.....

(Original Signature of Member)

117TH CONGRESS
1ST SESSION

H. R. _____

To establish a program to develop antimicrobial innovations targeting the most challenging pathogens and most threatening infections.

IN THE HOUSE OF REPRESENTATIVES

Mr. MICHAEL F. DOYLE of Pennsylvania introduced the following bill; which was referred to the Committee on _____

A BILL

To establish a program to develop antimicrobial innovations targeting the most challenging pathogens and most threatening infections.

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 ''Pioneering Antimicrobial Subscriptions To End Up surging Resistance Act of 2021'' or the ''PASTEUR Act''.

SEC. 2. DEVELOPING ANTIMICROBIAL INNOVATIONS.

Title III of the Public Health Service Act (42 U.S.C. 241 et seq.) is amended by adding at the end the following:

"PART W—DEVELOPING ANTIMICROBIAL INNOVATIONS

"SEC. 399OO. ESTABLISHMENT OF COMMITTEE; SUBSCRIPTION MODEL; ADVISORY GROUP.

''(a) IN GENERAL.—Not later than 60 days after the date of enactment of this part, the Secretary shall establish a Committee on Critical Need Antimicrobials and appoint members to the Committee.

''(b) MEMBERS.—

''(1) IN GENERAL.—The Committee shall consist of at least one representative from each of the National Institute of Allergy and Infectious Diseases, the Centers for Disease Control and Prevention, the Biomedical Advanced Research and Development Authority, the Food and Drug Administration, the Centers for Medicare & Medicaid Services, the Veterans Health Administration, and the Department of Defense.

''(2) CHAIR.—The Secretary shall appoint one of the members of the Committee to serve as the Chair of the Committee.

''(c) DUTIES.—Not later than 1 year after the appointment of all initial members of the Committee, the Secretary, in collaboration with the Committee, and in consultation with the Critical Need Antimicrobials Advisory Group established under subsection (g), shall do the following:

''(1) Develop a list of infections for which new antimicrobial drug development is needed, taking into account organisms, sites of infection, and type of infections for which there is an unmet medical need, findings from the most recent report entitled 'Antibiotic Resistance Threats in the United States' issued by the Centers for Disease Control and Prevention, or an anticipated unmet medical need, including a potential global health security threat. For the list developed under this paragraph, the Secretary, in collaboration with the Committee, may use the infection list in such most recent report for up to 3 years following the date of enactment of this part and subsequently update the list under this paragraph in accordance with subsection (e).

''(2) Develop regulations, in accordance with subsection (d), outlining favored characteristics of critical need antimicrobial drugs, that are evidence based, clinically focused, and designed to treat the

infections described in paragraph (1), and establishing criteria for how each such characteristic will adjust the monetary value of a subscription contract awarded under subsection (f) or section 399QQ. The favored characteristics shall be weighed for purposes of such monetary value such that meeting certain characteristics, or meeting more than one such characteristic, increases the monetary value. Such favored characteristics of an antimicrobial drug shall include—

''(A) treating infections on the list under paragraph (1);

''(B) improving clinical outcomes for patients with multi-drug-resistant infections;

''(C) being a first-approved antimicrobial drug that has the potential to address unmet medical needs for the treatment of a serious or life-threatening infection, and, to a lesser extent, second and third drugs that treat such infections;

''(D) route of administration, especially through oral administration;

''(E)(i) containing no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any suc-

cessor regulations)) that has been approved in any other application under section 505(b) of the Federal Food, Drug, and Cosmetic Act or intending to be the subject of a new original biologics license application under section 351(a);

''(ii) being a member of a new class of drugs with a novel target and novel mode of action that are distinctly different from the target or mode of any antimicrobial drug approved under section 505 of such Act or licensed under section 351, including reduced toxicity;

''(iii) not being affected by cross-resistance to any antimicrobial drug approved under such section 505 or licensed under such section 351;

''(F) addressing a multi-drug resistant infection through a novel chemical scaffold or mechanism of action;

''(G) having received a transitional subscription contract under subsection (f); and

''(H) any other characteristic the Secretary, in collaboration with the Committee, determines necessary.

