II

114TH CONGRESS
2D SESSION

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

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Patient Safety Improvement Act of 2016''.

SEC. 2. FINDINGS.

Congress finds the following:

(1) A 2014 prevalence survey published in the New England Journal of Medicine found that approximately 1 in 25 hospital patients in the United States has at least one health care-associated infection, adding up to an estimated 722,000 health care-associated infections in acute care hospitals in 2011. About 75,000 hospital patients with health care-associated infections died during their hospitalizations.

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

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

(4) Estimates of the annual impact of antibiotic-resistant infections on the United States economy vary but range from $20,000,000,000 to $35,000,000,000 in excess health care costs, and as

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

(5) The prevalence of health care-associated infections and the rise of antibiotic resistance are serious threats to human health and contribute to escalating health care costs. Strategies to reduce patient harm and preserve the effectiveness of existing antibiotics are needed to combat the rise of antibiotic resistance that is threatening the health of Americans and people around the world.

SEC. 3. IMPROVING DATA RELIABILITY AND SURVEILLANCE.

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

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

"SEC. 938. HEALTH CARE-ASSOCIATED INFECTIONS AND ANTIBIOTIC USE.

"(a) GAO STUDY ON DATA VALIDATION STRATEGIES.—

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

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

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

''(A) the types of external and internal data validation strategies that are conducted by the Centers for Disease Control and Prevention, State and local departments of health, and hospitals;

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

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

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

''(b) DATA RELIABILITY FRAMEWORK.—

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

''(2) REQUIREMENTS.—The framework developed under paragraph (1) shall—

''(A) address issues identified in the findings of the study conducted under subsection (a);

''(B) propose data validation and reliability methodologies; and

''(C) assess the effectiveness and the cost to implement proposed methodologies.

''(c) DATA COLLECTION PILOT PROGRAM.—

''(1) IN GENERAL.—The Administrator of the Agency for Healthcare Research and Quality, in collaboration with the Director of the Centers for Dis-

ease Control and Prevention, shall convene a meeting with relevant stakeholders to identify best practices and approaches for the collection and reporting of data on the incidence of health care-associated infections to the National Healthcare Safety Network by long-term care facilities, ambulatory surgical centers, and dialysis facilities.

''(2) PILOT PROGRAM.—After conducting the meeting under paragraph (1), the Administrator of the Agency shall establish and implement a pilot program to test best practices and approaches for the collection and reporting of data on the incidence of health care-associated infections by long-term care facilities, ambulatory surgical centers, and dialysis facilities. Such pilot program should incorporate applicable data validation methodologies and other recommendations described in the framework developed under subsection (b).

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

data collection and reporting in long-term care settings, ambulatory surgical centers, and dialysis facilities as well as recommended data validation methods for those settings.

''(4) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated, such sums as may be necessary to carry out this subsection. Amounts appropriated under the preceding sentence may be used for the purchase of software and technology that supports data collection and reporting.''.

SEC. 4. ALIGNING QUALITY MEASURES.

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

(1) Priorities for measure alignment.

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

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

SEC. 5. REDUCING THE INCIDENCE OF HEALTH CARE-ASSOCIATED INFECTIONS.

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

"SEC. 320B. EFFORTS TO REDUCE HEALTH CARE-ASSOCIATED INFECTIONS.

''(a) GRANT PROGRAM TO REDUCE HEALTH CARE-ASSOCIATED INFECTIONS.—

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

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

''(A) Inter-professional and inter-facility learning activities.

''(B) Building Statewide learning collaboratives.

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

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

''(E) Other activities determined appropriate by the Secretary.

''(3) ELIGIBILITY.—To be eligible to receive a grant under this subsection, an entity shall be a public or private nonprofit entity that submits to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including—

''(A) a description of the activities to be carried out under the grant, including the participants in any collaborative established to carry out such activities;

''(B) goals for the reduction in regional or Statewide rates of health care-associated infections;

''(C) an assurance that the entity will publicly report performance on a set of quality and outcomes measures determined by the Secretary; and

''(D) any other information determined appropriate by the Secretary.

