

116TH CONGRESS  
1ST SESSION

# S. 2304

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

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IN THE SENATE OF THE UNITED STATES

JULY 29, 2019

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.

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 “Strategies To Address  
5 Antibiotic Resistance Act” or the “STAAR Act”.

6 **SEC. 2. COMBATING ANTIMICROBIAL RESISTANCE.**

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

9 (1) in subsection (a)—

1 (A) in paragraph (1), in the first sentence,  
2 by striking “and coordinate Federal programs  
3 relating to antimicrobial resistance” and insert-  
4 ing “relating to antimicrobial resistance, coordi-  
5 nate Federal programs relating to antimicrobial  
6 resistance, and implement the objectives of the  
7 National Action Plan for Combating Antibiotic-  
8 Resistant Bacteria, published in March 2015 in  
9 response to Executive Order 13676 of Sep-  
10 tember 18, 2014 (79 Fed. Reg. 56931; relating  
11 to combating antibiotic-resistant bacteria) (re-  
12 ferred to in this section as the ‘Action Plan’”;

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

15 “(2) MEMBERS OF TASK FORCE.—The task  
16 force described in paragraph (1) shall be co-chaired  
17 by the Secretary of Health and Human Services, the  
18 Secretary of Agriculture, and the Secretary of De-  
19 fense, and shall be composed of representatives of  
20 relevant Federal agencies and such executive depart-  
21 ments, agencies, or offices as the co-chairs may des-  
22 ignate.”;

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

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

7           “(A) Federal activities to slow the emer-  
8 gence of antimicrobial-resistant bacteria and  
9 prevent the spread of resistant infections. Such  
10 activities may include optimal use of vaccines  
11 and other infection control measures to prevent  
12 infections, implementation of health care poli-  
13 cies and antimicrobial stewardship programs  
14 that improve patient outcomes, regional efforts  
15 to control transmission across community and  
16 health care settings, and public awareness cam-  
17 paigns.

18           “(B) Federal activities to strengthen na-  
19 tional One-Health surveillance efforts, which  
20 are efforts addressing the interactions between  
21 human, animal, and environmental health, to  
22 combat antibiotic resistance. One-Health sur-  
23 veillance efforts to combat antibiotic resistance  
24 may include enhanced data sharing and coordi-  
25 nation of surveillance and laboratory systems

1 across human and animal settings, and en-  
2 hanced monitoring of sales, usage, resistance,  
3 and management practices of antibiotic drugs  
4 along the food-production chain. Such surveil-  
5 lance and laboratory systems may include the  
6 National Healthcare Safety Network, the  
7 Emerging Infections Program, the National  
8 Antimicrobial Resistance Monitoring System,  
9 the National Animal Health Monitoring Sys-  
10 tem, the National Animal Health Laboratory  
11 Network, the Veterinary Laboratory Investiga-  
12 tion and Response Network, and the Antibiotic  
13 Resistance Laboratory Network.

14 “(C) Federal efforts to advance the devel-  
15 opment and use of rapid and innovative diag-  
16 nostic tests for identification and characteriza-  
17 tion of antibiotic-resistant bacteria. Such efforts  
18 may include development of new diagnostic  
19 tests and expansion of their availability and use  
20 to improve treatment, infection control, and  
21 outbreak response.

22 “(D) Federal efforts to accelerate basic  
23 and applied research and development for new  
24 antibiotic drugs, other therapeutics, prevention  
25 efforts, and vaccines. Such efforts may include

1 support for basic and applied research, provi-  
2 sion of scientific services and guidance to re-  
3 searchers, and fostering of public-private part-  
4 nerships.