''(d) REGULATIONS.—

''(1) IN GENERAL.—Not later than 1 year after the appointment of the initial members of the Committee, the Secretary shall issue proposed regulations which shall include—

''(A) a process by which the sponsors can apply for an antimicrobial drug to become a critical need antimicrobial drug under section 399PP;

''(B) how subscription contracts under such section shall be established and paid;

''(C) the favored characteristics under subsection (c)(2), how such characteristics will be weighed, and the minimum number and kind of favored characteristics needed for an antimicrobial drug to be designated a critical need antimicrobial drug; and

''(D) other elements of the subscription contract process, in accordance with this part.

''(2) DEVELOPMENT OF FINAL REGULATIONS.—Before finalizing the regulations under paragraph (1), the Secretary shall solicit public comment and hold public meetings for the period beginning on the date on which the proposed regulations are issued and ending on the date that is 120 days after such date of issuance. The Secretary shall fi-

nalize and publish such regulations not later than 120 days after the close of such period of public comment and meetings.

''(3) SUBSCRIPTION CONTRACT OFFICE.—Not later than 6 months after the date of enactment of this part, the Secretary shall propose an agency or office in the Department of Health and Human Services to manage the establishment and payment of subscription contracts awarded under section 399QQ, including eligibility, requirements, and contract amounts. The Secretary shall solicit public comment and finalize the agency or office no later than 45 days following the proposed agency or office. Such agency or office shall be referred to as the 'Subscription Contract Office'.

''(e) LIST OF INFECTIONS.—The Secretary, in collaboration with the Committee, shall update the list of infections under subsection (c)(1) at least every 2 years.

''(f) TRANSITIONAL SUBSCRIPTION CONTRACTS.—

''(1) IN GENERAL.—Not earlier than 30 days after the date of enactment of this part and ending on the date that the Secretary finalizes the subscription contract regulations under subsection (d), the Secretary may use up to $1,000,000,000 of the amount appropriated under section 399SS(a) to en-

gage in transitional subscription contracts of up to 3 years in length with antimicrobial developers, as determined by the Secretary, that have developed antimicrobial drugs treating infections listed in the most recent report entitled 'Antibiotic Resistance Threats in the United States' issued by the Centers for Disease Control and Prevention, and may include antimicrobial drugs that are qualified infectious disease products (as defined in section 505E(g) of the Federal Food, Drug, and Cosmetic Act), innovative biological products, or innovative drugs that achieve a clinical outcome through immunomodulation. Such a contract may authorize the contractor to use funds made available under the contract for completion of postmarketing clinical studies, manufacturing, and other preclinical and clinical efforts.

''(2) REQUIREMENTS.—

''(A) IN GENERAL.—The Secretary, through the office described in paragraph (4), may enter into a contract under paragraph (1)—

''(i) if the Secretary determines that the antimicrobial drug is intended to treat an infection for which there is an unmet

clinical need, an anticipated clinical need, or drug resistance;

''(ii) subject to terms including—

''(I) that the Secretary shall cease any payment installments under a transitional subscription contract if the sponsor does not—

''(aa) ensure commercial and Federal availability of the antimicrobial drug within 30 days of receiving first payment under the contract;

''(bb) identify, track, and publicly report drug resistance data and trends using available data related to the antimicrobial drug;

''(cc) develop and implement education and communications strategies, including communications for individuals with limited English proficiency and individuals with disabilities, for health care professionals and patients

about appropriate use of the antimicrobial drug;

''(dd) submit a plan for registering the antimicrobial drug in additional countries where an unmet medical need exists, which such plan may be consistent with the Stewardship and Access Plan (SAP) Development Guide (2021);

''(ee) subject to subparagraph (B), ensure a reliable drug supply chain, thus leading to an interruption of the supply of the antimicrobial drug in the United States for more than 60 days; or

''(ff) make meaningful progress toward completion of Food and Drug Administration-required postmarketing studies, including such studies that are evidence based; and

''(II) other terms as determined by the Secretary; and

''(iii) if—

''(I) a phase 3 clinical study has been initiated for the antimicrobial drug; or

''(II) the antimicrobial drug has been approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act or licensed under section 351(a).

''(B) WAIVER.—The requirement under subparagraph (A)(ii)(I)(ee) may be waived in the case that an emergency prohibits access to a reliable drug supply chain.

