115TH CONGRESS
2D SESSION

S. 2469

To amend the Public Health Service Act to enhance efforts to address antibiotic resistance, and for other purposes.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 28, 2018

Mr. BROWN 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 amend the Public Health Service Act to enhance efforts to address antibiotic resistance, 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 ''Strategies to Address Antibiotic Resistance Act'' or the ''STAAR Act''.

SEC. 2. FINDINGS.

Congress makes the following findings:

(1) Antibiotic resistance is one of the greatest threats to human health worldwide, necessitating increased prevention efforts, antimicrobial stewardship

programs and surveillance programs, and research and development of new antibiotics and rapid diagnostics.

(2) Since the discovery of antibiotic drugs, these powerful drugs have saved millions of lives and allowed for incredible medical progress. However, antibiotic resistance is accelerated by over- and inappropriate use of antibiotic drugs by which bacteria, through mutation and other mechanisms, can develop resistance to antibiotic drugs.

(3) Antibiotic-resistant infections significantly complicate a wide variety of complex medical services, including chemotherapy to treat cancer, solid organ and bone marrow transplants, joint replacements and other surgeries, and care of preterm infants and other immunocompromised individuals.

(4) According to the Centers for Disease Control and Prevention, each year in the United States at least 2,000,000 people become infected with bacteria that are resistant to antibiotics and at least 23,000 people die as a result of antibiotic-resistant infections. Many more people die from other conditions that were complicated by an antibiotic-resistant infection.

(5) According to a 2015 report from the New England Journal of Medicine, Clostridium difficile infects approximately 500,000 patients in the United States each year, resulting in almost 30,000 deaths and an estimated $4,800,000,000 in excess health care costs each year. Clostridium difficile infections are most common as a result of over-prescribing antibiotics, and antibiotic-resistant strains of Clostridium difficile are on the rise.

(6) The Centers for Disease Control and Prevention estimate that the annual impact of antibiotic-resistant infections on the United States economy is more than $20,000,000,000 in excess direct health care costs. Additional costs to the United States economy for lost productivity from antibiotic-resistant infections may be as great as $35,000,000,000 per year.

(7) Data from the Centers for Disease Control and Prevention indicate that at least 30 percent of antibiotic drugs used in hospitals are unnecessary or prescribed incorrectly. Similarly, the Centers for Disease Control and Prevention estimate that approximately 30 percent of antibiotic drugs prescribed in outpatient clinics are unnecessary and that approximately 40 percent of orders for antibiotic drugs

in nursing homes lacked important prescribing information. Thus, improvements in prescribing antibiotic drugs are necessary across health care settings.

(8) The National Action Plan for Combating Antibiotic-Resistant Bacteria, published in March 2015, in response to Executive Order 13676 of September 18, 2014 (79 Fed. Reg. 56931; relating to combating antibiotic-resistant bacteria), outlines the domestic and international efforts to be conducted by the United States to prevent, detect, and control illness and death related to infections caused by antibiotic-resistant bacteria.

SEC. 3. COMBATING ANTIMICROBIAL RESISTANCE.

Section 319E of the Public Health Service Act (42 U.S.C. 247d–5) is amended—

(1) in subsection (a)—

(A) in paragraph (1), in the first sentence, by striking ''and coordinate Federal programs relating to antimicrobial resistance'' and inserting ''relating to antimicrobial resistance, coordinate Federal programs relating to antimicrobial resistance, and implement the objectives of the National Action Plan for Combating Antibiotic-Resistant Bacteria, published in March 2015 in response to Executive Order 13676 of Sep-

tember 18, 2014 (79 Fed. Reg. 56931; relating to combating antibiotic-resistant bacteria) (referred to in this section as the 'Action Plan')'';

(B) by amending paragraph (2) to read as follows:

''(2) MEMBERS OF TASK FORCE.—The task force described in paragraph (1) shall be co-chaired by the Secretary of Health and Human Services, the Secretary of Agriculture, and the Secretary of Defense, and shall be composed of representatives of relevant Federal agencies and such executive departments, agencies, or offices as the co-chairs may designate.'';

(C) by amending paragraph (4) to read as follows:

''(4) MEETINGS.—At least twice a year, the task force described in paragraph (1) shall have a public meeting to assess progress and obstacles to implementing the objectives of the Action Plan. The task force may discuss and review based on need or concern the following (among other issues):

''(A) Federal activities to slow the emergence of antimicrobial-resistant bacteria and prevent the spread of resistant infections. Such activities may include optimal use of vaccines

and other infection control measures to prevent infections, implementation of health care policies and antimicrobial stewardship programs that improve patient outcomes, regional efforts to control transmission across community and health care settings, and public awareness campaigns.

