

[DISCUSSION DRAFT]117TH CONGRESS
1ST SESSION**H. R.** _____

To continue the acceleration of the discovery, development, and delivery of
21st century cures, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Ms. DEGETTE introduced the following bill; which was referred to the
Committee on _____

A BILL

To continue the acceleration of the discovery, development,
and delivery of 21st century cures, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Cures 2.0 Act”.

5 **SEC. 2. TABLE OF CONTENTS.**

6 The table of contents of this Act is as follows:

Sec. 1. Short title.

Sec. 2. Table of contents.

TITLE I—PUBLIC HEALTH

Sec. 101. Further understanding the implications of long COVID.

Sec. 102. National strategy to prevent and respond to pandemics.

- Sec. 103. Pandemic preparedness rare disease support program.
- Sec. 104. Vaccine and immunization programs.
- Sec. 105. Developing antimicrobial innovations.

TITLE II—PATIENTS AND CAREGIVERS

- Sec. 201. Educational programs and training for caregivers.
- Sec. 202. Increasing health literacy to promote better outcomes for patients.
- Sec. 203. Increasing diversity in clinical trials.
- Sec. 204. Patient experience data.
- Sec. 205. Ensuring coverage for clinical trials under existing standard of care.

TITLE III—FOOD AND DRUG ADMINISTRATION

- Sec. 301. Report on collaboration and alignment in regulating digital health technologies.
- Sec. 302. Grants for novel trial designs and other innovations in drug development.
- Sec. 303. FDA cell and gene therapy.
- Sec. 304. Increasing use of real world evidence.
- Sec. 305. Improving FDA-CMS communication regarding transformative new therapies.
- Sec. 306. Establishment of additional Intercenter Institutes at the Food and Drug Administration.
- Sec. 307. IND application not needed to initiate accelerated approval.
- Sec. 308. Guidance regarding development and submission of chemistry, manufacturing, and controls information for expedited approval.
- Sec. 309. Post-approval study requirements for accelerated approval.

TITLE IV—CENTERS FOR MEDICARE & MEDICAID SERVICES

- Sec. 401. GAO study and report.
- Sec. 402. Strategies to increase access to telehealth under Medicaid and Children's Health Insurance Program.
- Sec. 403. Extending Medicare telehealth flexibilities.
- Sec. 404. Coverage and payment for breakthrough devices under the medicare program.
- Sec. 405. Secretary of Health and Human Services report on coverage for innovative technologies.
- Sec. 406. Secretary of Health and Human Services report on CMS computer systems.
- Sec. 407. Expanding access to genetic testing.
- Sec. 408. Medicare coverage for precision medicine consultations.
- Sec. 409. Prohibiting the use of geographic tracking features and biometrics within Medicaid electronic visit verification systems.

TITLE I—RESEARCH

- Sec. 501. Advanced Research Projects Agency for Health [placeholder].
- Sec. 502. Research investment to spark the economy.

1 **TITLE I—PUBLIC HEALTH**

2 **SEC. 101. FURTHER UNDERSTANDING THE IMPLICATIONS**
3 **OF LONG COVID.**

4 (a) **SOURCES OF COVERAGE SURVEY.**—The Sec-
5 retary of Health and Human Services shall—

6 (1) conduct a large national survey of patients
7 who self-identify as having long COVID to assess
8 sources of health coverage, long-term care coverage,
9 and disability coverage for long COVID and related
10 symptoms; and

11 (2) not later than 6 months after the date of
12 enactment of this Act, complete such survey and
13 submit a report on the results of such survey to the
14 Committees on Energy and Commerce, Ways and
15 Means, and Education and Labor of the House of
16 Representatives and the Committees on Health,
17 Education, Labor, and Pensions and Finance of the
18 Senate.

19 (b) **LEARNING COLLABORATIVE.**—The Secretary of
20 Health and Human Services shall—

21 (1) convene a series of national virtual meetings
22 to serve as the basis of an ongoing long COVID
23 learning collaborative with individuals and organiza-
24 tions representing key sectors of the health care
25 community; and

1 (2) invite to participate in such meetings health
2 plan representatives, health care providers (including
3 hospitals, physicians, and nurses), medical and sci-
4 entific researchers, patient and consumer advocates,
5 data scientists, health care service providers, and de-
6 velopers of diagnostic and therapeutic products.

7 **SEC. 102. NATIONAL STRATEGY TO PREVENT AND RESPOND**
8 **TO PANDEMICS.**

9 (a) IN GENERAL.—Not later than 90 days after the
10 date of enactment of this Act, the President, acting
11 through the Secretary of Health and Human Services,
12 shall—

13 (1) develop and implement a national strategy
14 to prevent and respond to pandemics and other pub-
15 lic health emergencies for which a declaration is
16 made under section 319 of the Public Health Service
17 Act (42 U.S.C. 247d); and

18 (2) base such strategy on lessons learned, and
19 best practices developed, as a result of the COVID-
20 19 pandemic.

21 (b) CONTENTS.—The national strategy under sub-
22 section (a) shall at a minimum address each of the fol-
23 lowing:

24 (1) Strategies for testing (including point-of-
25 care testing and testing at nonmedical sites) to fos-

1 ter expedient results and personalized medical re-
2 sponses for patients and communities, including for
3 medically underserved populations.

4 (2) Methods of data sharing to use testing to
5 inform surveillance and other pandemic monitoring
6 and response efforts.

7 (3) Strategies to enable Americans to continue
8 to work, or return to work, safely.

9 (4) Modernizing and expanding domestic drug
10 manufacturing, including through the use of contin-
11 uous manufacturing.

12 (5) Developing and administering vaccines,
13 therapeutics, and other medical supplies.

14 **SEC. 103. PANDEMIC PREPAREDNESS RARE DISEASE SUP-**
15 **PORT PROGRAM.**

16 Subtitle B of title XXVIII of the Public Health Serv-
17 ice Act (42 U.S.C. 300hh–10 et seq.) is amended by in-
18 serting after section 2815 of such Act the following:

19 **“SEC. 2816. PANDEMIC PREPAREDNESS PLAN.**

20 “(a) IN GENERAL.—The Secretary, acting through
21 the Administrator of the Health Resources and Services
22 Administration and in collaboration with the Director of
23 the Centers for Disease Control and Prevention, shall
24 award grants to eligible organizations to develop a pan-
25 demic preparedness plan regarding—

1 “(1) the challenges faced by patients (served by
2 the respective eligible organizations) during the
3 COVID–19 pandemic;

4 “(2) potential challenges for the respective eligi-
5 ble organizations during future pandemics and other
6 public health emergencies;

7 “(3) how the respective eligible organizations
8 plan to overcome the challenges described in para-
9 graphs (1) and (2), including how the respective or-
10 ganizations plan to support patients, their families,
11 and health care providers to overcome such chal-
12 lenges; and

13 “(4) efforts to partner with local, State, and
14 Federal governments to promote a coordinated re-
15 sponse to future pandemics and other public health
16 emergencies.

17 “(b) PRIORITY.—In awarding grants under this sec-
18 tion, the Secretary shall give priority to eligible organiza-
19 tions that are rare disease or condition organizations.

20 “(c) DEFINITIONS.—In this section:

21 “(1) The term ‘eligible organization’ means an
22 organization that—

23 “(A) is described in section 501(c) of the
24 Internal Revenue Code of 1986 and exempt

1 from tax under section 501(a) of such Code;
2 and

3 “(B) provides support and other resources
4 to patients and their families for accessing and
5 paying for medical care.

6 “(2) The term ‘public health emergency’ means
7 a public health emergency declared under section
8 319.

9 “(3) The term ‘rare disease or condition’ has
10 the meaning given to such term in section 526(a) of
11 the Federal Food, Drug, and Cosmetic Act.

12 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
13 is authorized to be appropriated to carry out this section
14 \$25,000,000 for each of fiscal years 2022 through 2024.”.

15 **SEC. 104. VACCINE AND IMMUNIZATION PROGRAMS.**

16 (a) ADDITIONAL FUNDING FOR VACCINE AWARE-
17 NESS.—There are authorized to be appropriated to the
18 Centers for Disease Control and Prevention \$25,000,000
19 for each of fiscal years 2022 through 2024 for the purpose
20 of carrying out an awareness campaign to educate the
21 public with respect to the safety and importance of vac-
22 cines. The amounts authorized by the preceding sentence
23 are in addition to amounts otherwise available for such
24 purpose.

1 (b) STRENGTHENING THE IMMUNIZATION INFORMA-
2 TION SYSTEM.—There are authorized to be appropriated
3 to the Centers for Disease Control and Prevention
4 \$25,000,000 for each of fiscal years 2022 through 2024
5 for the purpose of strengthening immunization informa-
6 tion systems. The amounts authorized by the preceding
7 sentence are in addition to amounts otherwise available
8 for such purpose.

9 **SEC. 105. DEVELOPING ANTIMICROBIAL INNOVATIONS.**

10 Title III of the Public Health Service Act (42 U.S.C.
11 241 et seq.) is amended by adding at the end the fol-
12 lowing:

13 **“PART W—DEVELOPING ANTIMICROBIAL**
14 **INNOVATIONS**

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

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

21 “(b) MEMBERS.—

22 “(1) IN GENERAL.—The Committee shall con-
23 sist of at least one representative from each of the
24 National Institute of Allergy and Infectious Dis-
25 eases, the Centers for Disease Control and Preven-

1 tion, the Biomedical Advanced Research and Devel-
2 opment Authority, the Food and Drug Administra-
3 tion, the Centers for Medicare & Medicaid Services,
4 the Veterans Health Administration, and the De-
5 partment of Defense.

6 “(2) CHAIR.—The Secretary shall appoint one
7 of the members of the Committee to serve as the
8 Chair of the Committee.

9 “(c) DUTIES.—Not later than 1 year after the ap-
10 pointment of all initial members of the Committee, the
11 Secretary, in collaboration with the Committee, and in
12 consultation with the Critical Need Antimicrobials Advi-
13 sory Group established under subsection (g), shall do the
14 following:

15 “(1) Develop a list of infections for which new
16 antimicrobial drug development is needed, taking
17 into account organisms, sites of infection, and type
18 of infections for which there is an unmet medical
19 need, findings from the most recent report entitled
20 ‘Antibiotic Resistance Threats in the United States’
21 issued by the Centers for Disease Control and Pre-
22 vention, or an anticipated unmet medical need, in-
23 cluding a potential global health security threat. For
24 the list developed under this paragraph, the Sec-
25 retary, in collaboration with the Committee, may use

1 the infection list in such most recent report for up
2 to 3 years following the date of enactment of this
3 part and subsequently update the list under this
4 paragraph in accordance with subsection (e).

5 “(2) Develop regulations, in accordance with
6 subsection (d), outlining favored characteristics of
7 critical need antimicrobial drugs, that are evidence
8 based, clinically focused, and designed to treat the
9 infections described in paragraph (1), and estab-
10 lishing criteria for how each such characteristic will
11 adjust the monetary value of a subscription contract
12 awarded under subsection (f) or section 399QQ. The
13 favored characteristics shall be weighed for purposes
14 of such monetary value such that meeting certain
15 characteristics, or meeting more than one such char-
16 acteristic, increases the monetary value. Such fa-
17 vored characteristics of an antimicrobial drug shall
18 include—

19 “(A) treating infections on the list under
20 paragraph (1);

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

23 “(C) being a first-approved antimicrobial
24 drug that has the potential to address unmet
25 medical needs for the treatment of a serious or

1 life-threatening infection, and, to a lesser ex-
2 tent, second and third drugs that treat such in-
3 fections;

4 “(D) route of administration, especially
5 through oral administration;

6 “(E)(i) containing no active moiety (as de-
7 fined by the Secretary in section 314.3 of title
8 21, Code of Federal Regulations (or any suc-
9 cessor regulations)) that has been approved in
10 any other application under section 505(b) of
11 the Federal Food, Drug, and Cosmetic Act or
12 intending to be the subject of a new original
13 biologics license application under section
14 351(a);

15 “(ii) being a member of a new class of
16 drugs with a novel target and novel mode of ac-
17 tion that are distinctly different from the target
18 or mode of any antimicrobial drug approved
19 under section 505 of such Act or licensed under
20 section 351, including reduced toxicity;

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

1 “(F) addressing a multi-drug resistant in-
2 fection through a novel chemical scaffold or
3 mechanism of action;

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

6 “(H) any other characteristic the Sec-
7 retary, in collaboration with the Committee, de-
8 termines necessary.

9 “(d) REGULATIONS.—

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

14 “(A) a process by which the sponsors can
15 apply for an antimicrobial drug to become a
16 critical need antimicrobial drug under section
17 399PP;

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

20 “(C) the favored characteristics under sub-
21 section (c)(2), how such characteristics will be
22 weighed, and the minimum number and kind of
23 favored characteristics needed for an anti-
24 microbial drug to be designated a critical need
25 antimicrobial drug; and

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

3 “(2) DEVELOPMENT OF FINAL REGULA-
4 TIONS.—Before finalizing the regulations under
5 paragraph (1), the Secretary shall solicit public com-
6 ment and hold public meetings for the period begin-
7 ning on the date on which the proposed regulations
8 are issued and ending on the date that is 120 days
9 after such date of issuance. The Secretary shall fi-
10 nalize and publish such regulations not later than
11 120 days after the close of such period of public
12 comment and meetings.

13 “(3) SUBSCRIPTION CONTRACT OFFICE.—Not
14 later than 6 months after the date of enactment of
15 this part, the Secretary shall propose an agency or
16 office in the Department of Health and Human
17 Services to manage the establishment and payment
18 of subscription contracts awarded under section
19 399QQ, including eligibility, requirements, and con-
20 tract amounts. The Secretary shall solicit public
21 comment and finalize the agency or office no later
22 than 45 days following the proposed agency or of-
23 fice. Such agency or office shall be referred to as the
24 ‘Subscription Contract Office’.

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

4 “(f) TRANSITIONAL SUBSCRIPTION CONTRACTS.—

5 “(1) IN GENERAL.—Not earlier than 30 days
6 after the date of enactment of this part and ending
7 on the date that the Secretary finalizes the subscrip-
8 tion contract regulations under subsection (d), the
9 Secretary may use up to \$1,000,000,000 of the
10 amount appropriated under section 399SS(a) to en-
11 gage in transitional subscription contracts of up to
12 3 years in length with antimicrobial developers, as
13 determined by the Secretary, that have developed
14 antimicrobial drugs treating infections listed in the
15 most recent report entitled ‘Antibiotic Resistance
16 Threats in the United States’ issued by the Centers
17 for Disease Control and Prevention, and may include
18 antimicrobial drugs that are qualified infectious dis-
19 ease products (as defined in section 505E(g) of the
20 Federal Food, Drug, and Cosmetic Act), innovative
21 biological products, or innovative drugs that achieve
22 a clinical outcome through immunomodulation. Such
23 a contract may authorize the contractor to use funds
24 made available under the contract for completion of

1 postmarketing clinical studies, manufacturing, and
2 other preclinical and clinical efforts.