5 “(E) Federal efforts to improve inter-  
6 national collaboration and capacities for anti-  
7 biotic-resistance prevention, surveillance, and  
8 control and antibiotic research and develop-  
9 ment. Such efforts may include collaborations  
10 with foreign ministries of health and agri-  
11 culture, the World Health Organization, the  
12 Food and Agriculture Organization, the World  
13 Organization for Animal Health, and other mul-  
14 tinational organizations.”; and

15 (D) by adding at the end the following:

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

19 “(A) provide the Presidential Advisory  
20 Council on Combating Antibiotic-Resistant Bac-  
21 teria described in section 505 of the Pandemic  
22 and All-Hazards Preparedness and Advancing  
23 Innovation Act of 2019 with such information  
24 as may be required for carrying out the func-  
25 tions of such Advisory Council, including infor-

1           mation on progress in advancing the Action  
2           Plan, meeting minutes, and other key informa-  
3           tion of the task force; and

4           “(B) ensure that all information described  
5           in subparagraph (A) is made available on the  
6           websites of the Department of Health and  
7           Human Services, the Department of Agri-  
8           culture, and the Department of Defense.”;

9           (2) in subsection (h)—

10           (A) in the heading, by striking “INFORMA-  
11           TION RELATED TO”;

12           (B) by striking “The Secretary” and in-  
13           serting the following:

14           “(1) DISSEMINATION OF INFORMATION.—The  
15           Secretary”; and

16           (C) by adding at the end the following:

17           “(2) ENCOURAGING ANTIMICROBIAL STEWARD-  
18           SHIP PROGRAMS.—The Secretary shall encourage  
19           health care facilities to establish antimicrobial stew-  
20           ardship programs that are consistent with docu-  
21           ments issued by the Centers for Disease Control and  
22           Prevention relating to the core elements of anti-  
23           microbial stewardship programs.

24           “(3) DEFINITION OF ANTIMICROBIAL STEWARD-  
25           SHIP.—For purposes of this section, the term ‘anti-

1 microbial stewardship’ means coordinated interven-  
2 tions designed to improve and evaluate the appro-  
3 priate use of antimicrobial agents, including pro-  
4 moting the use of antimicrobial drugs only when  
5 clinically indicated, and, when antimicrobial drugs  
6 are clinically indicated, promoting the selection of  
7 the optimal antimicrobial drug regimen, including  
8 through factors such as dosage, duration of therapy,  
9 and route of administration.”;

10 (3) in subsection (m), by striking  
11 “\$40,000,000” and all that follows through the pe-  
12 riod at the end and inserting “such sums as may be  
13 necessary for each of fiscal years 2020 through  
14 2026.”; and

15 (4) by adding at the end the following:

16 “(n) ANNUAL REPORT ON IMPLEMENTING THE AC-  
17 TION PLAN OBJECTIVES.—Not later than 1 year after the  
18 date of the enactment of the Strategies to Address Anti-  
19 biotic Resistance Act, and annually thereafter, the Sec-  
20 retary, in cooperation with the Secretary of Agriculture,  
21 the Secretary of Defense, and the task force described in  
22 subsection (a), shall submit to the Committee on Health,  
23 Education, Labor, and Pensions of the Senate and the  
24 Committee on Energy and Commerce of the House of  
25 Representatives, and make available on the websites of the

1 Department of Health and Human Services, the Depart-  
2 ment of Agriculture, and the Department of Defense, a  
3 report on the progress made in implementing the objec-  
4 tives of the Action Plan.”.

5 **SEC. 3. ADDITIONAL STRATEGIES FOR COMBATING ANTI-**  
6 **BIOTIC RESISTANCE.**

7 Part B of title III of the Public Health Service Act  
8 (42 U.S.C. 243 et seq.) is amended by inserting after sec-  
9 tion 319E the following:

10 **“SEC. 319E-1. SURVEILLANCE AND REPORTING OF ANTI-**  
11 **BIOTIC USE AND RESISTANCE.**

12 “(a) IN GENERAL.—The Secretary, acting through  
13 the Director of the Centers for Disease Control and Pre-  
14 vention, shall use the National Healthcare Safety Network  
15 and other appropriate surveillance systems to assess—

16 “(1) appropriate conditions, outcomes, and  
17 measures causally related to antibacterial resistance,  
18 including types of infections, the causes for infec-  
19 tions, and whether infections are acquired in a com-  
20 munity or hospital setting, increased lengths of hos-  
21 pital stay, increased costs, and rates of mortality;  
22 and

23 “(2) changes in bacterial resistance to drugs in  
24 relation to patient outcomes, including changes in



1       percent resistance, prevalence of antibiotic-resistant  
2       infections, and other such changes.