''(3) TRANSITIONAL GUIDANCE.—Not later than 120 days after the appointment of the initial members of the Committee, the Secretary shall issue, in consultation with the Committee, transitional guidance outlining the antimicrobial drugs that are eligible for transitional subscription contracts under paragraph (1), the requirements to enter into a transitional subscription contract under paragraph (2), and the process by which drug developers can enter into transitional subscription contracts with the Secretary under this subsection.

''(4) PAYMENT OFFICE AND MECHANISM.—Not later than 30 days after the date of enactment of

this part, the Secretary shall determine the agency or office in the Department of Health and Human Services that will manage the transitional subscription contracts, including eligibility, requirements, and contract amounts, during the period described in paragraph (1).

''(g) CRITICAL NEED ANTIMICROBIAL ADVISORY GROUP.—

''(1) IN GENERAL.—Not later than 30 days after the appointment of all initial members of the Committee, the Secretary, in collaboration with the Committee, shall establish a Critical Need Antimicrobial Advisory Group (referred to in this subsection as the 'Advisory Group') and appoint members to the Advisory Group.

''(2) MEMBERS.—The members of the Advisory Group shall include—

''(A) not fewer than 6 individuals who are—

''(i) infectious disease specialists; or

''(ii) other health experts with expertise in researching antimicrobial resistance, health economics, or commercializing antimicrobial drugs; and

''(B) not fewer than 5 patient advocates.

''(3) CHAIR.—The Secretary shall appoint one of the members of the Advisory Group to serve as the Chair.

''(4) CONFLICTS OF INTEREST.—In appointing members under paragraph (2), the Secretary shall ensure that no member receives compensation in any manner from a commercial or for-profit entity that develops antimicrobials or that might benefit from antimicrobial development.

''(5) APPLICABILITY OF FACA.—Except as otherwise provided in this subsection, the Federal Advisory Committee Act shall apply to the Advisory Group.

''SEC. 399PP. CRITICAL NEED ANTIMICROBIAL DRUG APPLICATION AND PAYMENT THROUGH SUBSCRIPTION CONTRACTS.

''(a) IN GENERAL.—

''(1) SUBMISSION OF REQUEST.—The sponsor of an application under section 505(b) of the Federal Food, Drug, and Cosmetic Act or section 351(a) for an antimicrobial drug may request that the Secretary designate the drug as a critical need antimicrobial. A request for such designation may be submitted after the Secretary grants for such drug an investigational new drug exemption under section

505(i) of the Federal Food, Drug, and Cosmetic Act or section 351(a)(3), and shall be submitted not later than 5 years after the date of approval under section 505(c) of the Federal Food, Drug, and Cosmetic Act or licensure under section 351(a).

''(2) CONTENT OF REQUEST.—A request under paragraph (1) shall include information, such as clinical, preclinical and postmarketing data, a list of the favorable characteristics described in section 399OO(c)(2), and any other material that the Secretary in consultation with the Committee requires.

''(3) REVIEW BY SECRETARY.—The Secretary shall promptly review all requests for designation submitted under this subsection, assess all required application components, and determine if the antimicrobial drug is likely to meet the favorable characteristics identified in the application upon the completion of clinical development. After review, the Secretary shall approve or deny each request for designation not later than 90 days after receiving a request. If the Secretary approves a request, it shall publish the value of the contract that the critical need antimicrobial developer would be eligible to receive if such developer successfully demonstrates

that the drug meets the maximum value of the favored characteristics listed in the application.

''(4) LENGTH OF DESIGNATION PERIOD.—A designation granted under this section shall be in effect for a period of 10 years after the date that the designation is approved, and shall remain in effect for such period even if the infection treated by such drug is later removed from the list of infections under section 399OO(c)(1).

''(5) SUBSEQUENT REVIEWS.—No sooner than 2 years after a designation approval or denial under subsection (3), the sponsor may request a subsequent review to re-evaluate the value of a contract to include any new information.

''(b) DEVELOPMENT OF DESIGNATED DRUGS.—If a critical need antimicrobial designation is granted during clinical development of an antimicrobial drug, the Secretary may work with the sponsor to maximize the opportunity for the sponsor to successfully demonstrate that the antimicrobial drug possesses the favored characteristics of high-monetary valued products identified under section 399OO(c)(2).