3 “(2) REQUIREMENTS.—

4 “(A) IN GENERAL.—The Secretary,
5 through the office described in paragraph (4),
6 may enter into a contract under paragraph
7 (1)—

8 “(i) if the Secretary determines that
9 the antimicrobial drug is intended to treat
10 an infection for which there is an unmet
11 clinical need, an anticipated clinical need,
12 or drug resistance;

13 “(ii) subject to terms including—

14 “(I) that the Secretary shall
15 cease any payment installments under
16 a transitional subscription contract if
17 the sponsor does not—

18 “(aa) ensure commercial and
19 Federal availability of the anti-
20 microbial drug within 30 days of
21 receiving first payment under the
22 contract;

23 “(bb) identify, track, and
24 publicly report drug resistance
25 data and trends using available

1 data related to the antimicrobial
2 drug;

3 “(cc) develop and implement
4 education and communications
5 strategies, including communica-
6 tions for individuals with limited
7 English proficiency and individ-
8 uals with disabilities, for health
9 care professionals and patients
10 about appropriate use of the
11 antimicrobial drug;

12 “(dd) submit a plan for reg-
13 istering the antimicrobial drug in
14 additional countries where an
15 unmet medical need exists, which
16 such plan may be consistent with
17 the Stewardship and Access Plan
18 (SAP) Development Guide
19 (2021);

20 “(ee) subject to subpara-
21 graph (B), ensure a reliable drug
22 supply chain, thus leading to an
23 interruption of the supply of the
24 antimicrobial drug in the United
25 States for more than 60 days; or

1 “(ff) make meaningful
2 progress toward completion of
3 Food and Drug Administration-
4 required postmarketing studies,
5 including such studies that are
6 evidence based; and

7 “(II) other terms as determined
8 by the Secretary; and

9 “(iii) if—

10 “(I) a phase 3 clinical study has
11 been initiated for the antimicrobial
12 drug; or

13 “(II) the antimicrobial drug has
14 been approved under section 505(c) of
15 the Federal Food, Drug, and Cos-
16 metic Act or licensed under section
17 351(a).

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

22 “(3) TRANSITIONAL GUIDANCE.—Not later
23 than 120 days after the appointment of the initial
24 members of the Committee, the Secretary shall
25 issue, in consultation with the Committee, transi-

1 tional guidance outlining the antimicrobial drugs
2 that are eligible for transitional subscription con-
3 tracts under paragraph (1), the requirements to
4 enter into a transitional subscription contract under
5 paragraph (2), and the process by which drug devel-
6 opers can enter into transitional subscription con-
7 tracts with the Secretary under this subsection.

8 “(4) PAYMENT OFFICE AND MECHANISM.—Not
9 later than 30 days after the date of enactment of
10 this part, the Secretary shall determine the agency
11 or office in the Department of Health and Human
12 Services that will manage the transitional subscrip-
13 tion contracts, including eligibility, requirements,
14 and contract amounts, during the period described
15 in paragraph (1).

16 “(g) CRITICAL NEED ANTIMICROBIAL ADVISORY
17 GROUP.—

18 “(1) IN GENERAL.—Not later than 30 days
19 after the appointment of all initial members of the
20 Committee, the Secretary, in collaboration with the
21 Committee, shall establish a Critical Need Anti-
22 microbial Advisory Group (referred to in this sub-
23 section as the ‘Advisory Group’) and appoint mem-
24 bers to the Advisory Group.

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

3 “(A) not fewer than 6 individuals who
4 are—

5 “(i) infectious disease specialists; or

6 “(ii) other health experts with exper-
7 tise in researching antimicrobial resistance,
8 health economics, or commercializing anti-
9 microbial drugs; and

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

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

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

20 “(5) APPLICABILITY OF FACa.—Except as oth-
21 erwise provided in this subsection, the Federal Advi-
22 sory Committee Act shall apply to the Advisory
23 Group.

1 **“SEC. 399PP. CRITICAL NEED ANTIMICROBIAL DRUG APPLI-**
2 **CATION AND PAYMENT THROUGH SUBSCRIP-**
3 **TION CONTRACTS.**

4 “(a) IN GENERAL.—

5 “(1) SUBMISSION OF REQUEST.—The sponsor
6 of an application under section 505(b) of the Fed-
7 eral Food, Drug, and Cosmetic Act or section 351(a)
8 for an antimicrobial drug may request that the Sec-
9 retary designate the drug as a critical need anti-
10 microbial. A request for such designation may be
11 submitted after the Secretary grants for such drug
12 an investigational new drug exemption under section
13 505(i) of the Federal Food, Drug, and Cosmetic Act
14 or section 351(a)(3), and shall be submitted not
15 later than 5 years after the date of approval under
16 section 505(c) of the Federal Food, Drug, and Cos-
17 metic Act or licensure under section 351(a).

18 “(2) CONTENT OF REQUEST.—A request under
19 paragraph (1) shall include information, such as
20 clinical, preclinical and postmarketing data, a list of
21 the favorable characteristics described in section
22 39900(c)(2), and any other material that the Sec-
23 retary in consultation with the Committee requires.

24 “(3) REVIEW BY SECRETARY.—The Secretary
25 shall promptly review all requests for designation
26 submitted under this subsection, assess all required

1 application components, and determine if the anti-
2 microbial drug is likely to meet the favorable charac-
3 teristics identified in the application upon the com-
4 pletion of clinical development. After review, the Sec-
5 retary shall approve or deny each request for des-
6 ignation not later than 90 days after receiving a re-
7 quest. If the Secretary approves a request, it shall
8 publish the value of the contract that the critical
9 need antimicrobial developer would be eligible to re-
10 ceive if such developer successfully demonstrates
11 that the drug meets the maximum value of the fa-
12 vored characteristics listed in the application.

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

20 “(5) SUBSEQUENT REVIEWS.—No sooner than
21 2 years after a designation approval or denial under
22 subsection (3), the sponsor may request a subse-
23 quent review to re-evaluate the value of a contract
24 to include any new information.

1 “(b) DEVELOPMENT OF DESIGNATED DRUGS.—If a
2 critical need antimicrobial designation is granted during
3 clinical development of an antimicrobial drug, the Sec-
4 retary may work with the sponsor to maximize the oppor-
5 tunity for the sponsor to successfully demonstrate that the
6 antimicrobial drug possesses the favored characteristics of
7 high-monetary valued products identified under section
8 39900(c)(2).

9 “(c) APPROPRIATE USE OF CRITICAL NEED ANTI-
10 MICROBIAL.—

11 “(1) IN GENERAL.—The sponsor of an anti-
12 microbial drug that receives designation under sub-
13 section (a) shall within 90 days of such designation,
14 submit to the Secretary a plan for appropriate use
15 of diagnostics, in order for the Secretary and Com-
16 mittee to consider such plan in developing clinical
17 guidelines. An appropriate use plan—

18 “(A) shall include—

19 “(i) the appropriate use of the drug;
20 and

21 “(ii) the appropriate use of diagnostic
22 tools, where available, such as diagnostic
23 testing for biomarkers related to anti-
24 microbial-resistant pathogens, or other tar-

1 geted diagnostic approaches, to inform use
2 of the drug; and

3 “(B) may be developed in partnership with
4 the Secretary, infectious disease experts, diag-
5 nostic experts or developers, laboratory experts,
6 or another entity.

7 “(2) CONSULTATION.—The Secretary shall con-
8 sult with relevant professional societies and the Crit-
9 ical Need Antimicrobial Advisory Group established
10 under section 39900(g) to ensure that clinical
11 guidelines issued by the Secretary under paragraph
12 (3), with respect to an antimicrobial drug designated
13 under subsection (a), includes the use of appropriate
14 diagnostic approaches, taking into consideration the
15 diagnostic plan submitted by a sponsor under para-
16 graph (1).

17 “(3) PUBLICATION OF CLINICAL GUIDELINES.—
18 Not later than 1 year after the Secretary makes the
19 first designation under subsection (a), and not less
20 than every 3 years thereafter, the Secretary shall
21 publish clinical guidelines in consultation with rel-
22 evant professional societies with respect to each anti-
23 microbial drug that has been approved or licensed as
24 described in subsection (a)(1) and that has been des-
25 ignated under subsection (a), which guidelines shall

1 set forth the evidence-based recommendations for
2 prescribing the drug, in accordance with the submis-
3 sions of the sponsor under paragraph (1) and after
4 consultation under paragraph (2), as appropriate.

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

6 “(a) APPLICATION FOR A SUBSCRIPTION CON-
7 TRACT.—

8 “(1) SUBMISSION OF APPLICATIONS.—After ap-
9 proval under section 505(c) of the Federal Food,
10 Drug, and Cosmetic Act or licensure under section
11 351(a), the sponsor of an antimicrobial drug des-
12 ignated as a critical need antimicrobial under section
13 399PP may submit an application for a subscription
14 contract with the Secretary, under a procedure es-
15 tablished by the Secretary.

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

18 “(A) review all applications for subscrip-
19 tion contracts under paragraph (1) and assess
20 all required application components;

21 “(B) determine the extent to which the
22 critical need antimicrobial meets the favored
23 characteristics identified under section
24 399OO(c)(2), and deny any application for a

1 drug that meets none of such characteristics;
2 and

3 “(C) assign a monetary value to the con-
4 tract based on the regulations developed under
5 section 39900(d).

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

10 “(1) ensure commercial and Federal availability
11 of the antimicrobial drug within 30 days of receiving
12 first payment under the contract, and sufficient sup-
13 ply for susceptibility device manufacturers;

14 “(2) identify, track, and publicly report drug
15 resistance data and trends using available data re-
16 lated to the antimicrobial drug;

17 “(3) develop and implement education and com-
18 munications strategies, including communications
19 for individuals with limited English proficiency and
20 individuals with disabilities, for health care profes-
21 sionals and patients about appropriate use of the
22 antimicrobial drug;

23 “(4) submit an appropriate use assessment to
24 the Secretary, Committee, Food and Drug Adminis-
25 tration, and Centers for Disease Control and Pre-

1 vention every 2 years regarding use of the anti-
2 microbial drug, including how the drug is being mar-
3 keted;

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

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

10 “(7) complete any postmarketing studies re-
11 quired by the Food and Drug Administration in a
12 timely manner;

13 “(8) produce the drug at a reasonable volume
14 determined with the Secretary to ensure patient ac-
15 cess to the drug;

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

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

23 “(11) abide by other terms as the Secretary
24 may require.

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

1 “(1) AMOUNTS.—A subscription contract under
2 this section shall be for the sale to the Secretary of
3 any quantity of the antimicrobial drug needed over
4 the term of the contract under paragraph (2), at an
5 agreed upon price, for a total projected amount de-
6 termined by the Secretary that is not less than
7 \$750,000,000 and not more than \$3,000,000,000,
8 adjusted for inflation, accounting for the favored
9 characteristics of the drug, as determined by the
10 Secretary, in consultation with the Committee, under
11 subsection (a)(2), and shall be allocated from the
12 amount made available under section 399SS(a). Not
13 later than 6 months after the subscription contract
14 is granted under subsection (a), the Secretary shall
15 provide payments for purchased drugs in install-
16 ments established by the Secretary in consultation
17 with the sponsor of the antimicrobial drug and in ac-
18 cordance with subsection (d)(3). Funds received by
19 the sponsor shall be used to support criteria quali-
20 fication under subsection (b), the completion of post-
21 marketing clinical studies, manufacturing, other pre-
22 clinical and clinical activities, or other activities
23 agreed to by the Secretary and sponsor in the con-
24 tract.

25 “(2) TERMS.—

1 “(A) INITIAL TERM.—The initial term of a
2 contract under this subsection shall be no less
3 than 5 years or greater than the greater of 10
4 years or the remaining period of time during
5 which the sponsor has patent protections or a
6 remaining exclusivity period with respect to the
7 antimicrobial drug in the United States, as list-
8 ed in the publication of the Food and Drug Ad-
9 ministration entitled ‘Approved Drug Products
10 with Therapeutic Equivalence Evaluations’.
11 Payments may be in equal annual installments
12 with the option to redeem 50 percent of the last
13 year’s reimbursement in year 1 of the contract
14 in order to offset costs of establishing manufac-
15 turing capacity, or another subscription ar-
16 rangement to which the Secretary and sponsor
17 agree. Subscription contracts shall remain in ef-
18 fect for such period even if the infection treated
19 by such antimicrobial drug is later removed
20 from the list of infections under section
21 39900(c)(1).

22 “(B) EXTENSION OF CONTRACTS.—The
23 Secretary may extend a subscription contract
24 with a sponsor under this subsection beyond the
25 initial contract period. A single contract exten-

1 sion may be in effect not later than the date on
2 which all periods of exclusivity granted by the
3 Food and Drug Administration expire and shall
4 be in an amount not to exceed \$25,000,000 per
5 year. All other terms of an extended contract
6 shall be the same as the terms of the initial
7 contract. The total amount of funding used on
8 such contract extensions shall be no more than
9 \$1,000,000,000, and shall be allocated from the
10 amount made available under section 399SS.

11 “(C) MODIFICATION OF CONTRACTS.—The
12 Secretary or sponsor, 1 year after the start of
13 the contract period under this subsection and
14 every 2 years thereafter, may request a modi-
15 fication of the amount of the contract based on
16 information that adjusts favored characteristics
17 in section 399OO(c)(2).

18 “(3) ADJUSTMENT.—In the case of an anti-
19 microbial drug that received a transitional subscrip-
20 tion contract under section 399OO(f), the amount of
21 a subscription contract for such drug under this sec-
22 tion shall be reduced by the amount of the transi-
23 tional subscription contract under such section
24 399OO(f) for such drug.

1 “(4) CONTRACTS FOR GENERIC AND BIO-
2 SIMILAR VERSIONS.—Notwithstanding any other
3 provision in this part, the Secretary may award a
4 subscription contract under this section to a manu-
5 facturer of a generic or biosimilar version of an anti-
6 microbial drug for which a subscription contract has
7 been awarded under this section. Such contracts
8 shall be awarded in accordance with a procedure, in-
9 cluding for determining the terms and amounts of
10 such contracts, established by the Secretary.

