

117TH CONGRESS
1ST SESSION

H. R. 3932

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

IN THE HOUSE OF REPRESENTATIVES

JUNE 16, 2021

Mr. MICHAEL F. DOYLE of Pennsylvania (for himself and Mr. FERGUSON) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, Veterans' Affairs, Armed Services, the Judiciary, and Homeland Security, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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 of 2021”.

1 **SEC. 2. DEVELOPING ANTIMICROBIAL INNOVATIONS.**

2 Title III of the Public Health Service Act (42 U.S.C.
3 241 et seq.) is amended by adding at the end the fol-
4 lowing:

5 **“PART W—DEVELOPING ANTIMICROBIAL**
6 **INNOVATIONS**

7 **“SEC. 3990O. ESTABLISHMENT OF COMMITTEE; SUBSCRIP-**
8 **TION MODEL; ADVISORY GROUP.**

9 “(a) IN GENERAL.—Not later than 60 days after the
10 date of enactment of this part, the Secretary shall estab-
11 lish a Committee on Critical Need Antimicrobials and ap-
12 point members to the Committee.

13 “(b) MEMBERS.—

14 “(1) IN GENERAL.—The Committee shall con-
15 sist of at least one representative from each of the
16 National Institute of Allergy and Infectious Dis-
17 eases, the Centers for Disease Control and Preven-
18 tion, the Biomedical Advanced Research and Devel-
19 opment Authority, the Food and Drug Administra-
20 tion, the Centers for Medicare & Medicaid Services,
21 the Veterans Health Administration, and the De-
22 partment of Defense.

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

1 “(c) DUTIES.—Not later than 1 year after the ap-
2 pointment of all initial members of the Committee, the
3 Secretary, in collaboration with the Committee, and in
4 consultation with the Critical Need Antimicrobials Advi-
5 sory Group established under subsection (g), shall do the
6 following:

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

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

1 infections described in paragraph (1), and estab-
2 lishing criteria for how each such characteristic will
3 adjust the monetary value of a subscription contract
4 awarded under subsection (f) or section 399QQ. The
5 favored characteristics shall be weighed for purposes
6 of such monetary value such that meeting certain
7 characteristics, or meeting more than one such char-
8 acteristic, increases the monetary value. Such fa-
9 vored characteristics of an antimicrobial drug shall
10 include—

11 “(A) treating infections on the list under
12 paragraph (1);

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

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

21 “(D) route of administration, especially
22 through oral administration;

23 “(E)(i) containing no active moiety (as de-
24 fined by the Secretary in section 314.3 of title
25 21, Code of Federal Regulations (or any suc-

1 cessor regulations)) that has been approved in
2 any other application under section 505(b) of
3 the Federal Food, Drug, and Cosmetic Act or
4 intending to be the subject of a new original
5 biologics license application under section
6 351(a);

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

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

16 “(F) addressing a multi-drug resistant in-
17 fection through a novel chemical scaffold or
18 mechanism of action;

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

21 “(H) any other characteristic the Sec-
22 retary, in collaboration with the Committee, de-
23 termines necessary.

24 “(d) REGULATIONS.—

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

5 “(A) a process by which the sponsors can
6 apply for an antimicrobial drug to become a
7 critical need antimicrobial drug under section
8 399PP;

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

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

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

19 “(2) DEVELOPMENT OF FINAL REGULA-
20 TIONS.—Before finalizing the regulations under
21 paragraph (1), the Secretary shall solicit public com-
22 ment and hold public meetings for the period begin-
23 ning on the date on which the proposed regulations
24 are issued and ending on the date that is 120 days
25 after such date of issuance. The Secretary shall fi-

1 nalize and publish such regulations not later than
2 120 days after the close of such period of public
3 comment and meetings.

