

117TH CONGRESS  
1ST SESSION

**S.** \_\_\_\_\_

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

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IN THE SENATE OF THE UNITED STATES

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Mr. BENNET introduced the following bill; which was read twice and referred to the Committee on \_\_\_\_\_

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**A BILL**

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

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 “Pioneering Anti-  
5 microbial Subscriptions To End Up surging Resistance  
6 Act of 2021” or the “PASTEUR Act”.

7 **SEC. 2. DEVELOPING ANTIMICROBIAL INNOVATIONS.**

8 Title III of the Public Health Service Act (42 U.S.C.  
9 241 et seq.) is amended by adding at the end the fol-  
10 lowing:



1 sory Group established under subsection (g), shall do the  
2 following:

3           “(1) Develop a list of infections for which new  
4 antimicrobial drug development is needed, taking  
5 into account organisms, sites of infection, and type  
6 of infections for which there is an unmet medical  
7 need, findings from the most recent report entitled  
8 ‘Antibiotic Resistance Threats in the United States’  
9 issued by the Centers for Disease Control and Pre-  
10 vention, or an anticipated unmet medical need, in-  
11 cluding a potential global health security threat. For  
12 the list developed under this paragraph, the Sec-  
13 retary, in collaboration with the Committee, may use  
14 the infection list in such most recent report for up  
15 to 3 years following the date of enactment of this  
16 part and subsequently update the list under this  
17 paragraph in accordance with subsection (e).

18           “(2) Develop regulations, in accordance with  
19 subsection (d), outlining favored characteristics of  
20 critical need antimicrobial drugs, that are evidence  
21 based, clinically focused, and designed to treat the  
22 infections described in paragraph (1), and estab-  
23 lishing criteria for how each such characteristic will  
24 adjust the monetary value of a subscription contract  
25 awarded under subsection (f) or section 399QQ. The

1 favored characteristics shall be weighed for purposes  
2 of such monetary value such that meeting certain  
3 characteristics, or meeting more than one such char-  
4 acteristic, increases the monetary value. Such fa-  
5 vored characteristics of an antimicrobial drug shall  
6 include—

7 “(A) treating infections on the list under  
8 paragraph (1);

9 “(B) improving clinical outcomes for pa-  
10 tients with multi-drug-resistant infections;

11 “(C) being a first-approved antimicrobial  
12 drug that has the potential to address unmet  
13 medical needs for the treatment of a serious or  
14 life-threatening infection, and, to a lesser ex-  
15 tent, second and third drugs that treat such in-  
16 fections;

17 “(D) route of administration, especially  
18 through oral administration;

19 “(E)(i) containing no active moiety (as de-  
20 fined by the Secretary in section 314.3 of title  
21 21, Code of Federal Regulations (or any suc-  
22 cessor regulations)) that has been approved in  
23 any other application under section 505(b) of  
24 the Federal Food, Drug, and Cosmetic Act or  
25 intending to be the subject of a new original

1 biologics license application under section  
2 351(a);

3 “(ii) being a member of a new class of  
4 drugs with a novel target and novel mode of ac-  
5 tion that are distinctly different from the target  
6 or mode of any antimicrobial drug approved  
7 under section 505 of such Act or licensed under  
8 section 351, including reduced toxicity;

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

12 “(F) addressing a multi-drug resistant in-  
13 fection through a novel chemical scaffold or  
14 mechanism of action;

15 “(G) having received a transitional sub-  
16 scription contract under subsection (f); and

17 “(H) any other characteristic the Sec-  
18 retary, in collaboration with the Committee, de-  
19 termines necessary.

20 “(d) REGULATIONS.—

21 “(1) IN GENERAL.—Not later than 1 year after  
22 the appointment of the initial members of the Com-  
23 mittee, the Secretary shall issue proposed regula-  
24 tions which shall include—

1           “(A) a process by which the sponsors can  
2           apply for an antimicrobial drug to become a  
3           critical need antimicrobial drug under section  
4           399PP;

5           “(B) how subscription contracts under  
6           such section shall be established and paid;

7           “(C) the favored characteristics under sub-  
8           section (c)(2), how such characteristics will be  
9           weighed, and the minimum number and kind of  
10          favored characteristics needed for an anti-  
11          microbial drug to be designated a critical need  
12          antimicrobial drug; and

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

15          “(2) DEVELOPMENT OF FINAL REGULA-  
16          TIONS.—Before finalizing the regulations under  
17          paragraph (1), the Secretary shall solicit public com-  
18          ment and hold public meetings for the period begin-  
19          ning on the date on which the proposed regulations  
20          are issued and ending on the date that is 120 days  
21          after such date of issuance. The Secretary shall fi-  
22          nalize and publish such regulations not later than  
23          120 days after the close of such period of public  
24          comment and meetings.

1           “(3) SUBSCRIPTION CONTRACT OFFICE.—Not  
2 later than 6 months after the date of enactment of  
3 this part, the Secretary shall propose an agency or  
4 office in the Department of Health and Human  
5 Services to manage the establishment and payment  
6 of subscription contracts awarded under section  
7 399QQ, including eligibility, requirements, and con-  
8 tract amounts. The Secretary shall solicit public  
9 comment and finalize the agency or office no later  
10 than 45 days following the proposed agency or of-  
11 fice. Such agency or office shall be referred to as the  
12 ‘Subscription Contract Office’.