11 “(d) ANNUAL ANTIMICROBIAL DRUG SPONSOR REV-
12 ENUE LIMITATIONS.—

13 “(1) REPORTING REQUIREMENT.—

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

1 under contract with respect to such program for
2 such calendar year.

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

8 “(i) the per-unit ingredient cost, as
9 reported to the Secretary by prescription
10 drug plans and Medicare Advantage pre-
11 scription drug plans, minus any per-unit
12 rebate, discount, or other price concession
13 provided by the sponsor of such applicable
14 antimicrobial drug, as reported to the Sec-
15 retary by the prescription drug plans and
16 the Medicare Advantage prescription drug
17 plans; and

18 “(ii) the number of units of such ap-
19 plicable antimicrobial drug paid for under
20 such part D.

21 “(C) MEDICARE PART B PROGRAM.—

22 “(i) IN GENERAL.—For purposes of
23 subparagraph (A), the Secretary shall re-
24 port, for each applicable antimicrobial drug

1 covered under part B of title XVIII of the
2 Social Security Act, the product of—

3 “(I) the per-unit average sales
4 price (as defined in section 1847A(c)
5 of such Act) or the per-unit payment
6 rate under such part B for a sepa-
7 rately paid prescription drug without
8 a reported average sales price; and

9 “(II) the number of units of such
10 applicable antimicrobial drug paid for
11 under such part B.

12 “(ii) UNITS AND ALLOCATED
13 PRICES.—The Secretary shall establish a
14 process for determining the units and the
15 allocated price for purposes of this sub-
16 paragraph for those applicable anti-
17 microbial drugs that are not separately
18 payable or for which National Drug Codes
19 are not reported.

20 “(D) MEDICARE PART A PROGRAM.—

21 “(i) IN GENERAL.—For purposes of
22 subparagraph (A), the Secretary shall re-
23 port, for each applicable antimicrobial drug
24 covered under part A of title XVIII of the
25 Social Security Act, the product of—

1 “(I) the per-unit price under
2 such part A for the antimicrobial
3 drug; and

4 “(II) the number of units of such
5 antimicrobial drug paid for under
6 such part A.

7 “(ii) SPECIAL RULE.—For purposes of
8 clause (i), the Secretary shall establish a
9 process for determining the units and the
10 allocated price for those prescription drugs
11 that are not separately payable or for
12 which National Drug Codes are not re-
13 ported in the diagnosis-related groups.

14 “(E) MEDICAID PROGRAM.—Under the au-
15 thority of section 1902(a)(6) of the Social Secu-
16 rity Act, the Secretary shall require each State
17 that makes medical assistance available under
18 the State plan under title XIX of such Act (or
19 any waiver of such plan) for an applicable anti-
20 microbial drug (including, if applicable, any
21 such drug which is a covered outpatient drug
22 under a rebate agreement entered into under
23 section 1927 of such Act) to report, in a form
24 consistent with a standard reporting format es-

1 tablished by the Secretary, not later than the
2 date determined under subparagraph (A)—

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

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

17 “(I) the product of—

18 “(aa) the total number of
19 units dispensed under the State
20 plan or waiver during the pre-
21 ceding calendar year (as deter-
22 mined under clause (i)); and

23 “(bb) the per-unit ingredient
24 cost paid by the State for each
25 such unit; minus

1 “(II) any discounts or other price
2 concessions provided and rebates paid
3 to the State with respect to the dos-
4 age form and strength and package
5 size of such drug and such calendar
6 year (including rebates paid under a
7 rebate agreement under section 1927
8 of such Act and any State supple-
9 mental rebates paid under a supple-
10 mental rebate agreement).

11 “(F) DEPARTMENT OF VETERANS AF-
12 FAIRS.—For purposes of subparagraph (A), the
13 Secretary of Veterans Affairs shall report the
14 total amount paid for each applicable anti-
15 microbial drug procured by the Veterans Health
16 Administration for individuals who receive
17 health care from the Administration.

18 “(G) DEPARTMENT OF DEFENSE AND
19 TRICARE PROGRAM.—For purposes of subpara-
20 graph (A), the Secretary of Defense shall report
21 the sum of—

22 “(i) the total amount paid for each
23 applicable antimicrobial drug procured by
24 the Department of Defense for individuals

1 who receive health care from the Depart-
2 ment; and

3 “(ii) for each applicable antimicrobial
4 drug dispensed under the TRICARE retail
5 pharmacy program under section
6 1074g(a)(2)(E)(ii) of title 10, United
7 States Code, the product of—

8 “(I) the per-unit ingredient cost,
9 minus any per-unit rebate paid by the
10 sponsor of the applicable antimicrobial
11 drug; and

12 “(II) the number of units of such
13 applicable antimicrobial drug dis-
14 pensed under such program.

15 “(H) DEPARTMENT OF HOMELAND SECUR-
16 RITY.—For purposes of subparagraph (A), the
17 Secretary of Homeland Security shall report the
18 total amount paid for each applicable anti-
19 microbial drug procured by the Department of
20 Homeland Security for individuals who receive
21 health care through a program carried out by
22 the Department.

23 “(I) BUREAU OF PRISONS.—For purposes
24 of subparagraph (A), the Director of the Bu-
25 reau of Prisons shall report the total amount

1 paid for each applicable antimicrobial drug pro-
2 cured by the Bureau of Prisons for individuals
3 who receive health care through the Bureau.

4 “(J) INDIAN HEALTH SERVICE.—For pur-
5 poses of subparagraph (A), the Secretary, act-
6 ing through the Indian Health Service, shall re-
7 port the total amount paid for each applicable
8 antimicrobial drug procured by the Service for
9 individuals who receive health care through the
10 Service.

11 “(2) REGULATIONS.—Not later than 1 year
12 after the date of enactment of this part, the Sec-
13 retary, in consultation with the heads of Federal
14 agencies carrying out specified government pro-
15 grams, shall issue regulations to assist such heads
16 (or their designees) in carrying out the requirements
17 under this section.

18 “(3) SUBSCRIPTION CONTRACT ADJUSTMENT.—
19 Pursuant to the contract entered into under this sec-
20 tion with respect to an applicable antimicrobial drug,
21 for each year of the term of such contract, the Sec-
22 retary shall, not earlier than 6 months after the end
23 of each calendar year, subtract from the payment in-
24 stallments determined for such contract under sub-
25 section (c)(1) for such year the revenue of the spon-

1 sor of such drug from the previous year from sales
2 of the applicable antimicrobial drug reported under
3 paragraph (1) for specified government programs.

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

5 “(A) APPLICABLE ANTIMICROBIAL
6 DRUG.—The term ‘applicable antimicrobial
7 drug’ means an antimicrobial drug for which
8 the sponsor of such drug receives a subscription
9 contract under subsection (a).

10 “(B) SPECIFIED GOVERNMENT PRO-
11 GRAM.—The term ‘specified government pro-
12 gram’ means—

13 “(i) the Medicare part D program
14 under part D of title XVIII of the Social
15 Security Act;

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

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

20 “(iv) the Medicaid program estab-
21 lished under title XIX of the Social Secu-
22 rity Act and includes, with respect to a
23 State, any waiver in effect with respect to
24 such program;

1 “(v) any program under which pre-
2 scription drugs are procured by the De-
3 partment of Veterans Affairs;

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

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

10 “(viii) any program under which pre-
11 scription drugs are procured by the De-
12 partment of Homeland Security;

13 “(ix) any program under which pre-
14 scription drugs are procured by the Bu-
15 reau of Prisons; or

16 “(x) any program under which pre-
17 scription drugs are procured by the Indian
18 Health Service.

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

22 “(1) the sponsor—

23 “(A) permanently withdraws the anti-
24 microbial drug from the market in the United
25 States;

1 “(B) fails to meet criteria under subsection
2 (b); or

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

6 “(2) the annual international and private insur-
7 ance market revenues with respect to an anti-
8 microbial drug (not counting any subscription reve-
9 nues from any source pursuant to a contract under
10 this section or other international or private entities)
11 exceed 5 times the average annual amount of the
12 subscription contract paid by the Secretary as cer-
13 tified by the sponsor annually; or

14 “(3) if the total revenue of the sponsor from
15 specified government programs, as defined in sub-
16 section (d)(4), for a year exceeds the amount of the
17 subscription contract paid by the Secretary for that
18 year.

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

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

3 “(a) ESTABLISHMENT OF HOSPITAL GRANT PRO-
4 GRAM.—

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

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

24 “(B) to participate in the National
25 Healthcare Safety Network Antimicrobial Use
26 and Resistance Module or the Emerging Infec-

1 tions Program Healthcare-Associated Infections
2 Community Interface activity of the Centers for
3 Disease Control and Prevention or a similar re-
4 porting program, as specified by the Secretary,
5 relating to antimicrobial drugs.

6 “(2) PRIORITIZATION.—In awarding grants
7 under paragraph (1), the Secretary shall prioritize
8 hospitals without an existing program to judiciously
9 use antimicrobial drugs, subsection (d) hospitals (as
10 defined in subparagraph (B) of section 1886(d)(2)
11 of the Social Security Act that are located in rural
12 areas (as defined in subparagraph (D) of such sec-
13 tion), critical access hospitals (as defined in section
14 1861(mm)(1) of such Act), hospitals serving Tribal-
15 populations, and safety-net hospitals.

16 “(3) FUNDING.—Of the amounts appropriated
17 under section 399SS, the Secretary shall reserve
18 \$500,000,000 to carry out this subsection.

19 “(b) SURVEILLANCE AND REPORTING OF ANTIBIOTIC
20 USE AND RESISTANCE.—

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

1 “(A) appropriate conditions, outcomes, and
2 measures causally related to antibacterial resist-
3 ance, including types of infections, the causes
4 for infections, and whether infections are ac-
5 quired in a community or hospital setting, in-
6 creased lengths of hospital stay, increased costs,
7 and rates of mortality; and

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

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

1 cluding prescription data) by State or metropolitan
2 areas.

3 “(3) ANTIBIOTIC RESISTANCE TREND DATA.—

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

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

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

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

7 **“SEC. 399SS. APPROPRIATIONS.**

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

13 “(b) EMERGENCY DESIGNATION.—

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

18 “(2) DESIGNATION IN SENATE.—In the Senate,
19 this section is designated as an emergency require-
20 ment pursuant to section 4112(a) of H. Con. Res.
21 71 (115th Congress), the concurrent resolution on
22 the budget for fiscal year 2018.

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

24 “(a) IN GENERAL.—Not later than 6 years after the
25 date of enactment of this part, the Comptroller General

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

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

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

24 **“SEC. 399UU. DEFINITIONS.**

25 “In this part—

1 “(1) the term ‘antimicrobial drug’—

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

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

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

14 “(B) does not include—

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

20 “(ii) a vaccine; and

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

1 **TITLE II—PATIENTS AND**
2 **CAREGIVERS**

3 **SEC. 201. EDUCATIONAL PROGRAMS AND TRAINING FOR**
4 **CAREGIVERS.**

5 Part D of title VII of the Public Health Service Act
6 (42 U.S.C. 294 et seq.) is amended by adding at the end
7 the following:

8 **“SEC. 760A. EDUCATIONAL PROGRAMS AND TRAINING FOR**
9 **CAREGIVERS.**

10 “(a) IN GENERAL.—The Secretary may award grants
11 for educational programs and training for caregivers to
12 learn skills to allow them—

13 “(1) to augment a care team; and

14 “(2) to complement, not compete with, a clin-
15 ical visit.

16 “(b) TYPES OF PROGRAMS AND TRAINING.—Edu-
17 cational programs and training funded under subsection
18 (a) may include—

19 “(1) specialized training in medication adher-
20 ence and injections;

21 “(2) complementary strategies to ensure adher-
22 ence to physical and occupational therapy regimens;
23 and

24 “(3) nutritional compliance; and

25 “(4) other services provided in the home.

1 “(c) DEFINITION.—In this section, the term ‘care-
2 giver’ means an individual who takes care of an aging,
3 seriously ill, or disabled family member or friend.

4 “(d) AUTHORIZATION OF APPROPRIATIONS.—To
5 carry out this section, there is authorized to be appro-
6 priated \$25,000,000 for each of fiscal years 2022 through
7 2024.”.

8 **SEC. 202. INCREASING HEALTH LITERACY TO PROMOTE**
9 **BETTER OUTCOMES FOR PATIENTS.**

10 Not later than one year after the date of the enact-
11 ment of this Act, the Secretary of Health and Human
12 Services, acting through the Administrator of the Centers
13 for Medicare & Medicaid Services, shall issue a request
14 for information to solicit recommendations on ways the
15 Centers for Medicare & Medicaid Services can work with
16 Federal health care program (as defined in section
17 1128B(f) of the Social Security Act (42 U.S.C. 1320a-
18 7b)) stakeholders to promote increased patient health lit-
19 eracy, including recommendations for—

20 (1) identifying culturally competent, evidence-
21 based interventions that have been proven to im-
22 prove health literacy in populations served by such
23 programs;

24 (2) identifying evidence-based health literacy
25 approaches that can be used by the Medicare pro-

1 gram under title XVIII of the Social Security Act,
2 Medicaid State plans under title XIX of such Act,
3 or health care providers participating in such pro-
4 gram or plans and that—

5 (A) have been proven to, or show promise
6 to, reduce costs to individuals enrolled under
7 such program or receiving medical assistance
8 under such plans, respectively, and reduce ex-
9 penditures under such respective title; or

10 (B) have been proven to increase patient
11 satisfaction or improve the quality of care for
12 at-risk populations, including holistic and non-
13 medication-based forms of care;

14 (3) how the Centers for Medicare & Medicaid
15 Services can encourage the use of evidence-based
16 health literacy interventions through payment poli-
17 cies under the Medicare program under title XVIII
18 of the Social Security Act or Medicaid program
19 under title XIX of such Act; and

20 (4) improving patient health literacy with re-
21 spect to health insurance, including an under-
22 standing of in-network providers, deductibles, co-in-
23 surance, co-payments, and differences between
24 payors.

1 **SEC. 203. INCREASING DIVERSITY IN CLINICAL TRIALS.**

2 (a) UPDATED REPORTING ON INCLUSION OF DEMO-
3 GRAPHIC SUBGROUPS.—The Secretary of Health and
4 Human Services, acting through the Commissioner of
5 Food and Drugs, shall—

6 (1) not later than 90 days after the date of en-
7 actment of this Act, submit to the Food and Drug
8 Administration, and provide to the Congress, an up-
9 dated version of the report under section 907(a) of
10 the Food and Drug Administration Safety and Inno-
11 vation Act (Public Law 115–52); and

12 (2) not later than 1 year after the publication
13 of the updated report pursuant to paragraph (1),
14 publish on the website of the Food and Drug Ad-
15 ministration, and provide to the Congress, an up-
16 dated version of the action plan under section
17 907(b) of such Act.

