| (Original Signature of Member) |
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| 117TH CONGRESS H.R. |
| To amend the Public Health Service Act to enhance efforts to address antimicrobial resistance, and for other purposes. |
| IN THE HOUSE OF REPRESENTATIVES |
| Mr. Bera introduced the following bill; which was referred to the Committee on |
| A BILL |
| To amend the Public Health Service Act to enhance efforts to address antimicrobial 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. |

- 6 SEC. 2. COMBATING ANTIMICROBIAL RESISTANCE.
- 7 Section 319E of the Public Health Service Act (42

Antimicrobial Resistance Act" or the "STAAR Act".

This Act may be cited as the "Strategies To Address

- 8 U.S.C. 247d-5) is amended—
- 9 (1) in subsection (a)—

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| 1 | (A) in paragraph (1), in the first sentence, |
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| 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 pursue the goals of the National |
| 7 | Strategy for Combating Antibiotic-Resistant |
| 8 | Bacteria (referred to in this section as the 'Na- |
| 9 | tional Strategy')"; |
| 10 | (B) by amending paragraph (2) to read as |
| 11 | follows: |
| 12 | "(2) Members of task force.—The task |
| 13 | force described in paragraph (1) shall be co-chaired |
| 14 | by the Secretary of Health and Human Services, the |
| 15 | Secretary of Agriculture, and the Secretary of De- |
| 16 | fense, and shall be composed of representatives of |
| 17 | relevant Federal agencies and such executive depart- |
| 18 | ments, agencies, or offices as the co-chairs may des- |
| 19 | ignate."; |
| 20 | (C) by amending paragraph (4) to read as |
| 21 | follows: |
| 22 | "(4) Meetings.—At least twice a year, the |
| 23 | task force described in paragraph (1) shall have a |
| 24 | public meeting to assess progress and obstacles to |
| 25 | implementing the objectives of the National Strat- |

1 egy. The task force may discuss and review based on 2 need or concern the following (among other issues): "(A) Federal activities to slow the emer-3 gence of antimicrobial-resistant pathogens and prevent the spread of resistant infections. Such 6 activities may include optimal use of vaccines 7 and other infection control measures to prevent 8 infections, implementation of health care poli-9 cies and antimicrobial stewardship programs 10 that improve patient outcomes, regional efforts 11 to control transmission across community and 12 health care settings, and public awareness cam-13 paigns. "(B) Federal activities to strengthen na-14 15 tional One-Health surveillance efforts, which 16 are efforts addressing the interactions between 17 human, animal, and environmental health, to 18 combat antimicrobial resistance. One-Health 19 surveillance efforts to combat antimicrobial re-20 sistance may include enhanced data sharing 21 and coordination of surveillance and laboratory 22 systems across human and animal settings, and 23 enhanced monitoring of sales, usage, resistance, 24 and management practices of antimicrobial 25 drugs along the food-production chain. Such

| 1 | surveillance and laboratory systems may include |
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| 2 | the National Healthcare Safety Network, the |
| 3 | Emerging Infections Program, the National |
| 4 | Antimicrobial Resistance Monitoring System, |
| 5 | the National Animal Health Monitoring Sys- |
| 6 | tem, the National Animal Health Laboratory |
| 7 | Network, the Veterinary Laboratory Investiga- |
| 8 | tion and Response Network, and the anti- |
| 9 | microbial resistance Laboratory Network. |
| 10 | "(C) Federal efforts to advance the devel- |
| 11 | opment and use of rapid and innovative diag- |
| 12 | nostic tests for identification and characteriza- |
| 13 | tion of antimicrobial-resistant pathogens. Such |
| 14 | efforts may include development of new diag- |
| 15 | nostic tests and expansion of their availability |
| 16 | and use to improve treatment, infection control, |
| 17 | and outbreak response. |
| 18 | "(D) Federal efforts to accelerate basic |
| 19 | and applied research and development for new |
| 20 | antimicrobial drugs, other therapeutics, preven- |
| 21 | tion efforts, and vaccines. Such efforts may in- |
| 22 | clude support for basic and applied research, |
| 23 | provision of scientific services and guidance to |
| 24 | researchers, and fostering of public-private |
| 25 | partnerships. |