''(c) APPROPRIATE USE OF CRITICAL NEED ANTIMICROBIAL.—

''(1) IN GENERAL.—The sponsor of an antimicrobial drug that receives designation under subsection (a) shall within 90 days of such designation, submit to the Secretary a plan for appropriate use of diagnostics, in order for the Secretary and Committee to consider such plan in developing clinical guidelines. An appropriate use plan—

''(A) shall include—

''(i) the appropriate use of the drug; and

''(ii) the appropriate use of diagnostic tools, where available, such as diagnostic testing for biomarkers related to antimicrobial-resistant pathogens, or other targeted diagnostic approaches, to inform use of the drug; and

''(B) may be developed in partnership with the Secretary, infectious disease experts, diagnostic experts or developers, laboratory experts, or another entity.

''(2) CONSULTATION.—The Secretary shall consult with relevant professional societies and the Critical Need Antimicrobial Advisory Group established under section 399OO(g) to ensure that clinical guidelines issued by the Secretary under paragraph

(3), with respect to an antimicrobial drug designated under subsection (a), includes the use of appropriate diagnostic approaches, taking into consideration the diagnostic plan submitted by a sponsor under paragraph (1).

''(3) PUBLICATION OF CLINICAL GUIDELINES.—Not later than 1 year after the Secretary makes the first designation under subsection (a), and not less than every 3 years thereafter, the Secretary shall publish clinical guidelines in consultation with relevant professional societies with respect to each antimicrobial drug that has been approved or licensed as described in subsection (a)(1) and that has been designated under subsection (a), which guidelines shall set forth the evidence-based recommendations for prescribing the drug, in accordance with the submissions of the sponsor under paragraph (1) and after consultation under paragraph (2), as appropriate.

''SEC. 399QQ. SUBSCRIPTION CONTRACTS.

''(a) APPLICATION FOR A SUBSCRIPTION CONTRACT.—

''(1) SUBMISSION OF APPLICATIONS.—After approval under section 505(c) of the Federal Food, Drug, and Cosmetic Act or licensure under section 351(a), the sponsor of an antimicrobial drug des-

ignated as a critical need antimicrobial under section 399PP may submit an application for a subscription contract with the Secretary, under a procedure established by the Secretary.

''(2) REVIEW OF APPLICATIONS.—The Secretary shall, in consultation with the Committee—

''(A) review all applications for subscription contracts under paragraph (1) and assess all required application components;

''(B) determine the extent to which the critical need antimicrobial meets the favored characteristics identified under section 399OO(c)(2), and deny any application for a drug that meets none of such characteristics; and

''(C) assign a monetary value to the contract based on the regulations developed under section 399OO(d).

''(b) CRITERIA.—To qualify for a subscription contract under this section, the sponsor of an antimicrobial drug designated as a critical need antimicrobial shall agree to—

''(1) ensure commercial and Federal availability of the antimicrobial drug within 30 days of receiving

first payment under the contract, and sufficient supply for susceptibility device manufacturers;

''(2) identify, track, and publicly report drug resistance data and trends using available data related to the antimicrobial drug;

''(3) develop and implement education and communications strategies, including communications for individuals with limited English proficiency and individuals with disabilities, for health care professionals and patients about appropriate use of the antimicrobial drug;

''(4) submit an appropriate use assessment to the Secretary, Committee, Food and Drug Administration, and Centers for Disease Control and Prevention every 2 years regarding use of the antimicrobial drug, including how the drug is being marketed;

''(5) submit a plan for registering the drug in additional countries where an unmet medical need exists;

''(6) ensure a reliable drug supply chain, where any interruption to the supply chain will not last for more than 60 days in the United States;

''(7) complete any postmarketing studies required by the Food and Drug Administration in a timely manner;

''(8) produce the drug at a reasonable volume determined with the Secretary to ensure patient access to the drug;

''(9) price the drug at a price that is not lower than a comparable generic drug;

''(10) abide by the manufacturing and environmental best practices in the supply chain to ensure that there is no discharge into, or contamination of, the environment by antimicrobial agents or products as a result of the manufacturing process; and

''(11) abide by other terms as the Secretary may require.