18 (b) GAO STUDY ON BARRIERS TO PARTICIPATION.—
19 Not later than 1 year after the date of enactment of this
20 Act, the Comptroller General of the United States shall—

21 (1) complete a study—

22 (A) to review how the Department of
23 Health and Human Services addresses barriers
24 to participation by individuals from underrep-
25 resented populations in conducting or sup-
26 porting clinical trials; and

1 (B) to formulate recommendations for ad-
2 dressing such barriers; and

3 (2) submit a report to the Congress on the re-
4 sults of such study.

5 (c) PUBLIC AWARENESS CAMPAIGN.—The Secretary
6 of Health and Human Services shall—

7 (1) carry out a public awareness campaign to
8 increase awareness and understanding, particularly
9 in minority communities, of—

10 (A) upcoming and ongoing clinical trials;

11 (B) how to enroll as subjects in such clin-
12 ical trials; and

13 (C) the availability of databases and other
14 resources relevant to clinical trial enrollment,
15 such as ClinicalTrials.gov; and

16 (2) in carrying out such campaign, utilize a va-
17 riety of communication channels, including through
18 use of the explanation of Medicare benefits under
19 section 1806 of the Social Security Act (42 U.S.C.
20 1395b–7).

21 (d) TASK FORCE FOR MAKING CLINICALTRIALS.GOV
22 MORE USER-FRIENDLY.—

23 (1) IN GENERAL.—The Secretary of Health and
24 Human Services shall convene a permanent task
25 force to propose, on a biennial basis, recommenda-

1 tions for improving ClinicalTrials.gov by making it
2 more user-friendly, including for patients.

3 (2) MEMBERSHIP.—The membership of the
4 task force shall include representatives of—

5 (A) the National Institutes of Health;

6 (B) the Food and Drug Administration;

7 (C) academic researchers; and

8 (D) patient organizations.

9 (e) DEFINITION.—In this section, the term
10 “ClinicalTrials.gov” refers to the data bank described in
11 section 402(i) of the Public Health Service Act (42 U.S.C.
12 282(i)).

13 **SEC. 204. PATIENT EXPERIENCE DATA.**

14 (a) POLICY.—Section 569C of the Federal Food,
15 Drug, and Cosmetic Act (21 U.S.C. 360bbb–8c) is amend-
16 ed—

17 (1) by redesignating subsections (b) and (c) as
18 subsections (c) and (d), respectively; and

19 (2) by inserting after subsection (a) the fol-
20 lowing new subsection:

21 “(b) COLLECTION, SUBMISSION, AND USE OF
22 DATA.—

23 “(1) IN GENERAL.—The Secretary shall—

24 “(A) for any drug for which an exemption
25 is granted for investigational use under section

1 505(i) of this Act or section 351(a) of the Pub-
2 lic Health Service Act, require the sponsor of
3 the drug to collect standardized patient experi-
4 ence data as part of the clinical trials conducted
5 pursuant to such exemption;

6 “(B) require any application for the ap-
7 proval or licensing of such drug under section
8 505(b) of this Act or section 351(a) of the Pub-
9 lic Health Service Act to include—

10 “(i) the standardized patient experi-
11 ence data so collected; and

12 “(ii) such related information as the
13 Secretary may require; and

14 “(C) consider patient experience data and
15 related information that is submitted pursuant
16 to subparagraph (B) in deciding whether to ap-
17 prove or license, as applicable, the drug in-
18 volved.

19 “(2) APPLICABILITY.—Paragraph (1) applies
20 only with respect to drugs for which a request for
21 an exemption described in paragraph (1)(A) is sub-
22 mitted on or after the date of enactment of the
23 Cures 2.0 Act, or an application under section
24 505(b) of this Act or section 351(a) of the Public
25 Health Service Act is filed, as applicable, on or after

1 the day that is 1 year after the date of enactment
2 of the Cures 2.0 Act.”.

3 (b) REGULATIONS.—Not later than 1 year after the
4 date of enactment of this Act, the Secretary of Health and
5 Human Services, acting through the Commissioner of
6 Food and Drugs, shall promulgate final regulations to im-
7 plement section 569C(b) of the Federal Food, Drug, and
8 Cosmetic Act, as added by this section.

9 **SEC. 205. ENSURING COVERAGE FOR CLINICAL TRIALS**
10 **UNDER EXISTING STANDARD OF CARE.**

11 (a) REVISION TO DEFINITION OF APPROVED CLIN-
12 ICAL TRIAL IN INDIVIDUAL AND GROUP MARKET.—

13 (1) IN GENERAL.—Subsection (d)(1) of the first
14 section 2709 of the Public Health Service Act (42
15 U.S.C. 300gg–8) (relating to coverage for individ-
16 uals participating in approved clinical trials) is
17 amended by adding at the end the following new
18 subparagraph:

19 “(D) The study or investigation is ap-
20 proved or funded (which may include funding
21 through in-kind contributions) by the Patient
22 Centered Outcomes Research Institute estab-
23 lished under section 1181 of the Social Security
24 Act.”.

1 (2) EFFECTIVE DATE.—The amendment made
2 by this paragraph shall apply with respect to plan
3 years beginning on or after January 1, 2022.

4 (b) MEDICARE COVERAGE OF ROUTINE COSTS ASSO-
5 CIATED WITH CERTAIN CLINICAL TRIALS.—

6 (1) IN GENERAL.—Section 1862(m)(2) of the
7 Social Security Act (42 U.S.C.1395y(m)(2)) is
8 amended, in the matter preceding subparagraph (A),
9 by inserting “(including a trial funded by the Pa-
10 tient Centered Outcomes Research Institute estab-
11 lished under section 1181)” after “means a trial”.

12 (2) EFFECTIVE DATE.—The amendment made
13 by this paragraph shall apply with respect to items
14 and services furnished on or after the date of the en-
15 actment of this Act.

16 **TITLE III—FOOD AND DRUG** 17 **ADMINISTRATION**

18 **SEC. 301. REPORT ON COLLABORATION AND ALIGNMENT IN** 19 **REGULATING DIGITAL HEALTH TECH-** 20 **NOLOGIES.**

21 (a) IN GENERAL.—Not later than 1 year after the
22 date of enactment of this Act, the Secretary of Health and
23 Human Services, acting through the Commissioner of
24 Food and Drugs, shall submit a report to the Congress
25 on the efforts to ensure collaboration and alignment across

1 the centers and offices of the Food and Drug Administra-
2 tion with respect to the regulation of digital health tech-
3 nologies.

4 (b) CONTENTS.— The report under subsection (a)
5 shall include a description of the following:

6 (1) How the Commissioner of Food and Drugs
7 and the heads of the centers and offices of the Food
8 and Drug Administration collaborate in regulating
9 digital health technologies, including recommenda-
10 tions with respect to—

11 (A) the use of digital endpoints for regu-
12 latory review, including the validation and qual-
13 ification of digital endpoints and digital bio-
14 markers;

15 (B) the acceptance of decentralized trials;

16 (C) the use of digital health technologies in
17 patient-focused development of products; and

18 (D) the use and validation of digital health
19 technology tools;

20 (2) How the Food and Drug Administration co-
21 ordinates with foreign regulators to ensure harmoni-
22 zation on the regulation and use of digital health
23 technologies.

24 (c) DEFINITION.—In this section, the term “digital
25 health technologies” includes those technologies in health

1 care or society that help deliver or provide access to health
2 care products and services such as hardware (for example,
3 wearable sensors, virtual reality headsets, and digitally-en-
4 abled drug delivery devices), advanced analytics (for exam-
5 ple, artificial intelligence, machine learning, and sophisti-
6 cated computation), cloud services (for example, storage,
7 computing, and data processing), and software (for exam-
8 ple, mobile medical applications, and software as a medical
9 device).

10 **SEC. 302. GRANTS FOR NOVEL TRIAL DESIGNS AND OTHER**
11 **INNOVATIONS IN DRUG DEVELOPMENT.**

12 (a) IN GENERAL.—The Secretary of Health and
13 Human Services, acting through the Commissioner of
14 Food and Drugs, shall award grants for—

15 (1) incorporating complex adaptive and other
16 novel trial designs into clinical protocols and applica-
17 tions for drugs pursuant to an exemption for inves-
18 tigational use under section 505(i) of the Federal
19 Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) or
20 section 351(a) of the Public Health Service Act (42
21 U.S.C. 262(a)); and

22 (2) the collection of patient experience data
23 with respect to drugs and the use of such data and
24 related information in drug development.

1 (b) PRIORITIZATION.—In awarding grants under this
2 section, the Secretary shall prioritize the incorporation of
3 digital health technologies and real world evidence in drug
4 development.

5 (c) DEFINITIONS.—In this section:

6 (1) The term “digital health technologies” has
7 the meaning given to such term in section 301.

8 (2) The term “patient experience data” has the
9 meaning given to such term by section 569C(d) of
10 the Federal Food, Drug, and Cosmetic Act, as re-
11 designated by section 204 of this Act.

12 (3) The term “real world evidence” has the
13 meaning given to that term in section 505F of the
14 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
15 355g).

16 (d) AUTHORIZATION OF APPROPRIATIONS.—To carry
17 out this section, there is authorized to be appropriated
18 \$25,000,000 for each of fiscal years 2022 through 2024.

19 **SEC. 303. FDA CELL AND GENE THERAPY.**

20 Not later than 1 year after the date of enactment
21 of this Act, the Secretary of Health and Human Services,
22 acting through the Commissioner of Food and Drugs,
23 shall submit a report to the Congress on the following:

1 (1) The foreseeable challenges to the Food and
2 Drug Administration with respect to cell and gene
3 therapies during the next ten years.

4 (2) How the Food and Drug Administration
5 will address these challenges.

6 (3) The additional resources and authorities the
7 Food and Drug Administration needs to address
8 these challenges.

9 (4) The current state of cell and gene therapies
10 regulation by the Food and Drug Administration, in-
11 cluding—

12 (A) the amount and nature of the submis-
13 sions filed with the Food and Drug Administra-
14 tion;

15 (B) the status of such applications in the
16 review process; and

17 (C) the therapeutic areas intended to be
18 addressed by the products that are subject to
19 such applications.

20 **SEC. 304. INCREASING USE OF REAL WORLD EVIDENCE.**

21 (a) GUIDANCE.—

22 (1) ISSUANCE.—Not later than 6 months after
23 the date of enactment of this Act, the Secretary of
24 Health and Human Services (in this section referred
25 to as the “Secretary”) shall issue guidance on the

1 use of real world evidence in evaluating the safety
2 and effectiveness of drugs subsequent to the ap-
3 proval or licensing of such drugs pursuant to sub-
4 section (a), (b), or (c) of section 506 of the Federal
5 Food, Drug, and Cosmetic Act (21 U.S.C. 356) as
6 a breakthrough therapy, a fast track product, or a
7 product considered for accelerated approval.

8 (2) CONSIDERATIONS.—The guidance under
9 paragraph (1) shall take into consideration each of
10 the following:

11 (A) Special and underrepresented popu-
12 lations.

13 (B) Acceptable endpoints and outcomes
14 measures.

15 (C) Data quality standards.

16 (D) Data transparency requirements.

17 (E) Study design considerations.

18 (b) HHS IDENTIFICATION AND IMPLEMENTATION OF
19 APPROACHES.—

20 (1) IDENTIFICATION.—Consistent with the
21 framework established under 505F of the Federal
22 Food, Drug, and Cosmetic Act (21 U.S.C. 355g),
23 the Secretary of Health and Human Services shall,
24 by not later than 1 year after the date of enactment
25 of this Act—

1 (A) identify consistent, clear approaches
2 for the Department of Health and Human
3 Services to use real world evidence (as defined
4 in such section 505F)—

5 (i) in conducting and supporting re-
6 search; and

7 (ii) in regulating, purchasing, and
8 supporting the purchase of health care
9 products and services;

10 (B) include in such approaches rec-
11 ommendations for any additional statutory au-
12 thorities needed;

13 (C) publish such approaches in the Federal
14 Register; and

15 (D) submit a report to the Congress on
16 such approaches.

17 (2) IMPLEMENTATION.—Upon publication
18 under paragraph (1) of the approaches identified
19 pursuant to such paragraph, consistent with the au-
20 thorities vested in the Department of Health and
21 Human Services by other provisions of law, the Sec-
22 retary take such actions as may be appropriate to
23 implement the approaches identified pursuant to
24 paragraph (1).

25 (c) REAL WORLD EVIDENCE TASK FORCE.—

1 (1) ESTABLISHMENT.—The Secretary shall es-
2 tablish a permanent task force, to be known as the
3 Real World Evidence Task Force (in this subsection
4 referred to as the “Task Force”) to coordinate the
5 programs and activities of the Department of Health
6 and Human Services with regard to the collection
7 and use of real world evidence.

8 (2) MEMBERSHIP.—The members of the Task
9 Force shall include the following:

10 (A) The Secretary (or the Secretary’s des-
11 ignee), who shall serve as the Chair of the Task
12 Force.

13 (B) The Administrator of the Centers for
14 Medicare & Medicaid Services (or the Adminis-
15 trator’s designee).

16 (C) The Commissioner of Food and Drugs
17 (or the Commissioner’s designee).

18 (D) The Director of the National Insti-
19 tutes of Health (or the Director’s designee).

20 (E) Such additional Federal officials (or
21 their designees) as the Secretary determines ap-
22 propriate.

23 (F) Private sector representatives, to be
24 appointed by the Secretary.

1 (3) RECOMMENDATIONS.—In carrying para-
2 graph (1), the Task Force shall—

3 (A) develop and periodically update rec-
4 ommendations on ways to encourage patients
5 to—

6 (i) engage in the generation of real
7 world evidence; and

8 (ii) participate in postapproval clinical
9 trials for the collection of real world evi-
10 dence; and

11 (B) not later than 2 years after the date
12 of enactment of this Act, and every 2 years
13 thereafter, submit a report to the Congress on
14 such recommendations.