13           “(e) LIST OF INFECTIONS.—The Secretary, in col-  
14 laboration with the Committee, shall update the list of in-  
15 fections under subsection (c)(1) at least every 2 years.

16           “(f) TRANSITIONAL SUBSCRIPTION CONTRACTS.—

17           “(1) IN GENERAL.—Not earlier than 30 days  
18 after the date of enactment of this part and ending  
19 on the date that the Secretary finalizes the subscrip-  
20 tion contract regulations under subsection (d), the  
21 Secretary may use up to \$1,000,000,000 of the  
22 amount appropriated under section 399SS(a) to en-  
23 gage in transitional subscription contracts of up to  
24 3 years in length with antimicrobial developers, as  
25 determined by the Secretary, that have developed

1 antimicrobial drugs treating infections listed in the  
2 most recent report entitled ‘Antibiotic Resistance  
3 Threats in the United States’ issued by the Centers  
4 for Disease Control and Prevention, and may include  
5 antimicrobial drugs that are qualified infectious dis-  
6 ease products (as defined in section 505E(g) of the  
7 Federal Food, Drug, and Cosmetic Act), innovative  
8 biological products, or innovative drugs that achieve  
9 a clinical outcome through immunomodulation. Such  
10 a contract may authorize the contractor to use funds  
11 made available under the contract for completion of  
12 postmarketing clinical studies, manufacturing, and  
13 other preclinical and clinical efforts.

14 “(2) REQUIREMENTS.—

15 “(A) IN GENERAL.—The Secretary,  
16 through the office described in paragraph (4),  
17 may enter into a contract under paragraph  
18 (1)—

19 “(i) if the Secretary determines that  
20 the antimicrobial drug is intended to treat  
21 an infection for which there is an unmet  
22 clinical need, an anticipated clinical need,  
23 or drug resistance;

24 “(ii) subject to terms including—

1                   “(I) that the Secretary shall  
2                   cease any payment installments under  
3                   a transitional subscription contract if  
4                   the sponsor does not—

5                   “(aa) ensure commercial and  
6                   Federal availability of the anti-  
7                   microbial drug within 30 days of  
8                   receiving first payment under the  
9                   contract;

10                  “(bb) identify, track, and  
11                  publicly report drug resistance  
12                  data and trends using available  
13                  data related to the antimicrobial  
14                  drug;

15                  “(cc) develop and implement  
16                  education and communications  
17                  strategies, including communica-  
18                  tions for individuals with limited  
19                  English proficiency and individ-  
20                  uals with disabilities, for health  
21                  care professionals and patients  
22                  about appropriate use of the  
23                  antimicrobial drug;

24                  “(dd) submit a plan for reg-  
25                  istering the antimicrobial drug in

1 additional countries where an  
2 unmet medical need exists, which  
3 such plan may be consistent with  
4 the Stewardship and Access Plan  
5 (SAP) Development Guide  
6 (2021);

7 “(ee) subject to subpara-  
8 graph (B), ensure a reliable drug  
9 supply chain, thus leading to an  
10 interruption of the supply of the  
11 antimicrobial drug in the United  
12 States for more than 60 days; or

13 “(ff) make meaningful  
14 progress toward completion of  
15 Food and Drug Administration-  
16 required postmarketing studies,  
17 including such studies that are  
18 evidence based; and

19 “(II) other terms as determined  
20 by the Secretary; and

21 “(iii) if—

22 “(I) a phase 3 clinical study has  
23 been initiated for the antimicrobial  
24 drug; or

1                   “(II) the antimicrobial drug has  
2                   been approved under section 505(c) of  
3                   the Federal Food, Drug, and Cos-  
4                   metic Act or licensed under section  
5                   351(a).

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

10                  “(3) TRANSITIONAL GUIDANCE.—Not later  
11                  than 120 days after the appointment of the initial  
12                  members of the Committee, the Secretary shall  
13                  issue, in consultation with the Committee, transi-  
14                  tional guidance outlining the antimicrobial drugs  
15                  that are eligible for transitional subscription con-  
16                  tracts under paragraph (1), the requirements to  
17                  enter into a transitional subscription contract under  
18                  paragraph (2), and the process by which drug devel-  
19                  opers can enter into transitional subscription con-  
20                  tracts with the Secretary under this subsection.

21                  “(4) PAYMENT OFFICE AND MECHANISM.—Not  
22                  later than 30 days after the date of enactment of  
23                  this part, the Secretary shall determine the agency  
24                  or office in the Department of Health and Human  
25                  Services that will manage the transitional subscrip-

1       tion contracts, including eligibility, requirements,  
2       and contract amounts, during the period described  
3       in paragraph (1).

4       “(g) CRITICAL NEED ANTIMICROBIAL ADVISORY  
5 GROUP.—

6               “(1) IN GENERAL.—Not later than 30 days  
7       after the appointment of all initial members of the  
8       Committee, the Secretary, in collaboration with the  
9       Committee, shall establish a Critical Need Anti-  
10       microbial Advisory Group (referred to in this sub-  
11       section as the ‘Advisory Group’) and appoint mem-  
12       bers to the Advisory Group.