| 1 | "(E) Federal efforts to improve inter- |
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| 2 | national collaboration and capacities for anti- |
| 3 | microbial-resistance prevention, surveillance, |
| 4 | and control and antimicrobial research and de- |
| 5 | velopment. Such efforts may include collabora- |
| 6 | tions with foreign ministries of health and agri- |
| 7 | culture, the World Health Organization, the |
| 8 | Food and Agriculture Organization, the World |
| 9 | Organization for Animal Health, the United |
| 10 | Nations Environment Programme, and other |
| 11 | multinational organizations."; and |
| 12 | (D) by adding at the end the following: |
| 13 | "(5) AVAILABILITY OF INFORMATION.—The |
| 14 | task force described in paragraph (1), to the extent |
| 15 | permitted by law, shall— |
| 16 | "(A) provide the Presidential Advisory |
| 17 | Council on Combating Antibiotic-Resistant Bac- |
| 18 | teria described in section 505 of the Pandemic |
| 19 | and All-Hazards Preparedness and Advancing |
| 20 | Innovation Act of 2019 with such information |
| 21 | as may be required for carrying out the func- |
| 22 | tions of such Advisory Council, including infor- |
| 23 | mation on progress in advancing the National |
| 24 | Strategy, meeting minutes, and other key infor- |
| 25 | mation of the task force: and |

| 1 | "(B) ensure that all information described |
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| 2 | in subparagraph (A) is made available on the |
| 3 | websites of the Department of Health and |
| 4 | Human Services, the Department of Agri- |
| 5 | culture, and the Department of Defense."; |
| 6 | (2) in subsection (h)— |
| 7 | (A) in the heading, by striking "Informa- |
| 8 | TION RELATED TO"; |
| 9 | (B) by striking "The Secretary" and in- |
| 10 | serting the following: |
| 11 | "(1) Dissemination of information.—The |
| 12 | Secretary"; and |
| 13 | (C) by adding at the end the following: |
| 14 | "(2) Encouraging antimicrobial steward- |
| 15 | SHIP PROGRAMS.—The Secretary shall encourage |
| 16 | health care facilities to establish antimicrobial stew- |
| 17 | ardship programs that are consistent with docu- |
| 18 | ments issued by the Centers for Disease Control and |
| 19 | Prevention relating to the core elements of anti- |
| 20 | microbial stewardship programs. |
| 21 | "(3) Definition of antimicrobial steward- |
| 22 | SHIP.—For purposes of this section, the term 'anti- |
| 23 | microbial stewardship' means coordinated interven- |
| 24 | tions designed to improve and evaluate the appro- |
| 25 | priate use of antimicrobial agents, including pro- |

| 1 | moting the use of antimicrobial drugs only when |
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| 2 | clinically indicated, and, when antimicrobial drugs |
| 3 | are clinically indicated, promoting the selection of |
| 4 | the optimal antimicrobial drug regimen, including |
| 5 | through factors such as dosage, duration of therapy, |
| 6 | and route of administration."; |
| 7 | (3) in subsection (m), by striking |
| 8 | "\$40,000,000" and all that follows through the pe- |
| 9 | riod at the end and inserting "such sums as may be |
| 10 | necessary for each of fiscal years 2023 through |
| 11 | 2029."; and |
| 12 | (4) by adding at the end the following: |
| 13 | "(n) Annual Report on Implementing the Na- |
| 14 | TIONAL STRATEGY OBJECTIVES.—Not later than 1 year |
| 15 | after the date of the enactment of the Strategies To Ad- |
| 16 | dress Antimicrobial Resistance Act, and annually there- |
| 17 | after, the Secretary, in consultation with the Secretary of |
| 18 | Agriculture, the Secretary of Defense, and the task force |
| 19 | described in subsection (a), shall submit to the Committee |
| 20 | on Health, Education, Labor, and Pensions of the Senate |
| 21 | and the Committee on Energy and Commerce of the |
| 22 | House of Representatives, and make available on the |
| 23 | websites of the Department of Health and Human Serv- |
| 24 | ices, the Department of Agriculture, and the Department |

| 1 | of Defense, a report on the progress made in implementing |
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| 2 | the objectives of the National Strategy.". |
| 3 | SEC. 3. ADDITIONAL STRATEGIES FOR COMBATING ANTI- |
| 4 | MICROBIAL RESISTANCE. |
| 5 | Part B of title III of the Public Health Service Act |
| 6 | (42 U.S.C. 243 et seq.) is amended by inserting after sec- |
| 7 | tion 319E the following: |
| 8 | "SEC. 319E-1. SURVEILLANCE AND REPORTING OF ANTI- |
| 9 | MICROBIAL USE AND RESISTANCE. |
| 10 | "(a) In General.—The Secretary shall use the Na- |
| 11 | tional Healthcare Safety Network and other appropriate |
| 12 | surveillance systems to assess— |
| 13 | "(1) appropriate conditions, outcomes, and |
| 14 | measures causally related to antimicrobial resist- |
| 15 | ance, including types of infections, the causes for in- |
| 16 | fections, and whether infections are acquired in a |
| 17 | community or hospital setting, increased lengths of |
| 18 | hospital stay, increased costs, and rates of mortality; |
| 19 | and |
| 20 | "(2) changes in microbial resistance to drugs in |
| 21 | relation to patient outcomes, including changes in |
| 22 | percent resistance, prevalence of antimicrobial-resist- |
| 23 | ant infections, and other such changes. |
| 24 | "(b) Antimicrobial Use Data.—The Secretary |
| 25 | shall work with Federal agencies (including the Depart- |