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

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

19 “(f) TRANSITIONAL SUBSCRIPTION CONTRACTS.—

20 “(1) IN GENERAL.—Not earlier than 30 days
21 after the date of enactment of this part and ending
22 on the date that the Secretary finalizes the subscrip-
23 tion contract regulations under subsection (d), the
24 Secretary may use up to \$1,000,000,000 of the
25 amount appropriated under section 399SS(a) to en-

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

17 “(2) REQUIREMENTS.—

18 “(A) IN GENERAL.—The Secretary,
19 through the office described in paragraph (4),
20 may enter into a contract under paragraph
21 (1)—

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

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

3 “(ii) subject to terms including—

4 “(I) that the Secretary shall
5 cease any payment installments under
6 a transitional subscription contract if
7 the sponsor does not—

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

13 “(bb) identify, track, and
14 publicly report drug resistance
15 data and trends using available
16 data related to the antimicrobial
17 drug;

18 “(cc) develop and implement
19 education and communications
20 strategies, including communica-
21 tions for individuals with limited
22 English proficiency and individ-
23 uals with disabilities, for health
24 care professionals and patients

1 about appropriate use of the
2 antimicrobial drug;

3 “(dd) submit a plan for reg-
4 istering the antimicrobial drug in
5 additional countries where an
6 unmet medical need exists, which
7 such plan may be consistent with
8 the Stewardship and Access Plan
9 (SAP) Development Guide
10 (2021);

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

17 “(ff) make meaningful
18 progress toward completion of
19 Food and Drug Administration-
20 required postmarketing studies,
21 including such studies that are
22 evidence based; and

23 “(II) other terms as determined
24 by the Secretary; and

25 “(iii) if—

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

4 “(II) the antimicrobial drug has
5 been approved under section 505(c) of
6 the Federal Food, Drug, and Cos-
7 metic Act or licensed under section
8 351(a).

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

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

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

1 this part, the Secretary shall determine the agency
2 or office in the Department of Health and Human
3 Services that will manage the transitional subscrip-
4 tion contracts, including eligibility, requirements,
5 and contract amounts, during the period described
6 in paragraph (1).

7 “(g) CRITICAL NEED ANTIMICROBIAL ADVISORY
8 GROUP.—

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

16 “(2) MEMBERS.—The members of the Advisory
17 Group shall include—

18 “(A) not fewer than 6 individuals who
19 are—

20 “(i) infectious disease specialists; or

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

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

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

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

10 “(5) APPLICABILITY OF FACa.—Except as oth-
11 erwise provided in this subsection, the Federal Advi-
12 sory Committee Act shall apply to the Advisory
13 Group.

14 **“SEC. 399PP. CRITICAL NEED ANTIMICROBIAL DRUG APPLI-**
15 **CATION AND PAYMENT THROUGH SUBSCRIP-**
16 **TION CONTRACTS.**

17 “(a) IN GENERAL.—

18 “(1) SUBMISSION OF REQUEST.—The sponsor
19 of an application under section 505(b) of the Fed-
20 eral Food, Drug, and Cosmetic Act or section 351(a)
21 for an antimicrobial drug may request that the Sec-
22 retary designate the drug as a critical need anti-
23 microbial. A request for such designation may be
24 submitted after the Secretary grants for such drug
25 an investigational new drug exemption under section

1 505(i) of the Federal Food, Drug, and Cosmetic Act
2 or section 351(a)(3), and shall be submitted not
3 later than 5 years after the date of approval under
4 section 505(c) of the Federal Food, Drug, and Cos-
5 metic Act or licensure under section 351(a).

6 “(2) CONTENT OF REQUEST.—A request under
7 paragraph (1) shall include information, such as
8 clinical, preclinical and postmarketing data, a list of
9 the favorable characteristics described in section
10 39900(c)(2), and any other material that the Sec-
11 retary in consultation with the Committee requires.

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

1 that the drug meets the maximum value of the fa-
2 vored characteristics listed in the application.

3 “(4) LENGTH OF DESIGNATION PERIOD.—A
4 designation granted under this section shall be in ef-
5 fect for a period of 10 years after the date that the
6 designation is approved, and shall remain in effect
7 for such period even if the infection treated by such
8 drug is later removed from the list of infections
9 under section 39900(c)(1).

10 “(5) SUBSEQUENT REVIEWS.—No sooner than
11 2 years after a designation approval or denial under
12 subsection (3), the sponsor may request a subse-
13 quent review to re-evaluate the value of a contract
14 to include any new information.

15 “(b) DEVELOPMENT OF DESIGNATED DRUGS.—If a
16 critical need antimicrobial designation is granted during
17 clinical development of an antimicrobial drug, the Sec-
18 retary may work with the sponsor to maximize the oppor-
19 tunity for the sponsor to successfully demonstrate that the
20 antimicrobial drug possesses the favored characteristics of
21 high-monetary valued products identified under section
22 39900(c)(2).