15 **SEC. 305. IMPROVING FDA-CMS COMMUNICATION REGARD-**
16 **ING TRANSFORMATIVE NEW THERAPIES.**

17 Upon the designation of a product as a breakthrough
18 therapy, a fast track product, or a product eligible for ac-
19 celerated approval under subsection (a), (b), or (c), respec-
20 tively, of section 506 of the Federal Food, Drug, and Cos-
21 metic Act (21 U.S.C. 356), the Commissioner of Food and
22 Drugs and the Administrator of the Centers for Medicare
23 & Medicaid Services shall—

1 (1) maintain communication with each other re-
2 garding approval and coverage decisions with respect
3 to such product; and

4 (2) share such information with each other as
5 may be appropriate to inform and coordinate such
6 decisions.

7 **SEC. 306. ESTABLISHMENT OF ADDITIONAL INTERCENTER**
8 **INSTITUTES AT THE FOOD AND DRUG ADMIN-**
9 **ISTRATION.**

10 (a) **ESTABLISHMENT.**—Subsection (c) of section
11 1014 of the Federal Food, Drug, and Cosmetic Act (21
12 U.S.C. 399g(e)) is amended to read as follows:

13 “(c) **TIMING.**—Not later than the date that is one
14 year after the date of enactment of the Cures 2.0 Act or
15 the end of the coronavirus disease 2019 (COVID–19) pan-
16 demic public health emergency under section 319 of the
17 Public Health Service Act, whichever is later, the Sec-
18 retary shall establish, in accordance with this section, at
19 least two additional Institutes under subsection (a).”.

20 (b) **CRITERIA.**—In establishing the focus of the two
21 Institutes referenced in the amendment made by sub-
22 section (a), the Secretary of Health and Human Services
23 shall ensure the following:

24 (1) One of the Institutes focuses on a group of
25 diseases meeting the following criteria:

1 (A) Negatively affects at least one major
2 body system.

3 (B) Represents a major disease burden in
4 the United States.

5 (C) Represents a leading cause of mor-
6 tality or disability in the United States.

7 (D) According to the National Institutes of
8 Health, affects at least an estimated
9 50,000,000 Americans each year.

10 (E) Contributes to increasing health care
11 (personal, familial, private sector, and govern-
12 mental) expenditures and impacts the United
13 States economy as a whole.

14 (F) For which the SARS-CoV-2 virus ex-
15 acerbates symptoms or causes serious complica-
16 tions.

17 (G) For which medical products are ap-
18 proved by the Food and Drug Administration
19 at a much lower rate than products for other
20 disease areas, including in abbreviated path-
21 ways.

22 (2) One of the Institutes focuses on a group of
23 diseases meeting the following criteria:

24 (A) Affects, individually, fewer than
25 200,000 people in the United States.

1 (B) Over 90 percent of such diseases have
2 no therapy approved by the Food and Drug Ad-
3 ministration.

4 (C) Affects, in total, over 30,000,000
5 Americans.

6 (D) Over 50 percent of patients are chil-
7 dren.

8 (c) REPORT ON INTERCENTER INSTITUTES.—Not
9 later than 2 years after the date of enactment of this Act,
10 and annually thereafter, the Secretary of Health and
11 Human Services, acting through the Commissioner of
12 Food and Drugs, shall submit a report to the Committee
13 on Energy and Commerce of the House of Representatives
14 and the Committee on Health, Education, Labor, and
15 Pensions of the Senate on the activities of the Institutes
16 established pursuant to this section.

17 **SEC. 307. IND APPLICATION NOT NEEDED TO INITIATE AC-**
18 **CELERATED APPROVAL.**

19 (a) BREAKTHROUGH THERAPIES.—Section
20 506(a)(2) of the Federal Food, Drug, and Cosmetic Act
21 (21 U.S.C. 356(a)(2)) is amended by striking “A request
22 for the designation may be made concurrently with, or at
23 any time after, the submission of an application for the
24 investigation of the drug under section 505(i) or section
25 351(a)(3) of the Public Health Service Act” and inserting

1 “A request for the designation may be made at any point
2 before or after submission of an application for approval
3 of the drug under section 505(b) of this Act or licensure
4 of the drug under section 351(a)(2) of the Public Health
5 Service Act and shall include clinical evidence, including
6 preliminary clinical evidence from clinical trials conducted
7 outside of the United States”.

8 (b) REGENERATIVE ADVANCED THERAPIES.—Sec-
9 tion 506(g)(3) of the Federal Food, Drug, and Cosmetic
10 Act (21 U.S.C. 356(g)(3)) is amended by striking “con-
11 currently with, or at any time after, submission of an ap-
12 plication for the investigation of the drug under section
13 505(i) of this Act or section 351(a)(3) of the Public
14 Health Service Act” and inserting “at any point before
15 or after submission of an application for approval of the
16 drug under section 505(b) of this Act or licensure of the
17 drug under section 351(a)(2) of the Public Health Service
18 Act and shall include clinical evidence, including prelimi-
19 nary clinical evidence from clinical trials conducted outside
20 of the United States”.

1 **SEC. 308. GUIDANCE REGARDING DEVELOPMENT AND SUB-**
2 **MISSION OF CHEMISTRY, MANUFACTURING,**
3 **AND CONTROLS INFORMATION FOR EXPE-**
4 **DITED APPROVAL.**

5 (a) IN GENERAL.—The Secretary of Health and
6 Human Services shall—

7 (1) not later than 6 months after the date of
8 enactment of this Act, issue draft revised guidance
9 to provide clarity regarding the development and
10 submission of chemistry, manufacturing, and con-
11 trols information for purposes of subsections (a),
12 (b), (c), and (g) of section 506 of the Federal Food,
13 Drug, and Cosmetic Act (21 U.S.C. 356; relating to
14 breakthrough therapies, fast track products, acceler-
15 ated approval, and regenerative advanced therapies);
16 and

17 (2) not later than 90 days after the close of a
18 period of public comment on such draft guidance, fi-
19 nalize the guidance.

20 (b) CONTENTS.—The guidance under subsection (a)
21 shall address—

22 (1) how the Food and Drug Administration will
23 determine how, and by when, chemistry, manufac-
24 turing, and controls information is required to be
25 submitted throughout development and during the

1 pre- and post-approval phases, taking into consider-
2 ation—

3 (A) how such determinations will reflect
4 the risks and benefits of such information given
5 the seriousness or life-threatening nature of the
6 disease the product is intended to diagnose,
7 cure, mitigate, treat, or prevent;

8 (B) the phase and expedited nature of de-
9 velopment; and

10 (C) the availability of relevant data and in-
11 formation from nonclinical and clinical studies,
12 product applications, and post-approval over-
13 sight; and

14 (2) how the Food and Drug Administration will
15 provide ongoing advice and opportunities for spon-
16 sors to interact with the Food and Drug Administra-
17 tion on, and how the Food and Drug Administration
18 will facilitate, the submission of chemistry, manufac-
19 turing, and controls information throughout the life
20 cycle of the product.

21 **SEC. 309. POST-APPROVAL STUDY REQUIREMENTS FOR AC-**
22 **CELERATED APPROVAL.**

23 Section 506(c)(2)(A) of the Federal Food, Drug, and
24 Cosmetic Act (21 U.S.C. 356(c)(2)(A)) is amended after
25 “studies” by inserting “, or otherwise submit clinical evi-

1 dence, patient registries, or other sources of real world evi-
2 dence.”.

3 **TITLE IV—CENTERS FOR MEDI-**
4 **CARE & MEDICAID SERVICES**

5 **SEC. 401. GAO STUDY AND REPORT.**

6 Not later than one year after the date of the enact-
7 ment of this Act, the Comptroller General of the United
8 States shall submit to Congress a report on recommenda-
9 tions for administrative actions that may be taken by the
10 Secretary of Health and Human Services (as well as rec-
11 ommendations for legislative changes needed) to—

12 (1) enhance coverage and reimbursement ap-
13 proaches under the Medicare program under title
14 XVIII of the Social Security Act for innovative tech-
15 nologies that increase access to health care, improve
16 health care quality, decrease expenditures under
17 such program, or otherwise improve the Medicare
18 program or health care for beneficiaries under such
19 program; and

20 (2) better harmonize and integrate the oper-
21 ating structure of the Medicare program (and the
22 Centers for Medicare & Medicaid Services) to im-
23 prove interagency collaboration and communication.

1 **SEC. 402. STRATEGIES TO INCREASE ACCESS TO TELE-**
2 **HEALTH UNDER MEDICAID AND CHILDREN'S**
3 **HEALTH INSURANCE PROGRAM.**

4 (a) GUIDANCE.—Not later than one year after the
5 date of the enactment of this Act, the Secretary of Health
6 and Human Services shall issue and disseminate guidance
7 to States to clarify strategies to overcome existing barriers
8 and increase access to telehealth under the Medicaid pro-
9 gram under title XIX of the Social Security Act (42
10 U.S.C. 1396 et seq.) and the Children's Health Insurance
11 Program under title XXI of such Act (42 U.S.C. 1397aa
12 et seq.). Such guidance shall include technical assistance
13 and best practices regarding—

14 (1) existing strategies States can use to inte-
15 grate telehealth and other virtual health care serv-
16 ices into value-based health care models; and

17 (2) examples of States that have used waivers
18 under the Medicaid program to test expanded access
19 to telehealth, including during the emergency period
20 described in section 1135(g)(1)(B) of the Social Se-
21 curity Act (42 U.S.C. 1320b-5(g)(1)(B)).

22 (b) STUDIES.—

23 (1) TELEHEALTH IMPACT ON HEALTH CARE
24 ACCESS.—Not later than one year after the date of
25 the enactment of this Act, the Medicaid and CHIP
26 Payment and Access Commission shall conduct a

1 study, with respect to a minimum of 10 States
2 across geographic regions of the United States, and
3 submit to Congress a report, on the impact of tele-
4 health on health care access, utilization, cost, and
5 outcomes, broken down by race, ethnicity, sex, age,
6 disability status, and zip code. Such report shall—

7 (A) evaluate cost, access, utilization, out-
8 comes, and patient experience data from across
9 the health care field, including States, Medicaid
10 managed care organizations, provider organiza-
11 tions, and other organizations that provide or
12 pay for telehealth under the Medicaid program
13 and Children’s Health Insurance Program;

14 (B) identify barriers and potential solu-
15 tions to provider entry and participation in tele-
16 health that States are experiencing, as well as
17 barriers to providing telehealth across State
18 lines, including during times of public health
19 crisis or public health emergency;

20 (C) determine the frequency at which out-
21 of-State telehealth is provided to patients en-
22 rolled in the Medicaid program and the poten-
23 tial impact on access to telehealth if State Med-
24 icaid policies were more aligned; and

1 (D) identify and evaluate opportunities for
2 more alignment among such policies to promote
3 access to telehealth across all States, State
4 Medicaid plans under title XIX of the Social
5 Security Act (42 U.S.C. 1396 et seq.), State
6 child health plans under title XXI of such Act
7 (42 U.S.C. 1397aa et seq.), and Medicaid man-
8 aged care organizations, including the potential
9 for regional compacts or reciprocity agreements.

10 (2) FEDERAL AGENCY TELEHEALTH COLLABO-
11 RATION.—Not later than 1 year after the date of the
12 enactment of this Act, the Comptroller General of
13 the United States shall conduct a study and submit
14 to Congress a report evaluating collaboration be-
15 tween Federal agencies with respect to telehealth
16 services furnished under the Medicaid or CHIP pro-
17 gram to individuals under the age of 18, including
18 such services furnished to such individuals in early
19 care and education settings. Such report shall in-
20 clude recommendations on—

21 (A) opportunities for Federal agencies to
22 improve collaboration with respect to such tele-
23 health services; and

24 (B) opportunities for collaboration between
25 Federal agencies to expand telehealth access to

1 such individuals enrolled under the Medicaid or
2 CHIP program, including in early care and
3 education settings.

4 **SEC. 403. EXTENDING MEDICARE TELEHEALTH FLEXIBILI-**
5 **TIES.**

6 (a) **EXPANDING ACCESS TO TELEHEALTH SERV-**
7 **ICES.—**

8 (1) **IN GENERAL.—**Section 1834(m)(4)(C) of
9 the Social Security Act (42 U.S.C. 1395m(m)(4)(C))
10 is amended by adding at the end the following new
11 clause:

12 “(iii) **EXPANDING ACCESS TO TELE-**
13 **HEALTH SERVICES.—**With respect to tele-
14 health services furnished beginning on the
15 first day after the end of the emergency
16 period described in section 1135(g)(1)(B)
17 of this clause, the term ‘originating site’
18 means any site at which the eligible tele-
19 health individual is located at the time the
20 service is furnished via a telecommuni-
21 cations system, including the home of an
22 individual.”.

23 (2) **CONFORMING AMENDMENTS.—**Such section
24 is amended—

25 (A) in paragraph (2)(B)—

1 (i) in clause (i), in the matter pre-
2 ceding subclause (I), by striking “clause
3 (ii)” and inserting “clauses (ii) and (iii)”;
4 and

5 (ii) by adding at the end the following
6 new clause:

7 “(iii) NO FACILITY FEE FOR NEW
8 SITES.—With respect to telehealth services
9 furnished on or after the date of enact-
10 ment of this clause, a facility fee shall only
11 be paid under this subparagraph to an
12 originating site that is described in para-
13 graph (4)(C)(ii) (other than subclause (X)
14 of such paragraph).”;

15 (B) in paragraph (4)(C)—

16 (i) in clause (i), in the matter pre-
17 ceding subclause (I), by inserting “and
18 clause (iii)” after “and (7)”;

19 (ii) in clause (ii)(X), by inserting
20 “prior to the first day after the end of the
21 emergency period described in section
22 1135(g)(1)(B)” before the period;

23 (C) in paragraph (5), by inserting “and
24 prior to the first day after the end of the emer-

1 gency period described in section
2 1135(g)(1)(B)” after “January 1, 2019,”;

3 (D) in paragraph (6)(A), by inserting “and
4 prior to the first day after the end of the emer-
5 gency period described in section
6 1135(g)(1)(B),” after “January 1, 2019,”; and

7 (E) in paragraph (7), by adding at the end
8 the following new subparagraph:

9 “(C) SUNSET.—The provisions of this
10 paragraph shall not apply with respect to serv-
11 ices furnished on or after the first day after the
12 end of the emergency period described in sec-
13 tion 1135(g)(1)(B).”.