''(c) AMOUNT AND TERMS OF CONTRACTS.—

''(1) AMOUNTS.—A subscription contract under this section shall be for the sale to the Secretary of any quantity of the antimicrobial drug needed over the term of the contract under paragraph (2), at an agreed upon price, for a total projected amount determined by the Secretary that is not less than $750,000,000 and not more than $3,000,000,000, adjusted for inflation, accounting for the favored characteristics of the drug, as determined by the

Secretary, in consultation with the Committee, under subsection (a)(2), and shall be allocated from the amount made available under section 399SS(a). Not later than 6 months after the subscription contract is granted under subsection (a), the Secretary shall provide payments for purchased drugs in installments established by the Secretary in consultation with the sponsor of the antimicrobial drug and in accordance with subsection (d)(3). Funds received by the sponsor shall be used to support criteria qualification under subsection (b), the completion of postmarketing clinical studies, manufacturing, other preclinical and clinical activities, or other activities agreed to by the Secretary and sponsor in the contract.

''(2) TERMS.—

''(A) INITIAL TERM.—The initial term of a contract under this subsection shall be no less than 5 years or greater than the greater of 10 years or the remaining period of time during which the sponsor has patent protections or a remaining exclusivity period with respect to the antimicrobial drug in the United States, as listed in the publication of the Food and Drug Administration entitled 'Approved Drug Products

with Therapeutic Equivalence Evaluations'. Payments may be in equal annual installments with the option to redeem 50 percent of the last year's reimbursement in year 1 of the contract in order to offset costs of establishing manufacturing capacity, or another subscription arrangement to which the Secretary and sponsor agree. Subscription contracts shall remain in effect for such period even if the infection treated by such antimicrobial drug is later removed from the list of infections under section 399OO(c)(1).

''(B) EXTENSION OF CONTRACTS.—The Secretary may extend a subscription contract with a sponsor under this subsection beyond the initial contract period. A single contract extension may be in effect not later than the date on which all periods of exclusivity granted by the Food and Drug Administration expire and shall be in an amount not to exceed $25,000,000 per year. All other terms of an extended contract shall be the same as the terms of the initial contract. The total amount of funding used on such contract extensions shall be no more than

$1,000,000,000, and shall be allocated from the amount made available under section 399SS.

''(C) MODIFICATION OF CONTRACTS.—The Secretary or sponsor, 1 year after the start of the contract period under this subsection and every 2 years thereafter, may request a modification of the amount of the contract based on information that adjusts favored characteristics in section 399OO(c)(2).

''(3) ADJUSTMENT.—In the case of an antimicrobial drug that received a transitional subscription contract under section 399OO(f), the amount of a subscription contract for such drug under this section shall be reduced by the amount of the transitional subscription contract under such section 399OO(f) for such drug.

''(4) CONTRACTS FOR GENERIC AND BIOSIMILAR VERSIONS.—Notwithstanding any other provision in this part, the Secretary may award a subscription contract under this section to a manufacturer of a generic or biosimilar version of an antimicrobial drug for which a subscription contract has been awarded under this section. Such contracts shall be awarded in accordance with a procedure, in-

cluding for determining the terms and amounts of such contracts, established by the Secretary.

''(d) ANNUAL ANTIMICROBIAL DRUG SPONSOR REVENUE LIMITATIONS.—

''(1) REPORTING REQUIREMENT.—

''(A) IN GENERAL.—Not later than a date determined appropriate by the Secretary following the end of each calendar year, and not earlier than 6 months after the end of each calendar year, the head (or a designee of such head) of each Federal agency carrying out a specified government program shall, in accordance with this paragraph, report to the Subscription Contract Office established under section 399OO(d)(3) the total prescription drug sales for each applicable antimicrobial drug under contract with respect to such program for such calendar year.

''(B) MEDICARE PART D PROGRAM.—For purposes of subparagraph (A), the Secretary shall report, for each applicable antimicrobial drug covered under part D of title XVIII of the Social Security Act, the product of—

''(i) the per-unit ingredient cost, as reported to the Secretary by prescription

drug plans and Medicare Advantage prescription drug plans, minus any per-unit rebate, discount, or other price concession provided by the sponsor of such applicable antimicrobial drug, as reported to the Secretary by the prescription drug plans and the Medicare Advantage prescription drug plans; and

''(ii) the number of units of such applicable antimicrobial drug paid for under such part D.