13               “(2) MEMBERS.—The members of the Advisory  
14       Group shall include—

15                       “(A) not fewer than 6 individuals who  
16       are—

17                               “(i) infectious disease specialists; or

18                               “(ii) other health experts with exper-  
19       tise in researching antimicrobial resistance,  
20       health economics, or commercializing anti-  
21       microbial drugs; and

22                       “(B) not fewer than 5 patient advocates.

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

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

7           “(5) APPLICABILITY OF FACCA.—Except as oth-  
8           erwise provided in this subsection, the Federal Advi-  
9           sory Committee Act shall apply to the Advisory  
10          Group.

11   **“SEC. 399PP. CRITICAL NEED ANTIMICROBIAL DRUG APPLI-**  
12                           **CATION AND PAYMENT THROUGH SUBSCRIP-**  
13                           **TION CONTRACTS.**

14          “(a) IN GENERAL.—

15           “(1) SUBMISSION OF REQUEST.—The sponsor  
16           of an application under section 505(b) of the Fed-  
17           eral Food, Drug, and Cosmetic Act or section 351(a)  
18           for an antimicrobial drug may request that the Sec-  
19           retary designate the drug as a critical need anti-  
20           microbial. A request for such designation may be  
21           submitted after the Secretary grants for such drug  
22           an investigational new drug exemption under section  
23           505(i) of the Federal Food, Drug, and Cosmetic Act  
24           or section 351(a)(3), and shall be submitted not  
25           later than 5 years after the date of approval under

1 section 505(c) of the Federal Food, Drug, and Cos-  
2 metic Act or licensure under section 351(a).

3 “(2) CONTENT OF REQUEST.—A request under  
4 paragraph (1) shall include information, such as  
5 clinical, preclinical and postmarketing data, a list of  
6 the favorable characteristics described in section  
7 39900(c)(2), and any other material that the Sec-  
8 retary in consultation with the Committee requires.

9 “(3) REVIEW BY SECRETARY.—The Secretary  
10 shall promptly review all requests for designation  
11 submitted under this subsection, assess all required  
12 application components, and determine if the anti-  
13 microbial drug is likely to meet the favorable charac-  
14 teristics identified in the application upon the com-  
15 pletion of clinical development. After review, the Sec-  
16 retary shall approve or deny each request for des-  
17 ignation not later than 90 days after receiving a re-  
18 quest. If the Secretary approves a request, it shall  
19 publish the value of the contract that the critical  
20 need antimicrobial developer would be eligible to re-  
21 ceive if such developer successfully demonstrates  
22 that the drug meets the maximum value of the fa-  
23 vored characteristics listed in the application.

24 “(4) LENGTH OF DESIGNATION PERIOD.—A  
25 designation granted under this section shall be in ef-

1       fect for a period of 10 years after the date that the  
2       designation is approved, and shall remain in effect  
3       for such period even if the infection treated by such  
4       drug is later removed from the list of infections  
5       under section 39900(c)(1).

6               “(5) SUBSEQUENT REVIEWS.—No sooner than  
7       2 years after a designation approval or denial under  
8       subsection (3), the sponsor may request a subse-  
9       quent review to re-evaluate the value of a contract  
10       to include any new information.

11              “(b) DEVELOPMENT OF DESIGNATED DRUGS.—If a  
12       critical need antimicrobial designation is granted during  
13       clinical development of an antimicrobial drug, the Sec-  
14       retary may work with the sponsor to maximize the oppor-  
15       tunity for the sponsor to successfully demonstrate that the  
16       antimicrobial drug possesses the favored characteristics of  
17       high-monetary valued products identified under section  
18       39900(c)(2).

19              “(c) APPROPRIATE USE OF CRITICAL NEED ANTI-  
20       MICROBIAL.—

21              “(1) IN GENERAL.—The sponsor of an anti-  
22       microbial drug that receives designation under sub-  
23       section (a) shall within 90 days of such designation,  
24       submit to the Secretary a plan for appropriate use  
25       of diagnostics, in order for the Secretary and Com-

1       mittee to consider such plan in developing clinical  
2       guidelines. An appropriate use plan—

3               “(A) shall include—

4                       “(i) the appropriate use of the drug;  
5                       and

6                       “(ii) the appropriate use of diagnostic  
7                       tools, where available, such as diagnostic  
8                       testing for biomarkers related to anti-  
9                       microbial-resistant pathogens, or other tar-  
10                      geted diagnostic approaches, to inform use  
11                      of the drug; and

12               “(B) may be developed in partnership with  
13       the Secretary, infectious disease experts, diag-  
14       nostic experts or developers, laboratory experts,  
15       or another entity.

16               “(2) CONSULTATION.—The Secretary shall con-  
17       sult with relevant professional societies and the Crit-  
18       ical Need Antimicrobial Advisory Group established  
19       under section 39900(g) to ensure that clinical  
20       guidelines issued by the Secretary under paragraph  
21       (3), with respect to an antimicrobial drug designated  
22       under subsection (a), includes the use of appropriate  
23       diagnostic approaches, taking into consideration the  
24       diagnostic plan submitted by a sponsor under para-  
25       graph (1).