23 “(c) APPROPRIATE USE OF CRITICAL NEED ANTI-
24 MICROBIAL.—

1 “(1) IN GENERAL.—The sponsor of an anti-
2 microbial drug that receives designation under sub-
3 section (a) shall within 90 days of such designation,
4 submit to the Secretary a plan for appropriate use
5 of diagnostics, in order for the Secretary and Com-
6 mittee to consider such plan in developing clinical
7 guidelines. An appropriate use plan—

8 “(A) shall include—

9 “(i) the appropriate use of the drug;

10 and

11 “(ii) the appropriate use of diagnostic
12 tools, where available, such as diagnostic
13 testing for biomarkers related to anti-
14 microbial-resistant pathogens, or other tar-
15 geted diagnostic approaches, to inform use
16 of the drug; and

17 “(B) may be developed in partnership with
18 the Secretary, infectious disease experts, diag-
19 nostic experts or developers, laboratory experts,
20 or another entity.

21 “(2) CONSULTATION.—The Secretary shall con-
22 sult with relevant professional societies and the Crit-
23 ical Need Antimicrobial Advisory Group established
24 under section 39900(g) to ensure that clinical
25 guidelines issued by the Secretary under paragraph

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

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

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

20 “(a) APPLICATION FOR A SUBSCRIPTION CON-
21 TRACT.—

22 “(1) SUBMISSION OF APPLICATIONS.—After ap-
23 proval under section 505(c) of the Federal Food,
24 Drug, and Cosmetic Act or licensure under section
25 351(a), the sponsor of an antimicrobial drug des-

1 ignated as a critical need antimicrobial under section
2 399PP may submit an application for a subscription
3 contract with the Secretary, under a procedure es-
4 tablished by the Secretary.

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

7 “(A) review all applications for subscrip-
8 tion contracts under paragraph (1) and assess
9 all required application components;

10 “(B) determine the extent to which the
11 critical need antimicrobial meets the favored
12 characteristics identified under section
13 399OO(c)(2), and deny any application for a
14 drug that meets none of such characteristics;
15 and

16 “(C) assign a monetary value to the con-
17 tract based on the regulations developed under
18 section 399OO(d).

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

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

1 first payment under the contract, and sufficient sup-
2 ply for susceptibility device manufacturers;

3 “(2) identify, track, and publicly report drug
4 resistance data and trends using available data re-
5 lated to the antimicrobial drug;

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

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

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

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

1 “(7) complete any postmarketing studies re-
2 quired by the Food and Drug Administration in a
3 timely manner;

4 “(8) produce the drug at a reasonable volume
5 determined with the Secretary to ensure patient ac-
6 cess to the drug;

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

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

14 “(11) abide by other terms as the Secretary
15 may require.

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

17 “(1) AMOUNTS.—A subscription contract under
18 this section shall be for the sale to the Secretary of
19 any quantity of the antimicrobial drug needed over
20 the term of the contract under paragraph (2), at an
21 agreed upon price, for a total projected amount de-
22 termined by the Secretary that is not less than
23 \$750,000,000 and not more than \$3,000,000,000,
24 adjusted for inflation, accounting for the favored
25 characteristics of the drug, as determined by the

1 Secretary, in consultation with the Committee, under
2 subsection (a)(2), and shall be allocated from the
3 amount made available under section 399SS(a). Not
4 later than 6 months after the subscription contract
5 is granted under subsection (a), the Secretary shall
6 provide payments for purchased drugs in install-
7 ments established by the Secretary in consultation
8 with the sponsor of the antimicrobial drug and in ac-
9 cordance with subsection (d)(3). Funds received by
10 the sponsor shall be used to support criteria quali-
11 fication under subsection (b), the completion of post-
12 marketing clinical studies, manufacturing, other pre-
13 clinical and clinical activities, or other activities
14 agreed to by the Secretary and sponsor in the con-
15 tract.

16 “(2) TERMS.—

17 “(A) INITIAL TERM.—The initial term of a
18 contract under this subsection shall be no less
19 than 5 years or greater than the greater of 10
20 years or the remaining period of time during
21 which the sponsor has patent protections or a
22 remaining exclusivity period with respect to the
23 antimicrobial drug in the United States, as list-
24 ed in the publication of the Food and Drug Ad-
25 ministration entitled ‘Approved Drug Products

1 with Therapeutic Equivalence Evaluations’.
2 Payments may be in equal annual installments
3 with the option to redeem 50 percent of the last
4 year’s reimbursement in year 1 of the contract
5 in order to offset costs of establishing manufac-
6 turing capacity, or another subscription ar-
7 rangement to which the Secretary and sponsor
8 agree. Subscription contracts shall remain in ef-
9 fect for such period even if the infection treated
10 by such antimicrobial drug is later removed
11 from the list of infections under section
12 39900(c)(1).