3       “(b) ANTIBIOTIC USE DATA.—The Secretary, acting  
4 through the Director of the Centers for Disease Control  
5 and Prevention, shall work with Federal agencies (includ-  
6 ing the Department of Veterans Affairs, the Department  
7 of Defense, and the Centers for Medicare & Medicaid  
8 Services), private vendors, health care organizations, phar-  
9 macy benefit managers, and other entities as appropriate  
10 to obtain reliable and comparable human antibiotic drug  
11 consumption data (including, as available and appropriate,  
12 volume antibiotic distribution data and antibiotic use data,  
13 including prescription data) by State or metropolitan  
14 areas.

15       “(c) ANTIBIOTIC RESISTANCE TREND DATA.—The  
16 Secretary, acting through the Director of the Centers for  
17 Disease Control and Prevention, shall intensify and ex-  
18 pand efforts to collect antibiotic resistance data and en-  
19 courage adoption of the antibiotic resistance and use mod-  
20 ule within the National Healthcare Safety Network among  
21 all health care facilities across the continuum of care, in-  
22 cluding, as appropriate, acute care hospitals, dialysis fa-  
23 cilities, nursing homes, ambulatory surgical centers, and  
24 other ambulatory health care settings in which anti-  
25 microbial medications are routinely prescribed. The Sec-

1 retary shall seek to collect such data from electronic medi-  
 2 cation administration reports and laboratory systems to  
 3 produce the reports described in subsection (d).

4 “(d) PUBLIC AVAILABILITY OF DATA.—The Sec-  
 5 retary, acting through the Director of the Centers for Dis-  
 6 ease Control and Prevention, shall, for the purposes of im-  
 7 proving the monitoring of important trends in patient out-  
 8 comes in relation to antibacterial resistance—

9 “(1) make the data derived from surveillance  
 10 under this section publicly available through reports  
 11 issued on a regular basis that is not less than annu-  
 12 ally; and

13 “(2) examine opportunities to make such data  
 14 available in near real time.

15 **“SEC. 319E-2. DETECTING NETWORK OF ANTIBIOTIC RE-**  
 16 **SISTANCE REGIONAL LABORATORIES.**

17 “(a) IN GENERAL.—The Secretary, acting through  
 18 the Director of the Centers for Disease Control and Pre-  
 19 vention, shall establish not less than 7 Antibiotic Resist-  
 20 ance Surveillance and Laboratory Network sites, building  
 21 upon the intramural and extramural programs and labora-  
 22 tories of the Centers for Disease Control and Prevention,  
 23 to intensify, strengthen, and expand the national capacity  
 24 to—

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

3           “(2) describe, confirm, and, as necessary, facili-  
4 tate a response to, local or regional outbreaks of re-  
5 sistant bacteria;

6           “(3) assess and describe antibiotic resistance  
7 patterns to inform public health and improve preven-  
8 tion practices;

9           “(4) obtain isolates of pathogens, and in par-  
10 ticular, bacteria that show new or atypical patterns  
11 of resistance adversely affecting public health;

12           “(5) assist in studying the epidemiology of in-  
13 fections from such pathogens;

14           “(6) evaluate commonly used antibiotic suscep-  
15 tibility testing methods to improve the accuracy of  
16 resistance testing and reporting;

17           “(7) as necessary, develop or evaluate novel di-  
18 agnostic tests capable of detecting new or emerging  
19 resistance in bacteria;

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

23           “(9) provide laboratory assistance and reference  
24 testing of antibiotic-resistant bacteria to enhance in-

1 fection control and facilitate outbreak detection and  
2 response in health care and community settings.

3 “(b) GEOGRAPHIC DISTRIBUTION.—The sites estab-  
4 lished under subsection (a) shall be geographically distrib-  
5 uted across the United States.

6 “(c) NONDUPLICATION OF CURRENT NATIONAL CA-  
7 PACITY.—The sites established under subsection (a) may  
8 be based in academic centers, health departments, and ex-  
9 isting surveillance and laboratory sites.