1           “(3) PUBLICATION OF CLINICAL GUIDELINES.—  
2           Not later than 1 year after the Secretary makes the  
3           first designation under subsection (a), and not less  
4           than every 3 years thereafter, the Secretary shall  
5           publish clinical guidelines in consultation with rel-  
6           evant professional societies with respect to each anti-  
7           microbial drug that has been approved or licensed as  
8           described in subsection (a)(1) and that has been des-  
9           ignated under subsection (a), which guidelines shall  
10          set forth the evidence-based recommendations for  
11          prescribing the drug, in accordance with the submis-  
12          sions of the sponsor under paragraph (1) and after  
13          consultation under paragraph (2), as appropriate.

14 **“SEC. 399QQ. SUBSCRIPTION CONTRACTS.**

15          “(a) APPLICATION FOR A SUBSCRIPTION CON-  
16          TRACT.—

17                 “(1) SUBMISSION OF APPLICATIONS.—After ap-  
18                 proval under section 505(c) of the Federal Food,  
19                 Drug, and Cosmetic Act or licensure under section  
20                 351(a), the sponsor of an antimicrobial drug des-  
21                 ignated as a critical need antimicrobial under section  
22                 399PP may submit an application for a subscription  
23                 contract with the Secretary, under a procedure es-  
24                 tablished by the Secretary.

1           “(2) REVIEW OF APPLICATIONS.—The Sec-  
2           retary shall, in consultation with the Committee—

3                   “(A) review all applications for subscrip-  
4                   tion contracts under paragraph (1) and assess  
5                   all required application components;

6                   “(B) determine the extent to which the  
7                   critical need antimicrobial meets the favored  
8                   characteristics identified under section  
9                   39900(c)(2), and deny any application for a  
10                  drug that meets none of such characteristics;  
11                  and

12                  “(C) assign a monetary value to the con-  
13                  tract based on the regulations developed under  
14                  section 39900(d).

15           “(b) CRITERIA.—To qualify for a subscription con-  
16           tract under this section, the sponsor of an antimicrobial  
17           drug designated as a critical need antimicrobial shall agree  
18           to—

19                   “(1) ensure commercial and Federal availability  
20                   of the antimicrobial drug within 30 days of receiving  
21                   first payment under the contract, and sufficient sup-  
22                   ply for susceptibility device manufacturers;

23                   “(2) identify, track, and publicly report drug  
24                   resistance data and trends using available data re-  
25                   lated to the antimicrobial drug;

1           “(3) develop and implement education and com-  
2           munications strategies, including communications  
3           for individuals with limited English proficiency and  
4           individuals with disabilities, for health care profes-  
5           sionals and patients about appropriate use of the  
6           antimicrobial drug;

7           “(4) submit an appropriate use assessment to  
8           the Secretary, Committee, Food and Drug Adminis-  
9           tration, and Centers for Disease Control and Pre-  
10          vention every 2 years regarding use of the anti-  
11          microbial drug, including how the drug is being mar-  
12          keted;

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

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

19          “(7) complete any postmarketing studies re-  
20          quired by the Food and Drug Administration in a  
21          timely manner;

22          “(8) produce the drug at a reasonable volume  
23          determined with the Secretary to ensure patient ac-  
24          cess to the drug;

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

3           “(10) abide by the manufacturing and environ-  
4           mental best practices in the supply chain to ensure  
5           that there is no discharge into, or contamination of,  
6           the environment by antimicrobial agents or products  
7           as a result of the manufacturing process; and

8           “(11) abide by other terms as the Secretary  
9           may require.

10          “(c) AMOUNT AND TERMS OF CONTRACTS.—

11           “(1) AMOUNTS.—A subscription contract under  
12           this section shall be for the sale to the Secretary of  
13           any quantity of the antimicrobial drug needed over  
14           the term of the contract under paragraph (2), at an  
15           agreed upon price, for a total projected amount de-  
16           termined by the Secretary that is not less than  
17           \$750,000,000 and not more than \$3,000,000,000,  
18           adjusted for inflation, accounting for the favored  
19           characteristics of the drug, as determined by the  
20           Secretary, in consultation with the Committee, under  
21           subsection (a)(2), and shall be allocated from the  
22           amount made available under section 399SS(a). Not  
23           later than 6 months after the subscription contract  
24           is granted under subsection (a), the Secretary shall  
25           provide payments for purchased drugs in install-

1       ments established by the Secretary in consultation  
2       with the sponsor of the antimicrobial drug and in ac-  
3       cordance with subsection (d)(3). Funds received by  
4       the sponsor shall be used to support criteria quali-  
5       fication under subsection (b), the completion of post-  
6       marketing clinical studies, manufacturing, other pre-  
7       clinical and clinical activities, or other activities  
8       agreed to by the Secretary and sponsor in the con-  
9       tract.

10       “(2) TERMS.—

11               “(A) INITIAL TERM.—The initial term of a  
12       contract under this subsection shall be no less  
13       than 5 years or greater than the greater of 10  
14       years or the remaining period of time during  
15       which the sponsor has patent protections or a  
16       remaining exclusivity period with respect to the  
17       antimicrobial drug in the United States, as list-  
18       ed in the publication of the Food and Drug Ad-  
19       ministration entitled ‘Approved Drug Products  
20       with Therapeutic Equivalence Evaluations’.  
21       Payments may be in equal annual installments  
22       with the option to redeem 50 percent of the last  
23       year’s reimbursement in year 1 of the contract  
24       in order to offset costs of establishing manufac-  
25       turing capacity, or another subscription ar-

1           rangement to which the Secretary and sponsor  
2           agree. Subscription contracts shall remain in ef-  
3           fect for such period even if the infection treated  
4           by such antimicrobial drug is later removed  
5           from the list of infections under section  
6           39900(c)(1).