14 (b) EXPANDING PRACTITIONERS ELIGIBLE TO FUR-
15 NISH TELEHEALTH SERVICES.—Section 1834(m) of the
16 Social Security Act (42 U.S.C. 1395m(m)) is amended—

17 (1) in paragraph (1), by striking “(described in
18 section 1842(b)(18)(C))” and inserting “(defined in
19 paragraph (4)(E))”; and

20 (2) in paragraph (4)(E)—

21 (A) by striking “PRACTITIONER.—The
22 term” and inserting “PRACTITIONER.—

23 “(A) IN GENERAL.—Subject to subpara-
24 graph (B), the term”; and

1 (B) by adding at the end the following new
2 subparagraph:

3 “(B) EXPANSION.—The Secretary, after
4 consulting with stakeholders regarding services
5 that are clinically appropriate, may expand the
6 types of practitioners who may furnish tele-
7 health services to include any health care pro-
8 fessional that is eligible to bill the program
9 under this title for their professional services.”.

10 (c) RETENTION OF ADDITIONAL SERVICES AND SUB-
11 REGULATORY PROCESS FOR MODIFICATIONS FOLLOWING
12 EMERGENCY PERIOD.—Section 1834(m)(4)(F) of the So-
13 cial Security Act (42 U.S.C. 1395m(m)(4)(F)) is amend-
14 ed—

15 (1) in clause (i), by inserting “and clause (iii)”
16 after “paragraph (8)”;

17 (2) in clause (ii), by striking “The Secretary”
18 and inserting “Subject to clause (iii), the Sec-
19 retary”; and

20 (3) by adding at the end the following new
21 clause:

22 “(iii) RETENTION OF ADDITIONAL
23 SERVICES AND SUBREGULATORY PROCESS
24 FOR MODIFICATIONS FOLLOWING EMER-
25 GENCY PERIOD.—With respect to tele-

1 health services furnished after the last day
2 of the emergency period described in sec-
3 tion 1135(g)(1)(B), the Secretary may—

4 “(I) retain as appropriate the ex-
5 panded list of telehealth services spec-
6 ified in clause (i) pursuant to the
7 waiver authority under section
8 1135(b)(8) during such emergency pe-
9 riod; and

10 “(II) retain the subregulatory
11 process used to modify the services in-
12 cluded on the list of such telehealth
13 services pursuant to clause (ii) during
14 such emergency period.”.

15 (d) ENHANCING TELEHEALTH SERVICES FOR FED-
16 ERALLY QUALIFIED HEALTH CENTERS AND RURAL
17 HEALTH CLINICS.—Section 1834(m)(8) of the Social Se-
18 curity Act (42 U.S.C. 1395m(m)(8)) is amended—

19 (1) in the paragraph heading by inserting “AND
20 AFTER” after “DURING”;

21 (2) in subparagraph (A), in the matter pre-
22 ceding clause (i), by inserting “and after” after
23 “During”; and

24 (3) in the first sentence of subparagraph (B)(i),
25 by inserting “and after” after “during”.

1 (e) USE OF TELEHEALTH, AS CLINICALLY APPRO-
2 PRIATE, TO CONDUCT FACE-TO-FACE ENCOUNTER FOR
3 HOSPICE CARE.—Section 1814(a)(7)(D)(i)(II) of the So-
4 cial Security Act (42 U.S.C. 1395f(a)(7)(D)(i)(II)) is
5 amended by inserting “and after such emergency period
6 as clinically appropriate” after “1135(g)(1)(B)”.

7 (f) USE OF TELEHEALTH, AS CLINICALLY APPRO-
8 PRIATE, TO CONDUCT FACE-TO-FACE CLINICAL ASSESS-
9 MENTS FOR HOME DIALYSIS.—Clause (iii) of section
10 1881(b)(3)(B) of the Social Security Act (42 U.S.C.
11 1395rr(b)(3)(B)) is amended—

12 (1) by moving such clause 4 ems to the left;

13 and

14 (2) by inserting “and after such emergency pe-
15 riod as clinically appropriate” before the period.

16 (g) IMPLEMENTATION.—Notwithstanding any provi-
17 sion of law, the Secretary may implement the provisions
18 of, and amendments made by, this section by interim final
19 rule, program instruction, or otherwise.

20 **SEC. 404. COVERAGE AND PAYMENT FOR BREAKTHROUGH**
21 **DEVICES UNDER THE MEDICARE PROGRAM.**

22 (a) IN GENERAL.—Part E of title XVIII of the Social
23 Security Act (42 U.S.C. 1395x et seq.) is amended by add-
24 ing at the end the following new section:

1 **“SEC. 1899C. COVERAGE OF BREAKTHROUGH DEVICES.**

2 “(a) BREAKTHROUGH DEVICES.—For purposes of
3 this section, the term ‘breakthrough device’ means a med-
4 ical device that is a device (as defined in section 201 of
5 the Federal Food, Drug, and Cosmetic Act) and that is—

6 “(1) provided with review priority by the Sec-
7 retary under subsection (d)(5) of section 515 of such
8 Act; and

9 “(2) approved or cleared pursuant to section
10 510(k), 513(f), or 515 of such Act for use in treat-
11 ing an indication on or after March 15, 2021.

12 Such term also includes a breakthrough device that is a
13 specified breakthrough device (as defined in subsection
14 (e)(1)(B)) approved or cleared pursuant to section 510(k),
15 513(f), or 515 of such Act for use in treating an indication
16 on or after March 15, 2021.

17 “(b) COVERAGE.—

18 “(1) TRANSITIONAL COVERAGE.—

19 “(A) IN GENERAL.—During the transi-
20 tional coverage period (as defined in subpara-
21 graph (B)) a breakthrough device shall be—

22 “(i) deemed to be reasonable and nec-
23 essary for purposes of section
24 1862(a)(1)(A);

25 “(ii) deemed to be approved for an ad-
26 ditional payment under section

1 1886(d)(5)(K) (other than with respect to
2 the cost criterion under clause (ii)(I) of
3 such section);

4 “(iii) deemed to be approved for pass-
5 through payment under section 1833(t)(6)
6 and section 1833(i) (other than with re-
7 spect to the cost criterion under section
8 1833(t)(6)(A)(iv)); and

9 “(iv) insofar as such breakthrough de-
10 vice may be furnished in a setting for
11 which payment is made under an applica-
12 ble payment system described in subpara-
13 graphs (D) through (I) of subsection
14 (c)(4), deemed eligible for an additional
15 payment or payment adjustment, as the
16 case may be, pursuant to subsection (d)(3)
17 when furnished in a setting for which pay-
18 ment is made under such an applicable
19 payment system during such transitional
20 coverage period.

21 “(B) TRANSITIONAL COVERAGE PERIOD
22 DEFINED.—As used in this section, the term
23 ‘transitional coverage period’ means, with re-
24 spect to a breakthrough device, the period
25 that—

1 “(i) begins on the date of the approval
2 under section 515 of the Federal Food,
3 Drug, and Cosmetic Act or of the clear-
4 ance under section 510(k) of such Act, as
5 applicable, of such device by the Secretary
6 for the indication described in subsection
7 (a)(1); and

8 “(ii) ends on the last day of the 4-
9 year period that begins on the date that
10 the Secretary, pursuant to subsection
11 (c)(2), updates the relevant applicable pay-
12 ment system (as defined in subsection
13 (c)(4)) to recognize the unique temporary
14 or permanent code or codes assigned under
15 subsection (c)(1) to such breakthrough de-
16 vice, except as provided in subsections
17 (d)(1)(B) and (d)(2)(B).

18 “(C) DATA USED TO MEET THE NTAP AND
19 PASS-THROUGH COST CRITERIA.—In deter-
20 mining whether a breakthrough device qualifies
21 for an additional payment under section
22 1886(d)(5)(K) or for pass-through payment
23 under section 1833(t)(6) or section 1833(i), the
24 Secretary shall use the most recently available
25 data and information on the costs of such

1 breakthrough device, which may include list
2 prices and invoice prices charged for such
3 breakthrough device.

4 “(2) PROCESS FOR REGULAR COVERAGE.—For
5 purposes of the application of section 1862(a)(1)(A)
6 to a breakthrough device furnished after the transi-
7 tional coverage period (as defined in paragraph
8 (1)(B)) for such device, the Secretary shall establish
9 a process for the coverage of such breakthrough de-
10 vices under this title after such period as follows:

11 “(A) IDENTIFICATION OF ADDITIONAL EVI-
12 DENCE.—

13 “(i) IN GENERAL.—With respect to a
14 breakthrough device, not later than 1 year
15 after the date of the approval of such de-
16 vice under section 515 of the Federal
17 Food, Drug, and Cosmetic Act or of the
18 clearance of such device under section
19 510(k) of such Act, as applicable, the Sec-
20 retary shall identify whether any additional
21 data or evidence is required with respect to
22 any indications for such device for pur-
23 poses of the application of such section
24 1862(a)(1)(A) to such device for such indi-
25 cations.

1 “(ii) NON-DUPLICATION OF DATA RE-
2 QUESTS.—In carrying out clause (i) with
3 respect to a breakthrough device, the Sec-
4 retary shall ensure that data or evidence
5 identified—

6 “(I) does not duplicate data re-
7 quired to be collected by the Food and
8 Drug Administration with respect to
9 such breakthrough device;

10 “(II) minimizes the administra-
11 tive burdens of data collection and re-
12 porting on providers of services, sup-
13 pliers, and manufacturers of break-
14 through devices; and

15 “(III) is not otherwise unneces-
16 sary or redundant.

17 “(B) PROPOSAL FOR COVERAGE AFTER
18 THE TRANSITIONAL COVERAGE PERIOD.—Not
19 later than 2 years after the date of the approval
20 or clearance of a breakthrough device by the
21 Food and Drug Administration, the Secretary
22 shall develop a proposal for coverage under this
23 title of such breakthrough device for such indi-
24 cations as the Secretary determines to be ap-
25 propriate, based on the data and evidence col-

1 lected under subparagraph (A), for such devices
2 furnished after the transitional coverage period
3 under paragraph (1) for such device. If the Sec-
4 retary does not, on a date that is before the end
5 of such two-year period, take action to modify
6 the indications for which coverage of a break-
7 through device may be provided under this title
8 after such period, for purposes of section
9 1862(a)(1)(A) coverage under this title of such
10 breakthrough device shall be made for all indi-
11 cations for which such device is approved under
12 section 515 of the Federal Food, Drug, and
13 Cosmetic Act or cleared under section 510(k) of
14 such Act.

15 “(3) RULES OF CONSTRUCTION.—Nothing in
16 this section shall be construed to—

17 “(A) affect the ability of the manufacturer
18 of a breakthrough device to seek approval for
19 pass-through payment status under section
20 1833(t)(6) or to seek approval for an additional
21 payment under section 1886(d)(5)(K) insofar
22 as such breakthrough device does not qualify
23 for transitional coverage under paragraph (1);
24 or

1 “(B) affect the application and approval
2 process for pass-through payment status under
3 section 1833(t)(6) or for an additional payment
4 under section 1886(d)(5)(K) in the case of a
5 medical device that is not approved by the Food
6 and Drug Administration as a breakthrough de-
7 vice.

8 “(c) CODING.—

9 “(1) PROMPT ASSIGNMENT.—Not later than
10 three months after the date of approval or clearance
11 of a breakthrough device by the Food and Drug Ad-
12 ministration, the Secretary shall assign a unique
13 temporary or permanent code or codes for purposes
14 of coverage and payment for such breakthrough de-
15 vice under the applicable payment systems (de-
16 scribed in paragraph (4)).

17 “(2) UPDATES.—

18 “(A) IPPS.—The Secretary shall provide
19 for semiannual updates under the applicable
20 payment system described in paragraph (4)(A)
21 (relating to the inpatient hospital prospective
22 payment system) to recognize the code or codes
23 assigned under paragraph (1).

24 “(B) OPSS.—The Secretary shall provide
25 for quarterly updates under the applicable pay-

1 ment system described in paragraph (4)(B) (re-
2 lating to the outpatient hospital prospective
3 payment system) to recognize the code or codes
4 assigned under paragraph (1).

5 “(C) OTHER PAYMENT SYSTEMS.—The
6 Secretary shall provide for semiannual or quar-
7 terly updates, as the case may be, under the ap-
8 plicable payment systems described in subpara-
9 graphs (C) through (L) of paragraph (4) to rec-
10 ognize the code or codes assigned under para-
11 graph (1).

12 “(3) TRANSPARENCY.—The process for the as-
13 signment of a code or codes under this subsection
14 shall provide for public notice and a meaningful op-
15 portunity for public comment from affected parties.

16 “(4) APPLICABLE PAYMENT SYSTEMS DE-
17 SCRIBED.—For purposes of this subsection, the term
18 ‘applicable payment systems’ means—

19 “(A) with respect to inpatient hospital
20 services, the prospective payment system for in-
21 patient hospital services established under sec-
22 tion 1886(d);

23 “(B) with respect to outpatient hospital
24 services, the prospective payment system for

1 covered OPD services established under section
2 1833(t);

3 “(C) with respect to ambulatory surgical
4 center services, the fee schedule for such serv-
5 ices established under 1833(i);

6 “(D) with respect to physicians’ services,
7 the physician fee schedules established under
8 section 1848;

9 “(E) with respect to covered items of dura-
10 ble medical equipment, the applicable fee sched-
11 ules established under section 1834;

12 “(F) with respect to diagnostic laboratory
13 tests, the payment amounts under section
14 1834A and the fee schedules establish under
15 section 1848, as the case may be;

16 “(G) with respect to inpatient hospital
17 services furnished by rehabilitation facilities,
18 the prospective payment system established
19 under section 1886(j);

20 “(H) with respect to inpatient hospital
21 services furnished by long-term care hospitals,
22 the prospective payment system under section
23 1886(m);

24 “(I) with respect to inpatient hospital serv-
25 ices furnished by psychiatric hospitals and psy-

1 chiatric units, the prospective payment system
2 under section 1886(s);

3 “(K) with respect to home health services,
4 the prospective payment system under section
5 1895; and

6 “(L) with respect to items and services, or
7 a provider of services or supplier, not described
8 in subparagraphs (A) through (I), the payment
9 system established under this title for such
10 items and services when furnished by such pro-
11 vider of services or supplier.

12 “(d) PAYMENT.—

13 “(1) INPATIENT HOSPITAL PROSPECTIVE PAY-
14 MENT SYSTEM: DEEMED ELIGIBILITY FOR BREAK-
15 THROUGH PAYMENT.—The Secretary shall deem
16 each breakthrough device as approved for an addi-
17 tional payment under section 1886(d)(5)(K) for the
18 4-year period that begins—

19 “(A) except as provided in subparagraph
20 (B), on the date that the Secretary, pursuant to
21 subsection (c)(2)(A), updates the payment sys-
22 tem under section 1886(d) to recognize the
23 unique temporary or permanent code or codes
24 assigned under subsection (c)(1) to such break-
25 through device; or

1 “(B) in the case of a device that has not
2 received approval or clearance as a break-
3 through device by the Food and Drug Adminis-
4 tration before such payment system is updated
5 under subsection (c)(2)(A) to recognize the
6 unique temporary or permanent code or codes
7 assigned under subsection (c)(1) to such device,
8 on the date of such approval or clearance.