''(C) MEDICARE PART B PROGRAM.—

''(i) IN GENERAL.—For purposes of subparagraph (A), the Secretary shall report, for each applicable antimicrobial drug covered under part B of title XVIII of the Social Security Act, the product of—

''(I) the per-unit average sales price (as defined in section 1847A(c) of such Act) or the per-unit payment rate under such part B for a separately paid prescription drug without a reported average sales price; and

''(II) the number of units of such applicable antimicrobial drug paid for under such part B.

''(ii) UNITS AND ALLOCATED PRICES.—The Secretary shall establish a process for determining the units and the allocated price for purposes of this subparagraph for those applicable antimicrobial drugs that are not separately payable or for which National Drug Codes are not reported.

''(D) MEDICARE PART A PROGRAM.—

''(i) IN GENERAL.—For purposes of subparagraph (A), the Secretary shall report, for each applicable antimicrobial drug covered under part A of title XVIII of the Social Security Act, the product of—

''(I) the per-unit price under such part A for the antimicrobial drug; and

''(II) the number of units of such antimicrobial drug paid for under such part A.

''(ii) SPECIAL RULE.—For purposes of clause (i), the Secretary shall establish a

process for determining the units and the allocated price for those prescription drugs that are not separately payable or for which National Drug Codes are not reported in the diagnosis-related groups.

''(E) MEDICAID PROGRAM.—Under the authority of section 1902(a)(6) of the Social Security Act, the Secretary shall require each State that makes medical assistance available under the State plan under title XIX of such Act (or any waiver of such plan) for an applicable antimicrobial drug (including, if applicable, any such drug which is a covered outpatient drug under a rebate agreement entered into under section 1927 of such Act) to report, in a form consistent with a standard reporting format established by the Secretary, not later than the date determined under subparagraph (A)—

''(i) information on the total number of units of each dosage form and strength and package size of each applicable antimicrobial drug dispensed during the preceding calendar year under such State plan or waiver (including any such drugs dispensed to an individual enrolled with a

medicaid managed care organization or other specified entity (as such terms are defined in section 1903(m) of such Act)); and

''(ii) with respect to each dosage form and strength and package size of each such drug, the amount equal to—

''(I) the product of—

''(aa) the total number of units dispensed under the State plan or waiver during the preceding calendar year (as determined under clause (i)); and

''(bb) the per-unit ingredient cost paid by the State for each such unit; minus

''(II) any discounts or other price concessions provided and rebates paid to the State with respect to the dosage form and strength and package size of such drug and such calendar year (including rebates paid under a rebate agreement under section 1927 of such Act and any State supple-

mental rebates paid under a supplemental rebate agreement).

''(F) DEPARTMENT OF VETERANS AFFAIRS.—For purposes of subparagraph (A), the Secretary of Veterans Affairs shall report the total amount paid for each applicable antimicrobial drug procured by the Veterans Health Administration for individuals who receive health care from the Administration.

''(G) DEPARTMENT OF DEFENSE AND TRICARE PROGRAM.—For purposes of subparagraph (A), the Secretary of Defense shall report the sum of—

''(i) the total amount paid for each applicable antimicrobial drug procured by the Department of Defense for individuals who receive health care from the Department; and

''(ii) for each applicable antimicrobial drug dispensed under the TRICARE retail pharmacy program under section 1074g(a)(2)(E)(ii) of title 10, United States Code, the product of—

''(I) the per-unit ingredient cost, minus any per-unit rebate paid by the

sponsor of the applicable antimicrobial drug; and

''(II) the number of units of such applicable antimicrobial drug dispensed under such program.

''(H) DEPARTMENT OF HOMELAND SECURITY.—For purposes of subparagraph (A), the Secretary of Homeland Security shall report the total amount paid for each applicable antimicrobial drug procured by the Department of Homeland Security for individuals who receive health care through a program carried out by the Department.

''(I) BUREAU OF PRISONS.—For purposes of subparagraph (A), the Director of the Bureau of Prisons shall report the total amount paid for each applicable antimicrobial drug procured by the Bureau of Prisons for individuals who receive health care through the Bureau.