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

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

(b) IMPROVING COMMUNICATION OF PATIENT INFECTIONS IN MEDICARE AND MEDICAID.—

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

(A) in paragraph (1)—

(i) in subparagraph (X), by striking ''and'' at the end;

(ii) in subparagraph (Y), by striking the period at the end and inserting '', and''; and

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

"(Z) to comply with the requirement of paragraph (4) (relating to the transmission of information regarding infections)."; and

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

"(4)(A) For purposes of paragraph (1)(Z), the requirement of this paragraph is that a hospital transmit information about infections or colonizations that present in an individual receiving treatment not later than 24 hours upon receipt of the culture to—

"(i) the individual;

"(ii) in the case of an individual who is being transferred to another provider, the receiving provider; and

"(iii) the individual's primary care provider, if identified.

"(B) The information described in subparagraph (A) shall contain the information fields included in the Centers for Disease Control and Prevention's Inter-facility Infection Control Transfer Form and any other information the Secretary determines appropriate.

"(C) When transmitting information to a receiving provider under subparagraph (A)(ii), a pro-

vider shall, where practical, transmit such information electronically.''.

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

(A) in paragraph (80), by striking ''and'' at the end;

(B) in paragraph (81), by striking the period at the end and inserting ''; and''; and

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

''(82) in the case of any hospital (as defined in section 1861(e)) that is a participating provider under the State plan, provide that such hospital meet the requirements of subparagraph (Z) of section 1866(a)(1).''.

(c) STANDARDIZED FORM.—Not later than 6 months after the date of the enactment of this Act, the Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention, shall issue a standardized electronic version of the form for use by providers in transmitting information as required by the amendments made by subsection (b).

(d) EFFECTIVE DATE.—

(1) MEDICARE.—In the case of the requirements imposed by the amendments made by sub-

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

(2) MEDICAID.—

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

(B) DELAY PERMITTED IF STATE LEGISLATION REQUIRED.—In the case of a State plan for medical assistance under title XIX of the Social Security Act which the Secretary of Health and Human Services determines requires State legislation (other than legislation appropriating funds) in order for the plan to meet the additional requirements imposed by subsection (b)(2), the State plan shall not be regarded as failing to comply with the requirements of such title solely on the basis of its failure to meet these additional requirements before the first day of the first calendar quarter beginning after the close of the first regular

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

SEC. 6. STRENGTHENING ANTIBIOTIC STEWARDSHIP.

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

''(b) GRANT PROGRAM FOR STATE ANTIBIOTIC STEWARDSHIP ACTION PLANS.—

''(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall award grants to States for the development of State plans to promote antibiotic stewardship and prevent the spread of antimicrobial-resistant bacteria across health care settings.

''(2) ELIGIBILITY.—To be eligible to receive a grant under this subsection, a State shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including—

"(A) an assurance that development of the plan under the grant will be led by an infectious-disease trained physician or a pharmacist with expertise in infectious disease; and

"(B) an assurance that the plan will focus on collaboration across acute and ambulatory care settings and include a summary of resource gaps and challenges.

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

(b) ADVANCING HOSPITAL REPORTING ON ANTIBIOTIC USE AND ANTIMICROBIAL RESISTANCE.—Not later than January 1, 2018, the Administrator of the Centers for Medicare & Medicaid Services shall require that acute care hospitals report antibiotic use and antimicrobial resistance using the National Healthcare Safety Network's Antimicrobial Use and Resistance Module as part of the Hospital Inpatient Quality Reporting Program.

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

''(c) INFORMATION RELATED TO ANTIBIOTIC USE AND ANTIMICROBIAL RESISTANCE.—

''(1) IN GENERAL.—The Director of the Centers for Disease Control and Prevention shall annually prepare and issue a report concerning the aggregate national and regional trends of antibiotic use and bacterial resistance in humans to antibacterial drugs, including the identity of the 10 States with the highest number of prescriptions for antibiotics.