''(B) Federal activities to strengthen national One-Health surveillance efforts, which are efforts addressing the interactions between human, animal, and environmental health, to combat antibiotic resistance. One-Health surveillance efforts to combat antibiotic resistance may include enhanced data sharing and coordination of surveillance and laboratory systems across human and animal settings, and enhanced monitoring of sales, usage, resistance, and management practices of antibiotic drugs along the food-production chain. Such surveillance and laboratory systems may include the National Healthcare Safety Network, the Emerging Infections Program, the National Antimicrobial Resistance Monitoring System, the National Animal Health Monitoring System, the National Animal Health Laboratory

Network, the Veterinary Laboratory Investigation and Response Network, and the Antibiotic Resistance Laboratory Network.

''(C) Federal efforts to advance the development and use of rapid and innovative diagnostic tests for identification and characterization of antibiotic-resistant bacteria. Such efforts may include development of new diagnostic tests and expansion of their availability and use to improve treatment, infection control, and outbreak response.

''(D) Federal efforts to accelerate basic and applied research and development for new antibiotic drugs, other therapeutics, prevention efforts, and vaccines. Such efforts may include support for basic and applied research, provision of scientific services and guidance to researchers, and fostering of public-private partnerships.

''(E) Federal efforts to improve international collaboration and capacities for antibiotic-resistance prevention, surveillance, and control and antibiotic research and development. Such efforts may include collaborations with foreign ministries of health and agri-

culture, the World Health Organization, the Food and Agriculture Organization, the World Organization for Animal Health, and other multinational organizations.''; and

(D) by adding at the end the following:

''(5) AVAILABILITY OF INFORMATION.—The task force described in paragraph (1), to the extent permitted by law, shall—

''(A) provide the Advisory Council defined in section 319E–1(a) with such information as may be required for carrying out the functions of such Advisory Council, including information on progress in advancing the Action Plan, meeting minutes, and other key information of the task force; and

''(B) ensure that all information described in subparagraph (A) is made available on the websites of the Department of Health and Human Services, the Department of Agriculture, and the Department of Defense.'';

(2) in subsection (h)—

(A) in the heading, by striking ''INFORMATION RELATED TO'';

(B) by striking ''The Secretary'' and inserting the following:

''(1) DISSEMINATION OF INFORMATION.—The Secretary''; and

(C) by adding at the end the following:

''(2) ENCOURAGING ANTIMICROBIAL STEWARDSHIP PROGRAMS.—The Secretary shall encourage health care facilities to establish antimicrobial stewardship programs that are consistent with documents issued by the Centers for Disease Control and Prevention relating to the core elements of antimicrobial stewardship programs.

''(3) DEFINITION OF ANTIMICROBIAL STEWARDSHIP.—For purposes of this section, the term 'antimicrobial stewardship' means coordinated interventions designed to improve and evaluate the appropriate use of antimicrobial agents, including promoting the use of antimicrobial drugs only when clinically indicated, and, when antimicrobial drugs are clinically indicated, promoting the selection of the optimal antimicrobial drug regimen, including through factors such as dosage, duration of therapy, and route of administration.'';

(3) in subsection (m), by striking ''$40,000,000'' and all that follows through the period at the end and inserting ''such sums as may be

necessary for each of fiscal years 2018 through 2024.''; and

(4) by adding at the end the following:

''(n) ANNUAL REPORT ON IMPLEMENTING THE ACTION PLAN OBJECTIVES.—Not later than 1 year after the date of the enactment of the Strategies to Address Antibiotic Resistance Act, and annually thereafter, the Secretary, in cooperation with the Secretary of Agriculture, the Secretary of Defense, and the task force described in subsection (a), shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, and make available on the websites of the Department of Health and Human Services, the Department of Agriculture, and the Department of Defense, a report on the progress made in implementing the objectives of the Action Plan.''.

SEC. 4. ADDITIONAL STRATEGIES FOR COMBATING ANTIBIOTIC RESISTANCE.

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) is amended by inserting after section 319E the following:

''SEC. 319E–1. PRESIDENTIAL ADVISORY COUNCIL ON COMBATING ANTIBIOTIC-RESISTANT BACTERIA.

''(a) DEFINITIONS.—In this section:

''(1) ACTION PLAN.—The term 'Action Plan' means the Action Plan described in section 319E(a)(1).