9 Nothing in this paragraph shall be construed to af-
10 fect the authority of the Secretary to use claims
11 data to establish new diagnosis or procedure codes
12 for breakthrough devices or to identify appropriate
13 diagnosis-related groups for the assignment of
14 breakthrough devices under annual rulemaking to
15 carry out section 1886(d)(5)(K).

16 “(2) OUTPATIENT PROSPECTIVE PAYMENT SYS-
17 TEM: DEEMED ELIGIBILITY FOR PASS-THROUGH
18 PAYMENT.—The Secretary shall deem each break-
19 through device as approved for pass-through pay-
20 ment under section 1833(t)(6) (including for pur-
21 poses of section 1833(i)(2)(D)) during the 4-year pe-
22 riod that begins—

23 “(A) except as provided in subparagraph
24 (B), on the date that the Secretary, pursuant to
25 subsection (c)(2)(B), updates the payment sys-

1 tem under section 1833(t) to recognize the
2 unique temporary or permanent code or codes
3 assigned under subsection (c)(1) to such break-
4 through device; or

5 “(B) in the case of a device that has not
6 received approval or clearance as a break-
7 through device by the Food and Drug Adminis-
8 tration before such payment system is updated
9 under subsection (c)(2)(B) to recognize the
10 unique temporary or permanent code or codes
11 assigned under subsection (c)(1) to such device,
12 on the date of such approval or clearance.

13 Nothing in this paragraph shall be construed to af-
14 fect the authority of the Secretary to use claims
15 data to establish new ambulatory payment classifica-
16 tion groups for breakthrough devices or to revise
17 such groups to take into account breakthrough de-
18 vices under annual rulemaking to carry out section
19 1833(t).

20 “(3) OTHER PAYMENT SYSTEMS.—

21 “(A) IN GENERAL.—In the case of break-
22 through device that is furnished and for which
23 payment may be made under the payment sys-
24 tem established under section 1834, 1834A,
25 1848, 1886(j), 1886(m), 1886(s), or 1895 or

1 any other provision of this title (other than sec-
2 tions 1833(i), 1833(t), and 1886(d)), the Sec-
3 retary shall provide for an additional payment
4 for such breakthrough device under such appli-
5 cable payment system or an adjustment to such
6 applicable payment system, as the case may be.
7 The payment basis for such additional payment
8 or adjustment, as the case may be, shall equal
9 an amount that the Secretary determines covers
10 the costs of such breakthrough device.

11 “(B) COST INFORMATION.—In determining
12 the costs of a breakthrough device for purposes
13 of determining an additional payment or pay-
14 ment adjustment under subparagraph (A), the
15 Secretary shall use the most recently available
16 data and information on the costs of such
17 breakthrough device, which may include list
18 prices and invoice prices charged for such
19 breakthrough device.

20 “(C) RULE OF CONSTRUCTION.—Nothing
21 in this paragraph shall be construed to affect
22 the authority of the Secretary to use claims
23 data to establish new or modify existing ambu-
24 latory payment classification groups, diagnosis-
25 related groups, level II HCPCS codes or such

1 other groups or codes as the Secretary may es-
2 tablish under the annual rulemaking authority
3 under the provisions referred to in subpara-
4 graph (A).

5 “(D) CLINICAL DIAGNOSTIC LABORATORY
6 TESTS.—An additional payment or payment ad-
7 justment under subparagraph (A) for a break-
8 through device under the applicable payment
9 system established in section 1834A may be in
10 the form of an increase to the amount deter-
11 mined for the breakthrough device using cross-
12 walking under section 1834A(c)(1)(A), an ex-
13 tension of the initial period of payment applica-
14 ble to advance diagnostic laboratory tests under
15 section 1834A(d)(1)(A), and in such other form
16 or manner as the Secretary determines reflects
17 the costs for such breakthrough device under
18 the relevant provisions of section 1834A.

19 “(4) PAYMENT FOR BREAKTHROUGH DEVICES
20 AFTER THE TRANSITIONAL COVERAGE PERIOD.—
21 Payment for a breakthrough device that is furnished
22 after the conclusion of the transitional coverage pe-
23 riod under subsection (b)(1) for such device shall be
24 made pursuant to the applicable payment system in-

1 volved, taking into account the additional evidence
2 and data collected under subsection (b)(2).

3 “(e) SPECIAL RULES FOR CERTAIN BREAKTHROUGH
4 DEVICES.—

5 “(1) COVERAGE OF SPECIFIED BREAKTHROUGH
6 DEVICES.—

7 “(A) IN GENERAL.—Subject to the suc-
8 ceeding provisions of this subsection and not-
9 withstanding any other provision of law, the
10 Secretary shall provide for coverage and pay-
11 ment pursuant to this section of a specified
12 breakthrough device (as defined in subpara-
13 graph (B)).

14 “(B) SPECIFIED BREAKTHROUGH DEVICE
15 DEFINED.—In this section, the term ‘specified
16 breakthrough device’ means a breakthrough de-
17 vice with respect to which no Medicare benefit
18 category exists.

19 “(2) PERIOD OF TRANSITIONAL COVERAGE.—

20 “(A) IN GENERAL.—Subject to subpara-
21 graph (C), the provisions of subsection (b)(1)
22 (relating to the transitional coverage period and
23 payment for breakthrough devices, including the
24 use of the most recently available data and in-
25 formation on costs) shall apply to a specified

1 breakthrough device in the same manner as
2 such provisions apply to a breakthrough device.
3 The Secretary may use methodologies under ex-
4 isting payment systems established under this
5 title, may provide for appropriate adjustments
6 to such methodologies, or may establish a new
7 payment methodology under this title, to pro-
8 vide for payment for a specified breakthrough
9 device to ensure the payment basis for such
10 payment covers costs of the specified break-
11 through device are covered by such payment.

12 “(B) REPORT.—

13 “(i) IN GENERAL.—With respect to
14 each specified breakthrough device, the
15 Secretary shall submit to Congress a re-
16 port on the coverage of and payment for
17 such specified breakthrough device under
18 this section that includes the following in-
19 formation:

20 “(I) The manner in which cov-
21 erage is provided and payment is
22 made for the specified breakthrough
23 device, including how such device was
24 classified (such as an item of durable
25 medical equipment or otherwise) and

1 the payment methodology the Sec-
2 retary applied with respect to such de-
3 vice.

4 “(II) The impact of the avail-
5 ability of the specified breakthrough
6 device to Medicare beneficiaries, in-
7 cluding impacts on the quality of pa-
8 tient care, patient outcomes, and pa-
9 tient experience.

10 “(III) The impact of the avail-
11 ability of the specified breakthrough
12 device to Medicare beneficiaries on
13 program expenditures under this title.

14 “(IV) Such other information as
15 the Secretary determines to be appro-
16 priate.

17 “(ii) DEADLINE.—

18 “(I) IN GENERAL.—Except as
19 provided in subclause (II), the Sec-
20 retary shall submit a report required
21 under this subparagraph no later than
22 the end of the transitional period of
23 coverage and payment applicable to
24 such specified breakthrough device.

1 “(II) EXTENSION TO GENERATE
2 ADDITIONAL DATA.—If the Secretary
3 determines that additional data or evi-
4 dence is required to complete a report
5 required under this subparagraph
6 with respect to a specified break-
7 through device, the deadline under
8 this clause may be extended for an
9 additional two years.

10 “(C) ADDITIONAL PERIOD OF TRANSI-
11 TIONAL COVERAGE TO DEVELOP ADDITIONAL
12 DATA.—Insofar as the Secretary determines
13 that additional data or evidence is required to
14 complete a report required under subparagraph
15 (B) with respect to a specified breakthrough de-
16 vice, the transitional coverage period of cov-
17 erage and payment for such device shall be ex-
18 tended by the lesser of—

19 “(i) two years; or

20 “(ii) the amount of additional time re-
21 quired for the submission of the report
22 with respect to such device.

23 “(3) COVERAGE AND PAYMENT AFTER THE
24 TRANSITIONAL PERIOD.—The Secretary may con-
25 tinue to provide for coverage of and payment for a

1 specified breakthrough device after the end of the
2 transitional period of coverage and payment for
3 breakthrough devices through the national coverage
4 determination process if the Secretary determines
5 that the specified breakthrough device—

6 “(A) improves the quality of care and pa-
7 tient outcomes;

8 “(B) improves the delivery of care; or

9 “(C) reduces spending under this title
10 without reducing the quality of care.”.

11 (b) CONFORMING AMENDMENTS.—

12 (1) INPATIENT PROSPECTIVE PAYMENT SYS-
13 TEM.—Section 1886(d)(5)(K) of the Social Security
14 Act (42 U.S.C. 1395ww(d)(5)(K)) is amended by
15 adding at the end the following new clause:

16 “(x) Effective for discharges occurring on
17 or after October 1, 2019, in the case of a new
18 medical service or technology that is a break-
19 through device (as defined in section
20 1899C(a)), the additional payment established
21 for such breakthrough device under this sub-
22 paragraph shall be made for the 4-year period
23 applicable to such breakthrough device under
24 section 1899C(d)(1). In determining the
25 amount of the additional payment for a break-

1 through device under this subparagraph during
2 such 4-year period, the Secretary shall apply
3 section 412.88(b) of title 42, Code of Federal
4 Regulations, as in effect on the date of the en-
5 actment of this clause, except as if the ref-
6 erence in such section to ‘65 percent’ were a
7 reference to ‘65 percent (or such greater per-
8 cent specified by the Secretary)’.”.

9 (2) OUTPATIENT PROSPECTIVE PAYMENT SYS-
10 TEM.—Section 1833(t)(6)(C) of such Act (42 U.S.C.
11 1395l(t)(6)(C)) is amended by adding at the end the
12 following new clause:

13 “(iii) SPECIAL RULE FOR BREAK-
14 THROUGH DEVICES.—Notwithstanding
15 clause (i) or (ii), or any other provision of
16 this paragraph to the contrary, in the case
17 of a breakthrough device (as defined in
18 section 1899C(a)) that is furnished on or
19 after January 1, 2020, payment under this
20 paragraph for such breakthrough device
21 shall be made for the 4-year period appli-
22 cable to such breakthrough device under
23 section 1899C(d)(2). The provisions of this
24 clause shall also apply for purposes of

1 transitional pass-through payment under
2 section 1833(i)(2)(D).”.

3 (c) **EFFECTIVE DATE.**—This section, and the amend-
4 ments made by this section, shall take effect on the date
5 of the enactment of this Act and, unless otherwise speci-
6 fied in this section (or in an amendment made by this sec-
7 tion), shall apply to breakthrough devices (as defined in
8 section 1899C(a) of the Social Security Act, as added by
9 subsection (a)), approved or cleared on or after July 1,
10 2019, or, in the case of a specified breakthrough device
11 (as defined in such section as so added), approved or
12 cleared on or after December 1, 2018.

13 **SEC. 405. SECRETARY OF HEALTH AND HUMAN SERVICES**
14 **REPORT ON COVERAGE FOR INNOVATIVE**
15 **TECHNOLOGIES.**

16 Not later than [one year after the date of the enact-
17 ment of this Act,] the Secretary of Health and Human
18 Services, in collaboration with the Administrator of the
19 Centers for Medicare & Medicaid Services, and following
20 a request for information, shall submit to Congress a re-
21 port containing a proposal that—

22 (1) specifies, for purposes of payment and cov-
23 erage under title XVIII of the Social Security Act,
24 a definition for digital alternatives to treatment and

1 therapies, including wearables and digital applica-
2 tions and platforms;

3 (2) establishes a standardized process for deter-
4 mining which technologies satisfy the definition pur-
5 suant to paragraph (1);

6 (3) establishes a standardized process for deter-
7 mining coverage under such title of digital alter-
8 natives as defined pursuant to paragraph (1) that
9 are prescribed by a physician; and

10 (4) identifies an innovative system for payment
11 under such title for such alternatives.

12 **SEC. 406. SECRETARY OF HEALTH AND HUMAN SERVICES**

13 **REPORT ON CMS COMPUTER SYSTEMS.**

14 Not later than one year after the date of the enact-
15 ment of this Act, the Secretary of Health and Human
16 Services shall submit to Congress a report on the fol-
17 lowing:

18 (1) The current state of computer systems of
19 the Centers for Medicare & Medicaid Services, in-
20 cluding an analysis of the capabilities and defi-
21 ciencies of such systems in helping to managing the
22 operations of the programs administered by the Cen-
23 ters for Medicare & Medicaid Services.

1 (2) The cost, taking into account ways to lower
2 or defray costs to the Federal Government, of each
3 of the following:

4 (A) Replacing or updating such systems
5 identified under paragraph (1).

6 (B) Contractors and other third-parties to
7 solve for deficiencies in such system identified
8 under paragraph (1).