- 1 ment of Veterans Affairs, the Department of Defense, and
- 2 the Centers for Medicare & Medicaid Services), private
- 3 vendors, health care organizations, pharmacy benefit man-
- 4 agers, and other entities as appropriate to obtain reliable
- 5 and comparable human antimicrobial drug consumption
- 6 data (including, as available and appropriate, volume anti-
- 7 microbial distribution data and antimicrobial use data, in-
- 8 cluding prescription data) by State or metropolitan areas.
- 9 "(c) Antimicrobial Resistance Trend Data.—
- 10 The Secretary shall intensify and expand efforts to collect
- 11 antimicrobial resistance data and encourage adoption of
- 12 the antimicrobial resistance and use module within the
- 13 National Healthcare Safety Network among all health
- 14 care facilities across the continuum of care, including, as
- 15 appropriate, acute care hospitals, dialysis facilities, nurs-
- 16 ing homes, ambulatory surgical centers, and other ambula-
- 17 tory health care settings in which antimicrobial medica-
- 18 tions are routinely prescribed. The Secretary shall seek to
- 19 collect such data from electronic medication administra-
- 20 tion reports and laboratory systems to produce the reports
- 21 described in subsection (d).
- 22 "(d) Public Availability of Data.—The Sec-
- 23 retary shall, for the purposes of improving the monitoring
- 24 of important trends in patient outcomes in relation to
- 25 antimicrobial resistance—

| 1 | "(1) make the data derived from surveillance |
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| 2 | under this section publicly available through reports |
| 3 | issued on a regular basis that is not less than annu- |
| 4 | ally; and |
| 5 | "(2) examine opportunities to make such data |
| 6 | available in near real time. |
| 7 | "SEC. 319E-2. DETECTING NETWORK OF ANTIMICROBIAL |
| 8 | RESISTANCE REGIONAL LABORATORIES. |
| 9 | "(a) In General.—The Secretary shall establish not |
| 10 | less than 7 Antimicrobial Resistance Surveillance and |
| 11 | Laboratory Network sites, building upon the intramural |
| 12 | and extramural programs and laboratories of the Centers |
| 13 | for Disease Control and Prevention, to intensify, strength- |
| 14 | en, and expand the national capacity to— |
| 15 | "(1) monitor the emergence and changes in the |
| 16 | patterns of antimicrobial-resistant pathogens; |
| 17 | "(2) describe, confirm, and, as necessary, facili- |
| 18 | tate a response to, local or regional outbreaks of re- |
| 19 | sistant pathogens; |
| 20 | "(3) assess and describe antimicrobial resist- |
| 21 | ance patterns to inform public health and improve |
| 22 | prevention practices; |
| 23 | "(4) obtain isolates of pathogens, and in par- |
| 24 | ticular, pathogens that show new or atypical pat- |
| 25 | terns of resistance adversely affecting public health; |

| 1 | "(5) assist in studying the epidemiology of in- |
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| 2 | fections from such pathogens; |
| 3 | "(6) evaluate commonly used antimicrobial sus- |
| 4 | ceptibility testing methods to improve the accuracy |
| 5 | of resistance testing and reporting; |
| 6 | "(7) as necessary, develop or evaluate novel di- |
| 7 | agnostic tests capable of detecting new or emerging |
| 8 | resistance in pathogens; |
| 9 | "(8) link data generated by regional laboratory |
| 10 | networks under existing public health surveillance |
| 11 | networks and relevant government agencies; and |
| 12 | "(9) provide laboratory assistance and reference |
| 13 | testing of antimicrobial-resistant pathogens to en- |
| 14 | hance infection control and facilitate outbreak detec- |
| 15 | tion and response in health care and community set- |
| 16 | tings. |
| 17 | "(b) Geographic Distribution.—The sites estab- |
| 18 | lished under subsection (a) shall be geographically distrib- |
| 19 | uted across the United States. |
| 20 | "(c) Nonduplication of Current National Ca- |
| 21 | PACITY.—The sites established under subsection (a) may |
| 22 | be based in academic centers, health departments, and ex- |
| 23 | isting surveillance and laboratory sites. |