''(2) ADVISORY COUNCIL.—The term 'Advisory Council' means the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria established by Executive Order 13676 of September 18, 2014 (79 Fed. Reg. 56931; relating to combating antibiotic-resistant bacteria).

''(3) NATIONAL STRATEGY.—The term 'National Strategy' means the National Strategy for Combating Antibiotic-Resistant Bacteria issued by the White House in September 2014, and any subsequent update to such strategy or a successor strategy.

''(b) ADVISORY COUNCIL.—The Advisory Council shall provide advice, information, and recommendations to the Secretary regarding programs and policies intended to support and evaluate the implementation of Executive Order 13676 of September 18, 2014 (79 Fed. Reg. 56931; relating to combating antibiotic-resistant bacteria), including the National Strategy, and the Action Plan.

''(c) MEETINGS AND DUTIES.—

''(1) MEETINGS.—The Advisory Council shall meet as the Chair determines appropriate but not

less than twice per year, and, to the extent practicable, in conjunction with meetings of the task force described in section 319E.

''(2) RECOMMENDATIONS.—The Advisory Council shall make recommendations to the Secretary, in consultation with the Secretary of Agriculture and the Secretary of Defense, regarding programs and policies intended to—

''(A) preserve the effectiveness of antibiotics by optimizing their use;

''(B) advance research to develop improved methods for combating antibiotic resistance and conducting antimicrobial stewardship, as defined in section 319E(h)(3);

''(C) strengthen surveillance of antibiotic-resistant bacterial infections;

''(D) prevent the transmission of antibiotic-resistant bacterial infections;

''(E) advance the development of rapid point-of-care and agricultural diagnostics;

''(F) further research on new treatments for bacterial infections;

''(G) develop alternatives to antibiotics for animal health purposes;

''(H) maximize the dissemination of up-to-date information on the appropriate and proper use of antibiotics to the general public and human and animal health care providers; and

''(I) improve international coordination of efforts to combat antibiotic resistance.

"SEC. 319E–2. SURVEILLANCE AND REPORTING OF ANTIBIOTIC USE AND RESISTANCE.

''(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall use the National Healthcare Safety Network and other appropriate surveillance systems to assess—

''(1) appropriate conditions, outcomes, and measures causally related to antibacterial resistance, including types of infections, the causes for infections, and whether infections are acquired in a community or hospital setting, increased lengths of hospital stay, increased costs, and rates of mortality; and

''(2) changes in bacterial resistance to drugs in relation to patient outcomes, including changes in percent resistance, prevalence of antibiotic-resistant infections, and other such changes.

''(b) ANTIBIOTIC USE DATA.—The Secretary, acting through the Director of the Centers for Disease Control

and Prevention, shall work with Federal agencies (including the Department of Veterans Affairs, the Department of Defense, and the Centers for Medicare & Medicaid Services), private vendors, health care organizations, pharmacy benefit managers, and other entities as appropriate to obtain reliable and comparable human antibiotic drug consumption data (including, as available and appropriate, volume antibiotic distribution data and antibiotic use data, including prescription data) by State or metropolitan areas.

''(c) ANTIBIOTIC RESISTANCE TREND DATA.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall intensify and expand efforts to collect antibiotic resistance data and encourage adoption of the antibiotic resistance and use module within the National Healthcare Safety Network among all health care facilities across the continuum of care, including, as appropriate, acute care hospitals, dialysis facilities, nursing homes, and ambulatory surgical centers. The Secretary shall seek to collect such data from electronic medication administration reports and laboratory systems to produce the reports described in subsection (d).

''(d) PUBLIC AVAILABILITY OF DATA.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall, for the purposes of im-

proving the monitoring of important trends in patient outcomes in relation to antibacterial resistance—

''(1) make the data derived from surveillance under this section publicly available through reports issued on a regular basis that is not less than annually; and

''(2) examine opportunities to make such data available in near real time.

''SEC. 319E–3. DETECTING NETWORK OF ANTIBIOTIC RESISTANCE REGIONAL LABORATORIES.