''(2) STEWARDSHIP WORKSHOPS.—

''(A) IN GENERAL.—Beginning on January 1, 2019, and annually thereafter, the Director of the Centers for Disease Control and Prevention shall conduct at least one antibiotic stewardship workshop in a State identified in the report under paragraph (1).

''(B) REQUIREMENTS.—The workshop under subparagraph (A) shall identify regional strategies to support collaboration across the care continuum to promote antibiotic stewardship. In implementing such workshop, the Director of the Centers for Disease Control and Prevention should seek participation from relevant public and private stakeholders with ex-

pertise in infection control, quality improvement, and consumer engagement.

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

SEC. 7. OTHER IMPROVEMENTS.

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

''(d) CONTINUING EDUCATION ON INFECTION CONTROL AND PATIENT SAFETY.—

''(1) IN GENERAL.—The Secretary shall establish a program to provide incentives (in the form of grants or other assistance) to State medical boards that require health care professionals (as defined by the medical board) to complete accredited coursework or training in infection control, antibiotic stewardship, or other patient safety topics as a condition of receiving a renewed license to practice in the State.

''(2) EXEMPTION.—A State medical board that receives assistance under paragraph (1) may provide an exemption from the coursework or training requirement under such paragraph for those health

care professionals who have specialized training in infection control (such as an infectious disease specialist or certified infection control practitioner), who are not actively practicing in the State, or who do not provide direct patient care.

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

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

(1) MEDICARE.—Section 1866(a)(1) of the Social Security Act (42 U.S.C. 1395cc(a)(1)), as amended by section 4(a)(1), is amended—

(A) in subparagraph (Y), by striking ''and'' at the end;

(B) in subparagraph (Z), by striking the period and inserting '', and''; and

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

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

are relevant to a hospital (or critical access hospital, as the case may be) setting, such as infection prevention, care transitions, patient safety and quality of care measurement, and staff communication.''.

(2) MEDICAID.—Section 1902(a)(82) of the Social Security Act, as added by section (5)(a)(2)(C), is amended by striking ''subparagraph (Z)'' and inserting ''subparagraphs (Z) and (AA)'' before the period.

(3) CRITERIA.—Not later than 6 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall propose and finalize criteria, through notice and comment rulemaking, specifying the number of hours and type of training that shall satisfy the training requirements imposed by the amendments made by paragraphs (1) and (2). Such criteria shall be published on the Internet website of the Centers for Medicare & Medicaid Services.

(4) EFFECTIVE DATE.—

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

the date that is 30 days after the date of the publication of the criteria described in paragraph (3).

(B) MEDICAID.—

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

(ii) DELAY PERMITTED IF STATE LEGISLATION REQUIRED.—In the case of a State plan for medical assistance under title XIX of the Social Security Act which the Secretary of Health and Human Services determines requires State legislation (other than legislation appropriating funds) in order for the plan to meet the additional requirement imposed by paragraph (2), the State plan shall not be regarded as failing to comply with the requirements of such title solely on the basis of its failure to meet this additional requirement before the first day of the first calendar quarter beginning after the close

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

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

''(d) AUTHORITY FOR DIRECT REPORTING BY PATIENTS.—

''(1) IN GENERAL.—A patient safety organization may collect information reported directly by patients on patient safety incidents and unsafe conditions. Such information shall not be deemed to be 'identifiable patient safety work product'.

''(2) REQUIREMENTS.—In collecting patient safety information (including information submitted by patients under this subsection), a patient safety organization shall—

''(A) ensure that all such information (including any other patient safety work product

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

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

''(3) DEVELOPMENT OF BEST PRACTICES.—The Director of the Agency shall conduct research on best practices for enabling patient safety organizations to engage patients in reporting on patient safety incidents and for the collection by such organizations of such patient-reported information, including a standardized format for the submission of such data by patients. The Director shall disseminate such best practices for use by patient safety organizations.

''(4) ACCESSIBILITY.—The Director of the Agency shall establish a single access point on the Internet website of the Agency that may be accessed by the public to obtain patient safety data from the data that has been aggregated by the network of patient safety databases.

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

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