7           “(B) EXTENSION OF CONTRACTS.—The  
8           Secretary may extend a subscription contract  
9           with a sponsor under this subsection beyond the  
10          initial contract period. A single contract exten-  
11          sion may be in effect not later than the date on  
12          which all periods of exclusivity granted by the  
13          Food and Drug Administration expire and shall  
14          be in an amount not to exceed \$25,000,000 per  
15          year. All other terms of an extended contract  
16          shall be the same as the terms of the initial  
17          contract. The total amount of funding used on  
18          such contract extensions shall be no more than  
19          \$1,000,000,000, and shall be allocated from the  
20          amount made available under section 399SS.

21          “(C) MODIFICATION OF CONTRACTS.—The  
22          Secretary or sponsor, 1 year after the start of  
23          the contract period under this subsection and  
24          every 2 years thereafter, may request a modi-  
25          fication of the amount of the contract based on

1 information that adjusts favored characteristics  
2 in section 39900(c)(2).

3 “(3) ADJUSTMENT.—In the case of an anti-  
4 microbial drug that received a transitional subscrip-  
5 tion contract under section 39900(f), the amount of  
6 a subscription contract for such drug under this sec-  
7 tion shall be reduced by the amount of the transi-  
8 tional subscription contract under such section  
9 39900(f) for such drug.

10 “(4) CONTRACTS FOR GENERIC AND BIO-  
11 SIMILAR VERSIONS.—Notwithstanding any other  
12 provision in this part, the Secretary may award a  
13 subscription contract under this section to a manu-  
14 facturer of a generic or biosimilar version of an anti-  
15 microbial drug for which a subscription contract has  
16 been awarded under this section. Such contracts  
17 shall be awarded in accordance with a procedure, in-  
18 cluding for determining the terms and amounts of  
19 such contracts, established by the Secretary.

20 “(d) ANNUAL ANTIMICROBIAL DRUG SPONSOR REV-  
21 ENUE LIMITATIONS.—

22 “(1) REPORTING REQUIREMENT.—

23 “(A) IN GENERAL.—Not later than a date  
24 determined appropriate by the Secretary fol-  
25 lowing the end of each calendar year, and not

1 earlier than 6 months after the end of each cal-  
2 endar year, the head (or a designee of such  
3 head) of each Federal agency carrying out a  
4 specified government program shall, in accord-  
5 ance with this paragraph, report to the Sub-  
6 scription Contract Office established under sec-  
7 tion 39900(d)(3) the total prescription drug  
8 sales for each applicable antimicrobial drug  
9 under contract with respect to such program for  
10 such calendar year.

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

16 “(i) the per-unit ingredient cost, as  
17 reported to the Secretary by prescription  
18 drug plans and Medicare Advantage pre-  
19 scription drug plans, minus any per-unit  
20 rebate, discount, or other price concession  
21 provided by the sponsor of such applicable  
22 antimicrobial drug, as reported to the Sec-  
23 retary by the prescription drug plans and  
24 the Medicare Advantage prescription drug  
25 plans; and



1 payable or for which National Drug Codes  
2 are not reported.

3 “(D) MEDICARE PART A PROGRAM.—

4 “(i) IN GENERAL.—For purposes of  
5 subparagraph (A), the Secretary shall re-  
6 port, for each applicable antimicrobial drug  
7 covered under part A of title XVIII of the  
8 Social Security Act, the product of—

9 “(I) the per-unit price under  
10 such part A for the antimicrobial  
11 drug; and

12 “(II) the number of units of such  
13 antimicrobial drug paid for under  
14 such part A.

15 “(ii) SPECIAL RULE.—For purposes of  
16 clause (i), the Secretary shall establish a  
17 process for determining the units and the  
18 allocated price for those prescription drugs  
19 that are not separately payable or for  
20 which National Drug Codes are not re-  
21 ported in the diagnosis-related groups.

22 “(E) MEDICAID PROGRAM.—Under the au-  
23 thority of section 1902(a)(6) of the Social Secu-  
24 rity Act, the Secretary shall require each State  
25 that makes medical assistance available under

1 the State plan under title XIX of such Act (or  
2 any waiver of such plan) for an applicable anti-  
3 microbial drug (including, if applicable, any  
4 such drug which is a covered outpatient drug  
5 under a rebate agreement entered into under  
6 section 1927 of such Act) to report, in a form  
7 consistent with a standard reporting format es-  
8 tablished by the Secretary, not later than the  
9 date determined under subparagraph (A)—

10 “(i) information on the total number  
11 of units of each dosage form and strength  
12 and package size of each applicable anti-  
13 microbial drug dispensed during the pre-  
14 ceding calendar year under such State plan  
15 or waiver (including any such drugs dis-  
16 pensed to an individual enrolled with a  
17 medicaid managed care organization or  
18 other specified entity (as such terms are  
19 defined in section 1903(m) of such Act));  
20 and

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

24 “(I) the product of—

1                   “(aa) the total number of  
2                   units dispensed under the State  
3                   plan or waiver during the pre-  
4                   ceding calendar year (as deter-  
5                   mined under clause (i)); and

6                   “(bb) the per-unit ingredient  
7                   cost paid by the State for each  
8                   such unit; minus

9                   “(II) any discounts or other price  
10                  concessions provided and rebates paid  
11                  to the State with respect to the dos-  
12                  age form and strength and package  
13                  size of such drug and such calendar  
14                  year (including rebates paid under a  
15                  rebate agreement under section 1927  
16                  of such Act and any State supple-  
17                  mental rebates paid under a supple-  
18                  mental rebate agreement).