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

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

3 “(C) MODIFICATION OF CONTRACTS.—The
4 Secretary or sponsor, 1 year after the start of
5 the contract period under this subsection and
6 every 2 years thereafter, may request a modi-
7 fication of the amount of the contract based on
8 information that adjusts favored characteristics
9 in section 399OO(c)(2).

10 “(3) ADJUSTMENT.—In the case of an anti-
11 microbial drug that received a transitional subscrip-
12 tion contract under section 399OO(f), the amount of
13 a subscription contract for such drug under this sec-
14 tion shall be reduced by the amount of the transi-
15 tional subscription contract under such section
16 399OO(f) for such drug.

17 “(4) CONTRACTS FOR GENERIC AND BIO-
18 SIMILAR VERSIONS.—Notwithstanding any other
19 provision in this part, the Secretary may award a
20 subscription contract under this section to a manu-
21 facturer of a generic or biosimilar version of an anti-
22 microbial drug for which a subscription contract has
23 been awarded under this section. Such contracts
24 shall be awarded in accordance with a procedure, in-

1 including for determining the terms and amounts of
2 such contracts, established by the Secretary.

3 “(d) ANNUAL ANTIMICROBIAL DRUG SPONSOR REV-
4 ENUE LIMITATIONS.—

5 “(1) REPORTING REQUIREMENT.—

6 “(A) IN GENERAL.—Not later than a date
7 determined appropriate by the Secretary fol-
8 lowing the end of each calendar year, and not
9 earlier than 6 months after the end of each cal-
10 endar year, the head (or a designee of such
11 head) of each Federal agency carrying out a
12 specified government program shall, in accord-
13 ance with this paragraph, report to the Sub-
14 scription Contract Office established under sec-
15 tion 39900(d)(3) the total prescription drug
16 sales for each applicable antimicrobial drug
17 under contract with respect to such program for
18 such calendar year.

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

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

1 drug plans and Medicare Advantage pre-
2 scription drug plans, minus any per-unit
3 rebate, discount, or other price concession
4 provided by the sponsor of such applicable
5 antimicrobial drug, as reported to the Sec-
6 retary by the prescription drug plans and
7 the Medicare Advantage prescription drug
8 plans; and

9 “(ii) the number of units of such ap-
10 plicable antimicrobial drug paid for under
11 such part D.

12 “(C) MEDICARE PART B PROGRAM.—

13 “(i) IN GENERAL.—For purposes of
14 subparagraph (A), the Secretary shall re-
15 port, for each applicable antimicrobial drug
16 covered under part B of title XVIII of the
17 Social Security Act, the product of—

18 “(I) the per-unit average sales
19 price (as defined in section 1847A(c)
20 of such Act) or the per-unit payment
21 rate under such part B for a sepa-
22 rately paid prescription drug without
23 a reported average sales price; and

1 “(II) the number of units of such
2 applicable antimicrobial drug paid for
3 under such part B.

4 “(ii) UNITS AND ALLOCATED
5 PRICES.—The Secretary shall establish a
6 process for determining the units and the
7 allocated price for purposes of this sub-
8 paragraph for those applicable anti-
9 microbial drugs that are not separately
10 payable or for which National Drug Codes
11 are not reported.

12 “(D) MEDICARE PART A PROGRAM.—

13 “(i) IN GENERAL.—For purposes of
14 subparagraph (A), the Secretary shall re-
15 port, for each applicable antimicrobial drug
16 covered under part A of title XVIII of the
17 Social Security Act, the product of—

18 “(I) the per-unit price under
19 such part A for the antimicrobial
20 drug; and

21 “(II) the number of units of such
22 antimicrobial drug paid for under
23 such part A.

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

1 process for determining the units and the
2 allocated price for those prescription drugs
3 that are not separately payable or for
4 which National Drug Codes are not re-
5 ported in the diagnosis-related groups.