10 **“SEC. 319E-3. CLINICAL TRIALS NETWORK ON ANTI-  
11 BACTERIAL RESISTANCE.**

12 “(a) IN GENERAL.—The Secretary, acting through  
13 the Director of the National Institute of Allergy and Infec-  
14 tious Diseases, shall maintain a Clinical Trials Network  
15 on Antibacterial Resistance to enhance, strengthen, and  
16 expand research on clinical science, antibacterial and diag-  
17 nostic development, and optimal usage strategies with re-  
18 spect to addressing antibacterial resistance. Such Network  
19 shall, at a minimum—

20 “(1) facilitate research to better understand re-  
21 sistance mechanisms and how to prevent, control,  
22 and treat resistant organisms;

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

1           “(3) conduct clinical research to develop natural  
2 histories of resistant infectious diseases;

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

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

9           “(b) AUTHORIZATION OF APPROPRIATIONS.—There  
10 are authorized to be appropriated to carry out this section  
11 such sums as may be necessary for each of fiscal years  
12 2020 through 2026.

13 **“SEC. 319E-4. REGIONAL PREVENTION COLLABORATIVE EF-**  
14 **FORTS.**

15           “(a) IN GENERAL.—The Secretary, acting through  
16 the Director of the Centers for Disease Control and Pre-  
17 vention, shall work with State and local health depart-  
18 ments to support the expansion of collaborative efforts by  
19 groups of health care facilities that focus on preventing  
20 the spread of antibiotic-resistant bacteria that pose a seri-  
21 ous threat to public health, and that are designed to inter-  
22 rupt and prevent the transmission of significant antibiotic-  
23 resistant pathogens being transmitted across health care  
24 settings in a geographic region. Such collaborative efforts  
25 shall—

1           “(1) identify significant drug resistant patho-  
2           gens being transmitted across health care settings  
3           locally;

4           “(2) implement evidence-based interventions to  
5           interrupt the transmission of antibiotic-resistant  
6           strains of bacteria and prevent the infections caused  
7           by such bacteria, including evidence-based trans-  
8           mission prevention guidelines, rigorous hand-hygiene  
9           protocols, and infection control and prevention meas-  
10          ures;

11          “(3) assess compliance and identify barriers to  
12          adherence to such measures;

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

19          “(5) provide recommendations for improved  
20          outcomes and compliance with such measures.

21          “(b) PREVENTION EPICENTERS.—

22                 “(1) EXPANSION.—The Secretary, acting  
23                 through the Director of the Centers for Disease  
24                 Control and Prevention, may intensify and expand  
25                 academic public health partnerships through the

1 Prevention Epicenters Program to provide the re-  
2 gional prevention collaboration efforts described in  
3 subsection (a) with tools, strategies, and evidence-  
4 based interventions.

5 “(2) EVALUATIONS AND RESEARCH.—The Di-  
6 rector of the Centers for Disease Control and Pre-  
7 vention and the epicenters participating in the Pre-  
8 vention Epicenters Program shall work with entities,  
9 including the entities participating in the regional  
10 prevention collaborative efforts, to—

11 “(A) evaluate new and existing interven-  
12 tions to prevent or limit infection rates in  
13 health care facilities across the continuum of  
14 care and in community settings;

15 “(B) facilitate public health research on  
16 the prevention and control of resistant orga-  
17 nisms; and

18 “(C) assess the feasibility, cost-effective-  
19 ness, and appropriateness of surveillance and  
20 prevention programs in differing health care  
21 and institutional settings.

22 “(c) EDUCATIONAL MATERIALS.—The Secretary,  
23 acting through the Director of the Centers for Disease  
24 Control and Prevention, shall use the evaluations, re-  
25 search, and assessments described in subsection (b) to cre-

1 ate and disseminate educational materials focused on in-  
2 fection prevention and control for use in health care facili-  
3 ties across the continuum of care and in community set-  
4 tings.”.

5 **SEC. 4. PROTECTION OF CONFIDENTIAL AND NATIONAL SE-**  
6 **CURITY INFORMATION.**

7 This Act, and the amendments made by this Act,  
8 shall not be construed to permit the disclosure of any  
9 trade secret, confidential commercial information, or ma-  
10 terial inconsistent with national security, that is otherwise  
11 prohibited by law.

○