19                  “(F) DEPARTMENT OF VETERANS AF-  
20                  FAIRS.—For purposes of subparagraph (A), the  
21                  Secretary of Veterans Affairs shall report the  
22                  total amount paid for each applicable anti-  
23                  microbial drug procured by the Veterans Health  
24                  Administration for individuals who receive  
25                  health care from the Administration.

1                   “(G) DEPARTMENT OF DEFENSE AND  
2 TRICARE PROGRAM.—For purposes of subpara-  
3 graph (A), the Secretary of Defense shall report  
4 the sum of—

5                   “(i) the total amount paid for each  
6 applicable antimicrobial drug procured by  
7 the Department of Defense for individuals  
8 who receive health care from the Depart-  
9 ment; and

10                   “(ii) for each applicable antimicrobial  
11 drug dispensed under the TRICARE retail  
12 pharmacy program under section  
13 1074g(a)(2)(E)(ii) of title 10, United  
14 States Code, the product of—

15                   “(I) the per-unit ingredient cost,  
16 minus any per-unit rebate paid by the  
17 sponsor of the applicable antimicrobial  
18 drug; and

19                   “(II) the number of units of such  
20 applicable antimicrobial drug dis-  
21 pensed under such program.

22                   “(H) DEPARTMENT OF HOMELAND SECUR-  
23 ITY.—For purposes of subparagraph (A), the  
24 Secretary of Homeland Security shall report the  
25 total amount paid for each applicable anti-

1 microbial drug procured by the Department of  
2 Homeland Security for individuals who receive  
3 health care through a program carried out by  
4 the Department.

5 “(I) BUREAU OF PRISONS.—For purposes  
6 of subparagraph (A), the Director of the Bu-  
7 reau of Prisons shall report the total amount  
8 paid for each applicable antimicrobial drug pro-  
9 cured by the Bureau of Prisons for individuals  
10 who receive health care through the Bureau.

11 “(J) INDIAN HEALTH SERVICE.—For pur-  
12 poses of subparagraph (A), the Secretary, act-  
13 ing through the Indian Health Service, shall re-  
14 port the total amount paid for each applicable  
15 antimicrobial drug procured by the Service for  
16 individuals who receive health care through the  
17 Service.

18 “(2) REGULATIONS.—Not later than 1 year  
19 after the date of enactment of this part, the Sec-  
20 retary, in consultation with the heads of Federal  
21 agencies carrying out specified government pro-  
22 grams, shall issue regulations to assist such heads  
23 (or their designees) in carrying out the requirements  
24 under this section.

1           “(3) SUBSCRIPTION CONTRACT ADJUSTMENT.—  
2 Pursuant to the contract entered into under this sec-  
3 tion with respect to an applicable antimicrobial drug,  
4 for each year of the term of such contract, the Sec-  
5 retary shall, not earlier than 6 months after the end  
6 of each calendar year, subtract from the payment in-  
7 stallments determined for such contract under sub-  
8 section (c)(1) for such year the revenue of the spon-  
9 sor of such drug from the previous year from sales  
10 of the applicable antimicrobial drug reported under  
11 paragraph (1) for specified government programs.

12           “(4) DEFINITIONS.—In this subsection:

13           “(A)       APPLICABLE       ANTIMICROBIAL  
14 DRUG.—The term ‘applicable antimicrobial  
15 drug’ means an antimicrobial drug for which  
16 the sponsor of such drug receives a subscription  
17 contract under subsection (a).

18           “(B)       SPECIFIED       GOVERNMENT       PRO-  
19 GRAM.—The term ‘specified government pro-  
20 gram’ means—

21           “(i) the Medicare part D program  
22 under part D of title XVIII of the Social  
23 Security Act;

24           “(ii) the Medicare Part B program  
25 under part B of such title XVIII;

1           “(iii) the Medicare Part A program  
2           under part A of such title XVIII;

3           “(iv) the Medicaid program estab-  
4           lished under title XIX of the Social Secu-  
5           rity Act and includes, with respect to a  
6           State, any waiver in effect with respect to  
7           such program;

8           “(v) any program under which pre-  
9           scription drugs are procured by the De-  
10          partment of Veterans Affairs;

11          “(vi) any program under which pre-  
12          scription drugs are procured by the De-  
13          partment of Defense;

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

17          “(viii) any program under which pre-  
18          scription drugs are procured by the De-  
19          partment of Homeland Security;

20          “(ix) any program under which pre-  
21          scription drugs are procured by the Bu-  
22          reau of Prisons; or

23          “(x) any program under which pre-  
24          scription drugs are procured by the Indian  
25          Health Service.

