

12 (b) ADVANCING HOSPITAL REPORTING ON ANTI-
 13 BIOTIC USE AND ANTIMICROBIAL RESISTANCE.—Not
 14 later than January 1, 2018, the Administrator of the Cen-
 15 ters for Medicare & Medicaid Services shall require that
 16 acute care hospitals report antibiotic use and antimicrobial
 17 resistance using the National Healthcare Safety Net-
 18 work’s Antimicrobial Use and Resistance Module as part
 19 of the Hospital Inpatient Quality Reporting Program.

20 (c) INFORMATION RELATED TO ANTIBIOTIC USE
 21 AND ANTIMICROBIAL RESISTANCE.—Section 320B of the
 22 Public Health Service Act, as added by section 5(a) and
 23 amended by subsection (a), is further amended by adding
 24 at the end the following:

1 “(c) INFORMATION RELATED TO ANTIBIOTIC USE
2 AND ANTIMICROBIAL RESISTANCE.—

3 “(1) IN GENERAL.—The Director of the Cen-
4 ters for Disease Control and Prevention shall annu-
5 ally prepare and issue a report concerning the aggre-
6 gate national and regional trends of antibiotic use
7 and bacterial resistance in humans to antibacterial
8 drugs, including the identity of the 10 States with
9 the highest number of prescriptions for antibiotics.

10 “(2) STEWARDSHIP WORKSHOPS.—

11 “(A) IN GENERAL.—Beginning on January
12 1, 2019, and annually thereafter, the Director
13 of the Centers for Disease Control and Preven-
14 tion shall conduct at least one antibiotic stew-
15 ardship workshop in a State identified in the
16 report under paragraph (1).

17 “(B) REQUIREMENTS.—The workshop
18 under subparagraph (A) shall identify regional
19 strategies to support collaboration across the
20 care continuum to promote antibiotic steward-
21 ship. In implementing such workshop, the Di-
22 rector of the Centers for Disease Control and
23 Prevention should seek participation from rel-
24 evant public and private stakeholders with ex-

1 pertise in infection control, quality improve-
2 ment, and consumer engagement.

3 “(3) AUTHORIZATION OF APPROPRIATIONS.—

4 There is authorized to be appropriated, such sums
5 as may be necessary to carry out this subsection.”.

6 **SEC. 7. OTHER IMPROVEMENTS.**

7 (a) IN GENERAL.—Section 320B of the Public
8 Health Service Act, as added by section 5(a) and amended
9 by section 6(c), is further amended by adding at the end
10 the following:

11 “(d) CONTINUING EDUCATION ON INFECTION CON-
12 TROL AND PATIENT SAFETY.—

13 “(1) IN GENERAL.—The Secretary shall estab-
14 lish a program to provide incentives (in the form of
15 grants or other assistance) to State medical boards
16 that require health care professionals (as defined by
17 the medical board) to complete accredited
18 coursework or training in infection control, antibiotic
19 stewardship, or other patient safety topics as a con-
20 dition of receiving a renewed license to practice in
21 the State.

22 “(2) EXEMPTION.—A State medical board that
23 receives assistance under paragraph (1) may provide
24 an exemption from the coursework or training re-
25 quirement under such paragraph for those health

1 care professionals who have specialized training in
 2 infection control (such as an infectious disease spe-
 3 cialist or certified infection control practitioner), who
 4 are not actively practicing in the State, or who do
 5 not provide direct patient care.

6 “(3) AUTHORIZATION OF APPROPRIATIONS.—

7 There is authorized to be appropriated, such sums
 8 as may be necessary to carry out this subsection.”.

9 (b) ENGAGING HOSPITAL LEADERSHIP IN PATIENT
 10 SAFETY IN MEDICARE AND MEDICAID.—

11 (1) MEDICARE.—Section 1866(a)(1) of the So-
 12 cial Security Act (42 U.S.C. 1395cc(a)(1)), as
 13 amended by section 4(a)(1), is amended—

14 (A) in subparagraph (Y), by striking

15 “and” at the end;

16 (B) in subparagraph (Z), by striking the
 17 period and inserting “, and”; and

18 (C) by adding at the end the following new
 19 subparagraph:

20 “(AA) in the case of hospitals, including
 21 critical access hospitals, to require that new
 22 members of the board of such hospital, not later
 23 than 6 months after joining the board, receive
 24 training (in accordance with criteria established
 25 by the Secretary) on patient safety topics that

1 are relevant to a hospital (or critical access hos-
 2 pital, as the case may be) setting, such as infec-
 3 tion prevention, care transitions, patient safety
 4 and quality of care measurement, and staff
 5 communication.”.