''(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish not less than 7 Antibiotic Resistance Surveillance and Laboratory Network sites, building upon the intramural and extramural programs and laboratories of the Centers for Disease Control and Prevention, to intensify, strengthen, and expand the national capacity to—

''(1) monitor the emergence and changes in the patterns of antibiotic-resistant bacteria;

''(2) describe, confirm, and, as necessary, facilitate a response to, local or regional outbreaks of resistant bacteria;

''(3) assess and describe antibiotic resistance patterns to inform public health and improve prevention practices;

''(4) obtain isolates of pathogens, and in particular, bacteria that show new or atypical patterns of resistance adversely affecting public health;

''(5) assist in studying the epidemiology of infections from such pathogens;

''(6) evaluate commonly used antibiotic susceptibility testing methods to improve the accuracy of resistance testing and reporting;

''(7) as necessary, develop or evaluate novel diagnostic tests capable of detecting new or emerging resistance in bacteria;

''(8) link data generated by regional laboratory networks under existing public health surveillance networks and relevant government agencies; and

''(9) provide laboratory assistance and reference testing of antibiotic-resistant bacteria to enhance infection control and facilitate outbreak detection and response in health care and community settings.

''(b) GEOGRAPHIC DISTRIBUTION.—The sites established under subsection (a) shall be geographically distributed across the United States.

''(c) NONDUPLICATION OF CURRENT NATIONAL CAPACITY.—The sites established under subsection (a) may be based in academic centers, health departments, and existing surveillance and laboratory sites.

"SEC. 319E–4. CLINICAL TRIALS NETWORK ON ANTIBACTERIAL RESISTANCE.

''(a) IN GENERAL.—The Secretary, acting through the Director of the National Institute of Allergy and Infectious Diseases, shall maintain a Clinical Trials Network on Antibacterial Resistance to enhance, strengthen, and expand research on clinical science, antibacterial and diagnostic development, and optimal usage strategies with respect to addressing antibacterial resistance. Such Network shall, at a minimum—

''(1) facilitate research to better understand resistance mechanisms and how to prevent, control, and treat resistant organisms;

''(2) advance clinical trial efforts to develop antibiotics diagnostics, and evaluate and optimize the usage of such antibiotics diagnostics;

''(3) conduct clinical research to develop natural histories of resistant infectious diseases;

''(4) examine patient outcomes with currently available antibiotic therapy and validate and improve upon biomarkers and other surrogate endpoints; and

''(5) study shorter treatment duration and early cessation of antibiotic therapy for treatment efficacy and the effect on development of resistance.

''(b) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2018 through 2024.

''SEC. 319E–5. REGIONAL PREVENTION COLLABORATIVE EFFORTS.

''(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall work with State and local health departments to support the expansion of collaborative efforts by groups of health care facilities that focus on preventing the spread of antibiotic-resistant bacteria that pose a serious threat to public health, and that are designed to interrupt and prevent the transmission of significant antibiotic-resistant pathogens being transmitted across health care settings in a geographic region. Such collaborative efforts shall—

''(1) identify significant drug resistant pathogens being transmitted across health care settings locally;

''(2) implement evidence-based interventions to interrupt the transmission of antibiotic-resistant

strains of bacteria and prevent the infections caused by such bacteria, including evidence-based transmission prevention guidelines, rigorous hand-hygiene protocols, and infection control and prevention measures;

''(3) assess compliance and identify barriers to adherence to such measures;

''(4) evaluate the impact of such measures, to the extent possible, on hospital readmissions in health care facilities across the continuum of care, rates of health care associated infections, or any other relevant measures that characterize the health or economic impact of the collaborative efforts; and

''(5) provide recommendations for improved outcomes and compliance with such measures.

''(b) PREVENTION EPICENTERS.—

''(1) EXPANSION.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may intensify and expand academic public health partnerships through the Prevention Epicenters Program to provide the regional prevention collaboration efforts described in subsection (a) with tools, strategies, and evidence-based interventions.

''(2) EVALUATIONS AND RESEARCH.—The Director of the Centers for Disease Control and Prevention and the epicenters participating in the Prevention Epicenters Program shall work with entities, including the entities participating in the regional prevention collaborative efforts, to—

''(A) evaluate new and existing interventions to prevent or limit infection rates in health care facilities across the continuum of care and in community settings;

''(B) facilitate public health research on the prevention and control of resistant organisms; and

''(C) assess the feasibility, cost-effectiveness, and appropriateness of surveillance and prevention programs in differing health care and institutional settings.

''(c) EDUCATIONAL MATERIALS.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall use the evaluations, research, and assessments described in subsection (b) to create and disseminate educational materials focused on infection prevention and control for use in health care facilities across the continuum of care and in community settings.''.

SEC. 5. PROTECTION OF CONFIDENTIAL AND NATIONAL SECURITY INFORMATION.

This Act, and the amendments made by this Act, shall not be construed to permit the disclosure of any trade secret, confidential commercial information, or material inconsistent with national security, that is otherwise prohibited by law.

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