1       “(e) FAILURE TO ADHERE TO TERMS.—The Sec-  
2 retary shall cease any payment installments under a con-  
3 tract under this section if—

4           “(1) the sponsor—

5               “(A) permanently withdraws the anti-  
6 microbial drug from the market in the United  
7 States;

8               “(B) fails to meet criteria under subsection  
9 (b); or

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

13              “(2) the annual international and private insur-  
14 ance market revenues with respect to an anti-  
15 microbial drug (not counting any subscription reve-  
16 nues from any source pursuant to a contract under  
17 this section or other international or private entities)  
18 exceed 5 times the average annual amount of the  
19 subscription contract paid by the Secretary as cer-  
20 tified by the sponsor annually; or

21              “(3) if the total revenue of the sponsor from  
22 specified government programs, as defined in sub-  
23 section (d)(4), for a year exceeds the amount of the  
24 subscription contract paid by the Secretary for that  
25 year.

1 “(f) NEGLIGENCE.—

2 “(1) IN GENERAL.—In the case that the neg-  
3 ligence of the sponsor leads to the Secretary ceasing  
4 payments under subsection (e), the sponsor shall re-  
5 turn all or a part of the payment installments under  
6 the contract, as determined by the Secretary.

7 “(2) FIRST RIGHT.—In a case described in  
8 paragraph (1), if the sponsor is unable to return the  
9 payment installments determined under such para-  
10 graph, notwithstanding any other provision of law,  
11 the Secretary shall have the first opportunity to pur-  
12 chase the intellectual property with respect to the  
13 antimicrobial drug, the price for which shall be de-  
14 termined through a negotiation between the parties.

15 “(g) PRIVATE PAYER AND INTERNATIONAL PAYER  
16 PARTICIPATION.—The Secretary shall make efforts to in-  
17 crease the participation of domestic private payors and  
18 international payors in subscription contracts or other  
19 types of value-based arrangements that are similar to the  
20 subscription contracts authorized under this section.

21 **“SEC. 399RR. ENCOURAGING APPROPRIATE USE OF ANTI-  
22 BIOTICS AND COMBATING RESISTANCE.**

23 “(a) ESTABLISHMENT OF HOSPITAL GRANT PRO-  
24 GRAM.—

1           “(1) IN GENERAL.—Not later than 1 year after  
2           the date of enactment of this part, the Secretary and  
3           the Director of the Centers for Disease Control and  
4           Prevention shall coordinate with the Administrator  
5           of the Health Resources and Services Administra-  
6           tion, the Administrator of the Centers for Medicare  
7           & Medicaid Services, the National Coordinator for  
8           Health Information Technology, and other relevant  
9           agencies, to establish a grant program under the  
10          Centers for Disease Control and Prevention to sup-  
11          port hospital and other inpatient facility efforts—

12                   “(A) to judiciously use antimicrobial drugs,  
13                   such as by establishing or implementing appro-  
14                   priate use programs, including infectious dis-  
15                   ease telehealth programs, using appropriate di-  
16                   agnostic tools, partnering with academic hos-  
17                   pitals, increasing health care-associated infec-  
18                   tion reporting, and monitoring antimicrobial re-  
19                   sistance; and

20                   “(B) to participate in the National  
21                   Healthcare Safety Network Antimicrobial Use  
22                   and Resistance Module or the Emerging Infec-  
23                   tions Program Healthcare-Associated Infections  
24                   Community Interface activity of the Centers for  
25                   Disease Control and Prevention or a similar re-

1           porting program, as specified by the Secretary,  
2           relating to antimicrobial drugs.

3           “(2) PRIORITIZATION.—In awarding grants  
4           under paragraph (1), the Secretary shall prioritize  
5           hospitals without an existing program to judiciously  
6           use antimicrobial drugs, subsection (d) hospitals (as  
7           defined in subparagraph (B) of section 1886(d)(2)  
8           of the Social Security Act that are located in rural  
9           areas (as defined in subparagraph (D) of such sec-  
10          tion), critical access hospitals (as defined in section  
11          1861(mm)(1) of such Act), hospitals serving Tribal-  
12          populations, and safety-net hospitals.

13          “(3) FUNDING.—Of the amounts appropriated  
14          under section 399SS, the Secretary shall reserve  
15          \$500,000,000 to carry out this subsection.

16          “(b) SURVEILLANCE AND REPORTING OF ANTIBIOTIC  
17          USE AND RESISTANCE.—

18                 “(1) IN GENERAL.—The Secretary, acting  
19                 through the Director of the Centers for Disease  
20                 Control and Prevention, shall use the National  
21                 Healthcare Safety Network and other appropriate  
22                 surveillance systems to assess—

23                         “(A) appropriate conditions, outcomes, and  
24                         measures causally related to antibacterial resist-  
25                         ance, including types of infections, the causes

1 for infections, and whether infections are ac-  
2 quired in a community or hospital setting, in-  
3 creased lengths of hospital stay, increased costs,  
4 and rates of mortality; and

5 “(B) changes in bacterial resistance to  
6 antimicrobial drugs in relation to patient out-  
7 comes, including changes in percent resistance,  
8 prevalence of antibiotic-resistant infections, and  
9 other such changes.