''(J) INDIAN HEALTH SERVICE.—For purposes of subparagraph (A), the Secretary, acting through the Indian Health Service, shall report the total amount paid for each applicable antimicrobial drug procured by the Service for

individuals who receive health care through the Service.

''(2) REGULATIONS.—Not later than 1 year after the date of enactment of this part, the Secretary, in consultation with the heads of Federal agencies carrying out specified government programs, shall issue regulations to assist such heads (or their designees) in carrying out the requirements under this section.

''(3) SUBSCRIPTION CONTRACT ADJUSTMENT.—Pursuant to the contract entered into under this section with respect to an applicable antimicrobial drug, for each year of the term of such contract, the Secretary shall, not earlier than 6 months after the end of each calendar year, subtract from the payment installments determined for such contract under subsection (c)(1) for such year the revenue of the sponsor of such drug from the previous year from sales of the applicable antimicrobial drug reported under paragraph (1) for specified government programs.

''(4) DEFINITIONS.—In this subsection:

''(A) APPLICABLE ANTIMICROBIAL DRUG.—The term 'applicable antimicrobial drug' means an antimicrobial drug for which

the sponsor of such drug receives a subscription contract under subsection (a).

''(B) SPECIFIED GOVERNMENT PROGRAM.—The term 'specified government program' means—

''(i) the Medicare part D program under part D of title XVIII of the Social Security Act;

''(ii) the Medicare Part B program under part B of such title XVIII;

''(iii) the Medicare Part A program under part A of such title XVIII;

''(iv) the Medicaid program established under title XIX of the Social Security Act and includes, with respect to a State, any waiver in effect with respect to such program;

''(v) any program under which prescription drugs are procured by the Department of Veterans Affairs;

''(vi) any program under which prescription drugs are procured by the Department of Defense;

''(vii) the TRICARE retail pharmacy program under section 1074g(a)(2)(E)(ii) of title 10, United States Code;

''(viii) any program under which prescription drugs are procured by the Department of Homeland Security;

''(ix) any program under which prescription drugs are procured by the Bureau of Prisons; or

''(x) any program under which prescription drugs are procured by the Indian Health Service.

''(e) FAILURE TO ADHERE TO TERMS.—The Secretary shall cease any payment installments under a contract under this section if—

''(1) the sponsor—

''(A) permanently withdraws the antimicrobial drug from the market in the United States;

''(B) fails to meet criteria under subsection (b); or

''(C) does not complete a postmarket study required by the Food and Drug Administration during the length of the term of the contract;

''(2) the annual international and private insurance market revenues with respect to an antimicrobial drug (not counting any subscription revenues from any source pursuant to a contract under this section or other international or private entities) exceed 5 times the average annual amount of the subscription contract paid by the Secretary as certified by the sponsor annually; or

''(3) if the total revenue of the sponsor from specified government programs, as defined in subsection (d)(4), for a year exceeds the amount of the subscription contract paid by the Secretary for that year.

''(f) PRIVATE PAYER AND INTERNATIONAL PAYER PARTICIPATION.—The Secretary shall make efforts to increase the participation of domestic private payors and international payors in subscription contracts or other types of value-based arrangements that are similar to the subscription contracts authorized under this section.

''SEC. 399RR. ENCOURAGING APPROPRIATE USE OF ANTIBIOTICS AND COMBATING RESISTANCE.

''(a) ESTABLISHMENT OF HOSPITAL GRANT PROGRAM.—

''(1) IN GENERAL.—Not later than 1 year after the date of enactment of this part, the Secretary and

the Director of the Centers for Disease Control and Prevention shall coordinate with the Administrator of the Health Resources and Services Administration, the Administrator of the Centers for Medicare & Medicaid Services, the National Coordinator for Health Information Technology, and other relevant agencies, to establish a grant program under the Centers for Disease Control and Prevention to support hospital and other inpatient facility efforts—

''(A) to judiciously use antimicrobial drugs, such as by establishing or implementing appropriate use programs, including infectious disease telehealth programs, using appropriate diagnostic tools, partnering with academic hospitals, increasing health care-associated infection reporting, and monitoring antimicrobial resistance; and

''(B) to participate in the National Healthcare Safety Network Antimicrobial Use and Resistance Module or the Emerging Infections Program Healthcare-Associated Infections Community Interface activity of the Centers for Disease Control and Prevention or a similar reporting program, as specified by the Secretary, relating to antimicrobial drugs.