6 (2) MEDICAID.—Section 1902(a)(82) of the So-
 7 cial Security Act, as added by section (5)(a)(2)(C),
 8 is amended by striking “subparagraph (Z)” and in-
 9 serting “subparagraphs (Z) and (AA)” before the
 10 period.

11 (3) CRITERIA.—Not later than 6 months after
 12 the date of the enactment of this Act, the Secretary
 13 of Health and Human Services shall propose and fi-
 14 nalize criteria, through notice and comment rule-
 15 making, specifying the number of hours and type of
 16 training that shall satisfy the training requirements
 17 imposed by the amendments made by paragraphs
 18 (1) and (2). Such criteria shall be published on the
 19 Internet website of the Centers for Medicare & Med-
 20 icaid Services.

21 (4) EFFECTIVE DATE.—

22 (A) MEDICARE.—In the case of the re-
 23 quirement imposed by the amendments made by
 24 paragraph (1), such requirement shall apply to
 25 agreements entered into or renewed on or after

1 the date that is 30 days after the date of the
2 publication of the criteria described in para-
3 graph (3).

4 (B) MEDICAID.—

5 (i) IN GENERAL.—Except as provided
6 in clause (ii), the requirement imposed by
7 the amendment made by paragraph (2)
8 shall take effect on the date that is 30
9 days after the date of the publication of
10 the criteria described in paragraph (3).

11 (ii) DELAY PERMITTED IF STATE LEG-
12 ISLATION REQUIRED.—In the case of a
13 State plan for medical assistance under
14 title XIX of the Social Security Act which
15 the Secretary of Health and Human Serv-
16 ices determines requires State legislation
17 (other than legislation appropriating
18 funds) in order for the plan to meet the
19 additional requirement imposed by para-
20 graph (2), the State plan shall not be re-
21 garded as failing to comply with the re-
22 quirements of such title solely on the basis
23 of its failure to meet this additional re-
24 quirement before the first day of the first
25 calendar quarter beginning after the close

1 of the first regular session of the State leg-
 2 islature that begins after the date de-
 3 scribed in clause (i). For purposes of the
 4 previous sentence, in the case of a State
 5 that has a 2-year legislative session, each
 6 year of such session shall be deemed to be
 7 a separate regular session of the State leg-
 8 islature.

9 (c) IMPROVEMENTS TO THE PATIENT SAFETY AND
 10 QUALITY IMPROVEMENT ACT OF 2005.—Section 923 of
 11 the Public Health Service Act (42 U.S.C. 299b–23) is
 12 amended by adding at the end the following:

13 “(d) AUTHORITY FOR DIRECT REPORTING BY PA-
 14 TIENTS.—

15 “(1) IN GENERAL.—A patient safety organiza-
 16 tion may collect information reported directly by pa-
 17 tients on patient safety incidents and unsafe condi-
 18 tions. Such information shall not be deemed to be
 19 ‘identifiable patient safety work product’.

20 “(2) REQUIREMENTS.—In collecting patient
 21 safety information (including information submitted
 22 by patients under this subsection), a patient safety
 23 organization shall—

24 “(A) ensure that all such information (in-
 25 cluding any other patient safety work product

1 received by the organization) is submitted to
2 the network of patient safety databases; and

3 “(B) ensure that such information is de-
4 identified prior to submitting the information to
5 the network of patient safety databases.

6 “(3) DEVELOPMENT OF BEST PRACTICES.—The
7 Director of the Agency shall conduct research on
8 best practices for enabling patient safety organiza-
9 tions to engage patients in reporting on patient safe-
10 ty incidents and for the collection by such organiza-
11 tions of such patient-reported information, including
12 a standardized format for the submission of such
13 data by patients. The Director shall disseminate
14 such best practices for use by patient safety organi-
15 zations.

16 “(4) ACCESSIBILITY.—The Director of the
17 Agency shall establish a single access point on the
18 Internet website of the Agency that may be accessed
19 by the public to obtain patient safety data from the
20 data that has been aggregated by the network of pa-
21 tient safety databases.

22 “(5) AUTHORIZATION OF APPROPRIATIONS.—
23 There is authorized to be appropriated, such sums
24 as may be necessary to carry out this subsection.”.

○