| 1 | "SEC. 319E-3. CLINICAL TRIALS NETWORK ON ANTI- |
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| 2 | MICROBIAL RESISTANCE. |
| 3 | "(a) In General.—The Secretary shall maintain a |
| 4 | Clinical Trials Network on Antimicrobial Resistance to en- |
| 5 | hance, strengthen, and expand research on clinical science, |
| 6 | antimicrobial and diagnostic development, and optimal |
| 7 | usage strategies with respect to addressing antimicrobial |
| 8 | resistance. Such Network shall, at a minimum— |
| 9 | "(1) facilitate research to better understand re- |
| 10 | sistance mechanisms and how to prevent, control, |
| 11 | and treat resistant organisms; |
| 12 | "(2) advance clinical trial efforts to develop |
| 13 | antimicrobial diagnostics, and evaluate and optimize |
| 14 | the usage of such antimicrobial diagnostics; |
| 15 | "(3) conduct clinical research to develop natural |
| 16 | histories of resistant infectious diseases; |
| 17 | "(4) examine patient outcomes with currently |
| 18 | available antimicrobial therapy and validate and im- |
| 19 | prove upon biomarkers and other surrogate end- |
| 20 | points; and |
| 21 | "(5) study shorter treatment duration and early |
| 22 | cessation of antimicrobial therapy for treatment effi- |
| 23 | cacy and the effect on development of resistance. |
| 24 | "(b) Authorization of Appropriations.—There |
| 25 | are authorized to be appropriated to carry out this section |

| 1 | such sums as may be necessary for each of fiscal years |
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| 2 | 2023 through 2029. |
| 3 | "SEC. 319E-4. REGIONAL PREVENTION COLLABORATIVE EF- |
| 4 | FORTS. |
| 5 | "(a) In General.—The Secretary shall work with |
| 6 | State and local health departments to support the expan- |
| 7 | sion of collaborative efforts by groups of health care facili- |
| 8 | ties that focus on preventing the spread of antimicrobial- |
| 9 | resistant pathogens that pose a serious threat to public |
| 10 | health, and that are designed to interrupt and prevent the |
| 11 | transmission of significant antimicrobial-resistant patho- |
| 12 | gens being transmitted across health care settings in a ge- |
| 13 | ographic region. Such collaborative efforts shall— |
| 14 | "(1) identify significant drug resistant patho- |
| 15 | gens being transmitted across health care settings |
| 16 | locally; |
| 17 | "(2) implement evidence-based interventions to |
| 18 | interrupt the transmission of antimicrobial-resistant |
| 19 | strains of pathogens and prevent the infections |
| 20 | caused by such pathogens, including evidence-based |
| 21 | transmission prevention guidelines, rigorous hand- |
| 22 | hygiene protocols, and infection control and preven- |
| 23 | tion measures; |
| 24 | "(3) assess compliance and identify barriers to |
| 25 | adherence to such measures; |

| 1 | "(4) evaluate the impact of such measures, to |
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| 2 | the extent possible, on hospital readmissions in |
| 3 | health care facilities across the continuum of care, |
| 4 | rates of health care associated infections, or any |
| 5 | other relevant measures that characterize the health |
| 6 | or economic impact of the collaborative efforts; and |
| 7 | "(5) provide recommendations for improved |
| 8 | outcomes and compliance with such measures. |
| 9 | "(b) Prevention Epicenters.— |
| 10 | "(1) Expansion.—The Secretary may intensify |
| 11 | and expand academic public health partnerships |
| 12 | through the Prevention Epicenters Program to pro- |
| 13 | vide the regional prevention collaboration efforts de- |
| 14 | scribed in subsection (a) with tools, strategies, and |
| 15 | evidence-based interventions. |
| 16 | "(2) Evaluations and research.—The Di- |
| 17 | rector of the Centers for Disease Control and Pre- |
| 18 | vention and the epicenters participating in the Pre- |
| 19 | vention Epicenters Program shall work with entities, |
| 20 | including the entities participating in the regional |
| 21 | prevention collaborative efforts, to— |
| 22 | "(A) evaluate new and existing interven- |
| 23 | tions to prevent or limit infection rates in |
| 24 | health care facilities across the continuum of |
| 25 | care and in community settings; |

| 1 | "(B) facilitate public health research on |
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| 2 | the prevention and control of resistant orga- |
| 3 | nisms; and |
| 4 | "(C) assess the feasibility, cost-effective- |
| 5 | ness, and appropriateness of surveillance and |
| 6 | prevention programs in differing health care |
| 7 | and institutional settings. |
| 8 | "(c) Educational Materials.—The Secretary |
| 9 | shall use the evaluations, research, and assessments de- |
| 10 | scribed in subsection (b), along with other scientific evi- |
| 11 | dence, to create and disseminate educational materials fo- |
| 12 | cused on infection prevention and control for use in health |
| 13 | care facilities across the continuum of care and in commu- |
| 14 | nity settings.". |
| 15 | SEC. 4. PROTECTION OF CONFIDENTIAL AND NATIONAL SE- |
| 16 | CURITY INFORMATION. |
| 17 | This Act, and the amendments made by this Act, |
| 18 | shall not be construed to permit the disclosure of any |
| 19 | trade secret, confidential commercial information, or ma- |
| 20 | terial inconsistent with national security, that is otherwise |
| 21 | prohibited by law. |