6 “(E) MEDICAID PROGRAM.—Under the au-
7 thority of section 1902(a)(6) of the Social Secu-
8 rity Act, the Secretary shall require each State
9 that makes medical assistance available under
10 the State plan under title XIX of such Act (or
11 any waiver of such plan) for an applicable anti-
12 microbial drug (including, if applicable, any
13 such drug which is a covered outpatient drug
14 under a rebate agreement entered into under
15 section 1927 of such Act) to report, in a form
16 consistent with a standard reporting format es-
17 tablished by the Secretary, not later than the
18 date determined under subparagraph (A)—

19 “(i) information on the total number
20 of units of each dosage form and strength
21 and package size of each applicable anti-
22 microbial drug dispensed during the pre-
23 ceding calendar year under such State plan
24 or waiver (including any such drugs dis-
25 pensed to an individual enrolled with a

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

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

8 “(I) the product of—

9 “(aa) the total number of
10 units dispensed under the State
11 plan or waiver during the pre-
12 ceding calendar year (as deter-
13 mined under clause (i)); and

14 “(bb) the per-unit ingredient
15 cost paid by the State for each
16 such unit; minus

17 “(II) any discounts or other price
18 concessions provided and rebates paid
19 to the State with respect to the dos-
20 age form and strength and package
21 size of such drug and such calendar
22 year (including rebates paid under a
23 rebate agreement under section 1927
24 of such Act and any State supple-

1 mental rebates paid under a supple-
2 mental rebate agreement).

3 “(F) DEPARTMENT OF VETERANS AF-
4 FAIRS.—For purposes of subparagraph (A), the
5 Secretary of Veterans Affairs shall report the
6 total amount paid for each applicable anti-
7 microbial drug procured by the Veterans Health
8 Administration for individuals who receive
9 health care from the Administration.

10 “(G) DEPARTMENT OF DEFENSE AND
11 TRICARE PROGRAM.—For purposes of subpara-
12 graph (A), the Secretary of Defense shall report
13 the sum of—

14 “(i) the total amount paid for each
15 applicable antimicrobial drug procured by
16 the Department of Defense for individuals
17 who receive health care from the Depart-
18 ment; and

19 “(ii) for each applicable antimicrobial
20 drug dispensed under the TRICARE retail
21 pharmacy program under section
22 1074g(a)(2)(E)(ii) of title 10, United
23 States Code, the product of—

24 “(I) the per-unit ingredient cost,
25 minus any per-unit rebate paid by the

1 sponsor of the applicable antimicrobial
2 drug; and

3 “(II) the number of units of such
4 applicable antimicrobial drug dis-
5 pensed under such program.

6 “(H) DEPARTMENT OF HOMELAND SECU-
7 RITY.—For purposes of subparagraph (A), the
8 Secretary of Homeland Security shall report the
9 total amount paid for each applicable anti-
10 microbial drug procured by the Department of
11 Homeland Security for individuals who receive
12 health care through a program carried out by
13 the Department.

14 “(I) BUREAU OF PRISONS.—For purposes
15 of subparagraph (A), the Director of the Bu-
16 reau of Prisons shall report the total amount
17 paid for each applicable antimicrobial drug pro-
18 cured by the Bureau of Prisons for individuals
19 who receive health care through the Bureau.

20 “(J) INDIAN HEALTH SERVICE.—For pur-
21 poses of subparagraph (A), the Secretary, act-
22 ing through the Indian Health Service, shall re-
23 port the total amount paid for each applicable
24 antimicrobial drug procured by the Service for

1 individuals who receive health care through the
2 Service.

3 “(2) REGULATIONS.—Not later than 1 year
4 after the date of enactment of this part, the Sec-
5 retary, in consultation with the heads of Federal
6 agencies carrying out specified government pro-
7 grams, shall issue regulations to assist such heads
8 (or their designees) in carrying out the requirements
9 under this section.

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

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

22 “(A) APPLICABLE ANTIMICROBIAL
23 DRUG.—The term ‘applicable antimicrobial
24 drug’ means an antimicrobial drug for which

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

3 “(B) SPECIFIED GOVERNMENT PRO-
4 GRAM.—The term ‘specified government pro-
5 gram’ means—

6 “(i) the Medicare part D program
7 under part D of title XVIII of the Social
8 Security Act;

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

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

13 “(iv) the Medicaid program estab-
14 lished under title XIX of the Social Secu-
15 rity Act and includes, with respect to a
16 State, any waiver in effect with respect to
17 such program;

18 “(v) any program under which pre-
19 scription drugs are procured by the De-
20 partment of Veterans Affairs;

21 “(vi) any program under which pre-
22 scription drugs are procured by the De-
23 partment of Defense;

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

4 “(viii) any program under which pre-
5 scription drugs are procured by the De-
6 partment of Homeland Security;

7 “(ix) any program under which pre-
8 scription drugs are procured by the Bu-
9 reau of Prisons; or

10 “(x) any program under which pre-
11 scription drugs are procured by the Indian
12 Health Service.