''(2) PRIORITIZATION.—In awarding grants under paragraph (1), the Secretary shall prioritize hospitals without an existing program to judiciously use antimicrobial drugs, subsection (d) hospitals (as defined in subparagraph (B) of section 1886(d)(2) of the Social Security Act that are located in rural areas (as defined in subparagraph (D) of such section), critical access hospitals (as defined in section 1861(mm)(1) of such Act), hospitals serving Tribal-populations, and safety-net hospitals.

''(3) FUNDING.—Of the amounts appropriated under section 399SS, the Secretary shall reserve $500,000,000 to carry out this subsection.

''(b) SURVEILLANCE AND REPORTING OF ANTIBIOTIC USE AND RESISTANCE.—

''(1) 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—

''(A) 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, in-

creased lengths of hospital stay, increased costs, and rates of mortality; and

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

''(2) 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, the Department of Homeland Security, the Bureau of Prisons, the Indian Health Service, 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.

''(3) ANTIBIOTIC RESISTANCE TREND DATA.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall in-

tensify and expand efforts to collect antibiotic resistance data and encourage adoption of the Antibiotic Use and Resistance 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, ambulatory surgical centers, and other ambulatory health care settings in which antimicrobial drugs are routinely prescribed. The Secretary shall seek to collect such data from electronic medication administration reports and laboratory systems to produce the reports described in paragraph (4).

''(4) PUBLIC AVAILABILITY OF DATA.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall, for the purposes of improving the monitoring of important trends in patient outcomes in relation to antibacterial resistance—

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

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

"SEC. 399SS. APPROPRIATIONS.

"(a) IN GENERAL.—To carry out this part, there are hereby appropriated to the Secretary, out of amounts in the Treasury not otherwise appropriated, $11,000,000,000, for fiscal year 2022, to remain available until expended.

"(b) EMERGENCY DESIGNATION.—

"(1) IN GENERAL.—The amounts provided by this section are designated as an emergency requirement pursuant to section 4(g) of the Statutory Pay-As-You-Go Act of 2010.

"(2) DESIGNATION IN SENATE.—In the Senate, this section is designated as an emergency requirement pursuant to section 4112(a) of H. Con. Res. 71 (115th Congress), the concurrent resolution on the budget for fiscal year 2018.

"SEC. 399TT. STUDIES AND REPORTS.

"(a) IN GENERAL.—Not later than 6 years after the date of enactment of this part, the Comptroller General of the United States shall complete a study on the effectiveness of this part in developing priority antimicrobial drugs. Such study shall examine the indications for, usage of, development of resistance with respect to, and private and societal value of critical need antimicrobial drugs, and the impact of the programs under this part on patients and markets of critical need antimicrobial drugs. The

Comptroller General shall report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on the findings of such study.

''(b) ANTIBIOTIC USE IN THE UNITED STATES; ANNUAL REPORTS.—The Director of the Centers for Disease Control and Prevention shall, each year, update the report entitled 'Antibiotic Use in the United States' to include updated information on progress and opportunities with respect to data, programs, and resources for prescribers to promote appropriate use of antimicrobial drugs.

''(c) REPORT ON ANTIMICROBIAL PROPHYLACTICS.—Not later than 3 years after the date of enactment of this part, the Director of the Centers for Disease Control and Prevention shall publish a report on antimicrobial prophylactics.

''SEC. 399UU. DEFINITIONS.

''In this part—

''(1) the term 'antimicrobial drug'—

''(A) means, subject to subparagraph (B), a product that is—

''(i) a drug that directly inhibits replication of or kills bacteria or fungi relevant to the proposed indication at concentrations likely to be attainable in hu-

mans to achieve the intended therapeutic effect; or

''(ii) a biological product that acts directly on bacteria or fungi or on the substances produced by such bacteria or fungi; and

''(B) does not include—

''(i) a drug that achieves the effect described by subparagraph (A)(i) only at a concentration that cannot reasonably be studied in humans because of its anticipated toxicity; or

''(ii) a vaccine; and

''(2) the term 'Committee' means the Committee on Critical Need Antimicrobials established under section 399OO.''.