10 “(2) ANTIBIOTIC USE DATA.—The Secretary,  
11 acting through the Director of the Centers for Dis-  
12 ease Control and Prevention, shall work with Fed-  
13 eral agencies (including the Department of Veterans  
14 Affairs, the Department of Defense, the Department  
15 of Homeland Security, the Bureau of Prisons, the  
16 Indian Health Service, and the Centers for Medicare  
17 & Medicaid Services), private vendors, health care  
18 organizations, pharmacy benefit managers, and  
19 other entities as appropriate to obtain reliable and  
20 comparable human antibiotic drug consumption data  
21 (including, as available and appropriate, volume an-  
22 tibiotic distribution data and antibiotic use data, in-  
23 cluding prescription data) by State or metropolitan  
24 areas.

1           “(3) ANTIBIOTIC RESISTANCE TREND DATA.—

2           The Secretary, acting through the Director of the  
3           Centers for Disease Control and Prevention, shall in-  
4           tensify and expand efforts to collect antibiotic resist-  
5           ance data and encourage adoption of the Antibiotic  
6           Use and Resistance Module within the National  
7           Healthcare Safety Network among all health care fa-  
8           cilities across the continuum of care, including, as  
9           appropriate, acute care hospitals, dialysis facilities,  
10          nursing homes, ambulatory surgical centers, and  
11          other ambulatory health care settings in which anti-  
12          microbial drugs are routinely prescribed. The Sec-  
13          retary shall seek to collect such data from electronic  
14          medication administration reports and laboratory  
15          systems to produce the reports described in para-  
16          graph (4).

17          “(4) PUBLIC AVAILABILITY OF DATA.—The  
18          Secretary, acting through the Director of the Cen-  
19          ters for Disease Control and Prevention, shall, for  
20          the purposes of improving the monitoring of impor-  
21          tant trends in patient outcomes in relation to anti-  
22          bacterial resistance—

23                  “(A) make the data derived from surveil-  
24                  lance under this subsection publicly available

1 through reports issued on a regular basis that  
2 is not less than annually; and

3 “(B) examine opportunities to make such  
4 data available in near real time.

5 **“SEC. 399SS. APPROPRIATIONS.**

6 “(a) IN GENERAL.—To carry out this part, there are  
7 hereby appropriated to the Secretary, out of amounts in  
8 the Treasury not otherwise appropriated,  
9 \$11,000,000,000, for fiscal year 2022, to remain available  
10 until expended.

11 “(b) EMERGENCY DESIGNATION.—

12 “(1) IN GENERAL.—The amounts provided by  
13 this section are designated as an emergency require-  
14 ment pursuant to section 4(g) of the Statutory Pay-  
15 As-You-Go Act of 2010.

16 “(2) DESIGNATION IN SENATE.—In the Senate,  
17 this section is designated as an emergency require-  
18 ment pursuant to section 4112(a) of H. Con. Res.  
19 71 (115th Congress), the concurrent resolution on  
20 the budget for fiscal year 2018.

21 **“SEC. 399TT. STUDIES AND REPORTS.**

22 “(a) IN GENERAL.—Not later than 6 years after the  
23 date of enactment of this part, the Comptroller General  
24 of the United States shall complete a study on the effec-  
25 tiveness of this part in developing priority antimicrobial

1 drugs. Such study shall examine the indications for, usage  
2 of, development of resistance with respect to, and private  
3 and societal value of critical need antimicrobial drugs, and  
4 the impact of the programs under this part on patients  
5 and markets of critical need antimicrobial drugs. The  
6 Comptroller General shall report to the Committee on  
7 Health, Education, Labor, and Pensions of the Senate and  
8 the Committee on Energy and Commerce of the House  
9 of Representatives on the findings of such study.

10       “(b) ANTIBIOTIC USE IN THE UNITED STATES; AN-  
11 NUAL REPORTS.—The Director of the Centers for Disease  
12 Control and Prevention shall, each year, update the report  
13 entitled ‘Antibiotic Use in the United States’ to include  
14 updated information on progress and opportunities with  
15 respect to data, programs, and resources for prescribers  
16 to promote appropriate use of antimicrobial drugs.

17       “(c) REPORT ON ANTIMICROBIAL PROPHYLACTICS.—  
18 Not later than 3 years after the date of enactment of this  
19 part, the Director of the Centers for Disease Control and  
20 Prevention shall publish a report on antimicrobial prophyl-  
21 lactics.

22 **“SEC. 399UU. DEFINITIONS.**

23       “‘In this part—

24               “(1) the term ‘antimicrobial drug’—

1           “(A) means, subject to subparagraph (B),  
2           a product that is—

3                   “(i) a drug that directly inhibits rep-  
4                   lication of or kills bacteria or fungi rel-  
5                   evant to the proposed indication at con-  
6                   centrations likely to be attainable in hu-  
7                   mans to achieve the intended therapeutic  
8                   effect; or

9                   “(ii) a biological product that acts di-  
10                  rectly on bacteria or fungi or on the sub-  
11                  stances produced by such bacteria or fungi;  
12                  and

13               “(B) does not include—

14                   “(i) a drug that achieves the effect de-  
15                   scribed by subparagraph (A)(i) only at a  
16                   concentration that cannot reasonably be  
17                   studied in humans because of its antici-  
18                   pated toxicity; or

19                   “(ii) a vaccine; and

20               “(2) the term ‘Committee’ means the Com-  
21               mittee on Critical Need Antimicrobials established  
22               under section 39900.”.