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

16 “(1) the sponsor—

17 “(A) permanently withdraws the anti-
18 microbial drug from the market in the United
19 States;

20 “(B) fails to meet criteria under subsection
21 (b); or

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

1 the Director of the Centers for Disease Control and
2 Prevention shall coordinate with the Administrator
3 of the Health Resources and Services Administra-
4 tion, the Administrator of the Centers for Medicare
5 & Medicaid Services, the National Coordinator for
6 Health Information Technology, and other relevant
7 agencies, to establish a grant program under the
8 Centers for Disease Control and Prevention to sup-
9 port hospital and other inpatient facility efforts—

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

18 “(B) to participate in the National
19 Healthcare Safety Network Antimicrobial Use
20 and Resistance Module or the Emerging Infec-
21 tions Program Healthcare-Associated Infections
22 Community Interface activity of the Centers for
23 Disease Control and Prevention or a similar re-
24 porting program, as specified by the Secretary,
25 relating to antimicrobial drugs.

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

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

14 “(b) SURVEILLANCE AND REPORTING OF ANTIBIOTIC
15 USE AND RESISTANCE.—

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

21 “(A) appropriate conditions, outcomes, and
22 measures causally related to antibacterial resist-
23 ance, including types of infections, the causes
24 for infections, and whether infections are ac-
25 quired in a community or hospital setting, in-

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

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

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

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

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

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

20 “(A) make the data derived from surveil-
21 lance under this subsection publicly available
22 through reports issued on a regular basis that
23 is not less than annually; and

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

1 **“SEC. 399SS. APPROPRIATIONS.**

2 “(a) IN GENERAL.—To carry out this part, there are
3 hereby appropriated to the Secretary, out of amounts in
4 the Treasury not otherwise appropriated,
5 \$11,000,000,000, for fiscal year 2022, to remain available
6 until expended.

7 “(b) EMERGENCY DESIGNATION.—

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

12 “(2) DESIGNATION IN SENATE.—In the Senate,
13 this section is designated as an emergency require-
14 ment pursuant to section 4112(a) of H. Con. Res.
15 71 (115th Congress), the concurrent resolution on
16 the budget for fiscal year 2018.

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

18 “(a) IN GENERAL.—Not later than 6 years after the
19 date of enactment of this part, the Comptroller General
20 of the United States shall complete a study on the effec-
21 tiveness of this part in developing priority antimicrobial
22 drugs. Such study shall examine the indications for, usage
23 of, development of resistance with respect to, and private
24 and societal value of critical need antimicrobial drugs, and
25 the impact of the programs under this part on patients
26 and markets of critical need antimicrobial drugs. The

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

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

12 “(c) REPORT ON ANTIMICROBIAL PROPHYLACTICS.—
13 Not later than 3 years after the date of enactment of this
14 part, the Director of the Centers for Disease Control and
15 Prevention shall publish a report on antimicrobial prophyl-
16 lactics.

17 **“SEC. 399UU. DEFINITIONS.**

18 “In this part—

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

20 “(A) means, subject to subparagraph (B),
21 a product that is—

22 “(i) a drug that directly inhibits rep-
23 lication of or kills bacteria or fungi rel-
24 evant to the proposed indication at con-
25 centrations likely to be attainable in hu-

1 mans to achieve the intended therapeutic
2 effect; or

3 “(ii) a biological product that acts di-
4 rectly on bacteria or fungi or on the sub-
5 stances produced by such bacteria or fungi;
6 and

7 “(B) does not include—

8 “(i) a drug that achieves the effect de-
9 scribed by subparagraph (A)(i) only at a
10 concentration that cannot reasonably be
11 studied in humans because of its antici-
12 pated toxicity; or

13 “(ii) a vaccine; and

14 “(2) the term ‘Committee’ means the Com-
15 mittee on Critical Need Antimicrobials established
16 under section 39900.”.

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