9 **SEC. 407. EXPANDING ACCESS TO GENETIC TESTING.**

10 **[(a) DEMONSTRATION PROGRAM TO PRO-**
11 **VIDE DNA SEQUENCING CLINICAL SERVICES**
12 **FOR CERTAIN CHILDREN [ALTERNATIVE OPTION AS**
13 **A PILOT PROGRAM].—]**

14 **[(1) IN GENERAL.—**The Secretary of Health
15 and Human Services shall enter into agreements
16 with up to 5 States submitting applications under
17 paragraph (3) for the purpose of conducting, in ac-
18 cordance with this paragraph, demonstration
19 projects under section 1115 of the Social Security
20 Act (42 U.S.C. 1315) in such States during the 3-
21 year period beginning on the first date of the first
22 fiscal quarter than begins on or after the date of the
23 enactment of this subsection to test and evaluate the
24 provision of medical assistance under the State plans
25 under title XIX of such Act (or waivers of such

1 plans) to eligible individuals for purposes of pro-
2 viding such individuals with DNA sequencing clinical
3 services.】

4 【(2) DEMONSTRATION PROJECT PAYMENT RE-
5 QUIREMENTS.—Under each demonstration project
6 under this section conducted by a State, the fol-
7 lowing shall apply:】

8 【(A) The State shall provide a health care
9 provider (as defined by the State) with pay-
10 ments for the provision of DNA sequencing
11 clinical services to any eligible individual. Pay-
12 ments made to a health care provider for such
13 services shall be treated as medical assistance
14 for purposes of section 1903(a) of the Social
15 Security Act (42 U.S.C. 1396b(a)), except that
16 the Federal medical assistance percentage ap-
17 plicable to such payments shall be equal to 100
18 percent.】

19 【(B) The State shall specify the method-
20 ology the State will use for determining pay-
21 ment for the provision of DNA sequencing clin-
22 ical services. Such methodology for determining
23 payment shall be established consistent with
24 section 1902(a)(30)(A) of such Act (42 U.S.C.
25 1396a(a)(30)(A)).】

1 **[(3) MINIMUM APPLICATION REQUIREMENTS.—**
2 A State desiring to enter into an agreement under
3 paragraph (1) with the Secretary for conducting a
4 demonstration project shall submit to the Secretary
5 an application, in accordance with such form and
6 manner, and application priorities, as specified by
7 the Secretary and that at a minimum includes the
8 following:】

9 **[(A) An explanation of how and the extent**
10 to which DNA sequencing clinical services
11 under the demonstration project of the State
12 will provide information and data on how such
13 services improve the diagnosing of rare dis-
14 eases.】

15 **[(B) An explanation of how and the extent**
16 to which coverage under the State plan (or
17 waiver) pursuant to the demonstration project
18 will improve the use of genetic and genomic
19 testing that may improve clinical outcomes for
20 eligible individuals.】

21 **[(C) Procedures for referring any eligible**
22 individual who seeks or needs treatment in a
23 hospital emergency department to a health care
24 provider who is qualified (as determined by the

1 State) to provide DNA sequencing clinical serv-
2 ices.】

3 【(D) An explanation of how genetic and
4 genomic testing may improve health outcomes
5 for all populations in the State, including—】

6 【(i) individuals with a rare disease,
7 including a metabolic disease, a hereditary
8 cancer syndrome, and a neurologic disease
9 with known treatments; and】

10 【(ii) special populations, including in-
11 fants and children, critically ill (non-infec-
12 tious and non-trauma) patients, transplant
13 patients, individuals with cardiac disease,
14 and 【(v)】 *【should this be a new clause?】*
15 individuals with, or who have a family his-
16 tory of, a birth defect or developmental
17 disability.】

18 【(4) PREFERENCES IN CONSIDERING APPLICA-
19 TIONS.—In considering applications submitted under
20 paragraph (3), the Secretary of Health and Human
21 Services shall give preference to States that do not,
22 as of the date of the enactment of this section, cover
23 DNA sequencing clinical services under (or do not
24 cover the majority of DNA sequencing clinical serv-

1 ices under) the State plan under title XIX of the So-
2 cial Security Act (or waiver of such plan).】

3 【(5) TECHNICAL ASSISTANCE.—The Secretary
4 of Health and Human Services shall provide tech-
5 nical assistance to assist States in planning and de-
6 signing the demonstration project for purposes of
7 applying for conducting such project under this sub-
8 section.】

9 【(6) REPORTS BY STATES.—Not later than
10 four years after the date on which a State enters
11 into an agreement under paragraph (1) with the
12 Secretary for conducting a demonstration project,
13 the State shall submit a report to the Administrator
14 of the Centers for Medicare & Medicaid Services and
15 the Administrator of the Health Resources and Serv-
16 ices Administration on the extent to which DNA se-
17 quencing clinical services reduce health disparities.】

18 【(7) REPORTS BY HEALTH CARE PROVIDERS.—
19 As a condition for receiving payment for DNA se-
20 quencing clinical services provided to an eligible indi-
21 vidual under a demonstration project conducted by
22 a State under this section, a health care provider
23 shall report to the State, in accordance with such re-
24 quirements as the Secretary shall specify, on all ap-

1 plicable measures for determining the quality and ef-
2 ficacy of such services.】

3 【(8) DEFINITIONS.—In this subsection:】

4 【(A) ELIGIBLE INDIVIDUAL.—The term
5 “eligible individual” means, with respect to a
6 State, an individual who—】

7 【(i) is eligible for medical assistance
8 under the State plan under title XIX of
9 the Social Security Act (or a waiver of
10 such plan);】

11 【(ii) is under the age of 21 (or, at the
12 option of the State, under the age of 20,
13 19, or 18 as the State may choose), or in
14 the case of an individual described in sec-
15 tion 1902(a)(10)(A)(i)(IX) of such Act (42
16 U.S.C. 1396a(a)(10)(A)(i)(IX)), under the
17 age of 26;】

18 【(iii) has been referred or admitted to
19 an intensive care unit, or has been seen by
20 at least one medical specialist, for a sus-
21 pected genetic or undiagnosed disease; or】

22 【(iv) is suspected by at least one med-
23 ical specialist to have a neonatal-onset or
24 pediatric-onset genetic disease.】

1 **[(B) [DNA SEQUENCING CLINICAL SERV-**
2 **ICES][change to “genetic and genomic testing**
3 **services”?].—**The term “DNA sequencing clin-
4 ical services”, with respect to an eligible indi-
5 vidual—**]**

6 **[(i) means the determination of an**
7 **[Is this necessary?: exact] sequence of**
8 deoxyribonucleic acid bases in the genome
9 of such individual, and, if for the sole ben-
10 efit of the individual, a biological parent of
11 such individual for the purpose of deter-
12 mining whether one or more potentially
13 disease-causing genetic variants are
14 present in the genome of such individual or
15 such biological parent; and**]**

16 **[(ii) includes—]**

17 **[(I) sequencing of the entire ge-**
18 **nome, of the exome, [of a panel of**
19 genes, or other regions of the ge-
20 nome**]; and]**

21 **[(II) any analysis, interpretation,**
22 and data report derived from such se-
23 quencing.**]**

24 **(b) NATIONAL ACADEMY OF MEDICINE STUDY.—**

1 (1) IN GENERAL.—Not later than three years
2 after the date of the enactment of this subsection,
3 the Secretary of Health and Human Services shall
4 enter into an arrangement with the National Acad-
5 emy of Medicine under which the Academy agrees to
6 study—

7 (A) how genetic and genomic testing may
8 improve preventative care and precision medi-
9 cine;

10 (B) how genetic and genomic testing may
11 reduce health disparities;

12 (C) how genetic and genomic testing may
13 be used to reduce health disparities in
14 marginalized communities;

15 (D) how the Federal Government may help
16 to reduce barriers to genetic and genomic test-
17 ing, including—

18 (i) encouraging the expansion of
19 health insurance coverage of genetic and
20 genomic testing, including diagnostic, pre-
21 dictive, and presymptomatic testing, and
22 DNA sequencing clinical services (as de-
23 fined in subsection (a)(8)(B));

24 (ii) supporting the collection of evi-
25 dence for the clinical utility and appro-

1 priate use of genetic and genomic tests;
2 and

3 (iii) improving access to genetic coun-
4 selors, pathologists, and other relevant pro-
5 fessions, including strengthening related
6 workforce education and training efforts;

7 (E)(i) the extent to which coverage provi-
8 sions in the Medicare and Medicaid programs
9 under titles XVIII and XIX of the Social Secu-
10 rity Act (42 U.S.C. 1395 et seq., 1396 et seq.)
11 may restrain the use of genetic and genomic
12 testing that may improve clinical outcomes for
13 beneficiaries;

14 (ii) the extent to which coverage provided
15 pursuant to subsection (a) increased the use of
16 genetic and genomic testing and improved clin-
17 ical outcomes for beneficiaries; and

18 (iii) how the Centers for Medicare & Med-
19 icaid Services may make coverage determina-
20 tions that better suit a precision medicine ap-
21 proach to treatment; and

22 (F) how genetic and genomic testing may
23 improve health outcomes for all populations in
24 the United States, including—

- 1 (i) individuals with a rare disease, in-
2 cluding—
- 3 (I) a metabolic disease;
 - 4 (II) a hereditary cancer syn-
5 drome; and
 - 6 (III) a neurologic disease with
7 known treatments; and
- 8 (ii) special populations, including—
- 9 (I) infants and children;
 - 10 (II) critically ill (non-infectious
11 and non-trauma) patients;
 - 12 (III) transplant patients;
 - 13 (IV) individuals with cardiac dis-
14 ease; and
 - 15 (V) individuals with, or who have
16 a family history of, a birth defect or
17 developmental disability.

18 (2) REPORT.—

19 (A) IN GENERAL.—The arrangement
20 under paragraph (1) shall provide for the Na-
21 tional Academy of Medicine to submit, not later
22 than 6 years after the date of enactment of this
23 section, a report on the results of the study
24 under paragraph (1) to—

1 (i) the Secretary of Health and
2 Human Services;

3 (ii) the Committee on Ways and
4 Means and the Committee on Energy and
5 Commerce of the House of Representa-
6 tives; and

7 (iii) the Committee on Finance and
8 the Committee on Health, Education,
9 Labor, and Pensions of the Senate.

10 (B) CONSULTATION.—The arrangement
11 under paragraph (1) shall provide for the Na-
12 tional Academy of Medicine, in developing the
13 report required by subparagraph (A), to consult
14 with physicians, other health professionals,
15 health educators, health professional organiza-
16 tions, relevant companies, patients, patient or-
17 ganizations, the Health Resources and Services
18 Administration, the National Cancer Institute,
19 the National Institutes of Health, the Agency
20 for Healthcare Research and Quality, and the
21 Centers for Medicare & Medicaid Services.

22 (C) USE OF INFORMATION.—The National
23 Academy of Medicine shall, to the extent pos-
24 sible, in conducting the study under paragraph
25 (1), utilize information included in the reports

1 submitted pursuant to paragraphs (6) and (7)
2 of subsection (a).

3 (c) CENTERS FOR MEDICARE & MEDICAID SERVICES
4 REPORT ON MEDICAID COVERAGE FOR DNA SEQUENC-
5 ING CLINICAL SERVICES.—Not later than two years after
6 the date of the enactment of this section, the Centers for
7 Medicare & Medicaid Services shall submit to the Sec-
8 retary of Health and Human Services, the Committees on
9 Ways and Means and on Energy and Commerce of the
10 House of Representatives, and the Committees on Finance
11 and Health, Education, Labor, and Pensions of the Senate
12 a report on the extent to which each of the 50 States pro-
13 vide coverage under the State plan under title XIX of the
14 Social Security Act (or waiver of such plan) of DNA se-
15 quencing clinical services (as defined in subsection
16 (a)(8)(B)), including which types of DNA clinical sequenc-
17 ing options (if any) are so covered and under what cir-
18 cumstances (if any), the impact of coverage on patient
19 outcomes, and the impact of coverage on subsequent
20 health care costs.

21 **SEC. 408. MEDICARE COVERAGE FOR PRECISION MEDICINE**
22 **CONSULTATIONS.**

23 (a) INCLUSION OF PRECISION MEDICINE CONSULTA-
24 TIONS AS A MEDICARE BENEFIT.—Section 1861 of the
25 Social Security Act (42 U.S.C. 1395x) is amended—

1 (1) in subsection (s)(2)—

2 (A) by striking “and” at the end of sub-
3 paragraph (GG);

4 (B) by striking the period at the end of
5 subparagraph (HH) and inserting “; and”; and

6 (C) by adding at the end the following new
7 subparagraph:

8 “(II) genomic precision medicine consulta-
9 tions provided by a qualified clinical pharmacist
10 (as such terms are defined in subsection (III)).”;
11 and

12 (2) by adding at the end the following new sub-
13 section:

14 “(III) GENOMIC PRECISION MEDICINE CONSULTA-
15 TION.—

16 “(1) GENOMIC PRECISION MEDICINE CON-
17 SULTATION DEFINED.—The term ‘genomic precision
18 medicine consultation’ means, with respect to a ge-
19 netic or genomic test (including next generation se-
20 quencing) furnished to an individual, an interpreta-
21 tion of such test (or a consultation with respect to
22 such test) provided to the physician treating such in-
23 dividual to provide such physician [based on such
24 test] with advice and recommendations regarding

1 the efficacy and propriety of particular drugs,
2 biologicals, and other treatments for the individual.

3 “(2) QUALIFIED CLINICAL PHARMACIST.—The
4 term ‘qualified clinical pharmacist’ means an indi-
5 vidual—

6 “(A) with a doctoral degree in pharmacy;

7 “(B) who is licensed as a pharmacist in
8 the State in which such individual furnishes
9 genomic precision medicine consultations;

10 “(C) has appropriate pharmacy specialty
11 certifications or appropriate training, as deter-
12 mined by the Secretary; and

13 “(D) meets other qualifications as specified
14 by the Secretary.”.

15 (b) PAYMENT FOR GENOMIC PRECISION MEDICINE
16 CONSULTATION.—Section 1832(a)(2) of the Social Secu-
17 rity Act (42 U.S.C. 1395k(a)(2)) is amended—

18 (1) by striking “and” at the end of subpara-
19 graph (I);

20 (2) by striking the period at the end of sub-
21 paragraph (J) and inserting “; and”; and

22 (3) by adding at the end the following new sub-
23 paragraph:

24 “(K) genomic precision medicine consulta-
25 tions (as defined in subsection (lll)).”.

1 (c) EFFECTIVE DATE.—The amendments made by
2 subsections (a) and (b) shall apply to genomic precision
3 medicine consultations furnished during a cost reporting
4 period beginning on or after the date of the enactment
5 of such subsections.

6 **SEC. 409. PROHIBITING THE USE OF GEOGRAPHIC TRACK-**
7 **ING FEATURES AND BIOMETRICS WITHIN**
8 **MEDICAID ELECTRONIC VISIT VERIFICATION**
9 **SYSTEMS.**

10 (a) IN GENERAL.—Section 1903(l)(5)(A) of the So-
11 cial Security Act (42 U.S.C. 1396b(l)(5)(A)) is amended
12 by inserting “(without the use of geographic tracking or
13 biometrics)” after “electronically verified”.

14 (b) EFFECTIVE DATE.—The amendment made by
15 subsection (a) shall apply with respect to calendar quar-
16 ters beginning on or after [_____].

17 **TITLE I—RESEARCH**

18 **[SEC. 501. ADVANCED RESEARCH PROJECTS AGENCY FOR**
19 **HEALTH [PLACEHOLDER].**

20 The mission of the Advanced Research Projects
21 Agency for Health (ARPA–H) will be to speed trans-
22 formational innovation in health research and speed appli-
23 cation and implementation of health breakthroughs by
24 funding projects that could—】

1 【(1) tackle bold challenges requiring large
2 scale, sustained coordination;】

3 【(2) create new capabilities (e.g., technologies,
4 data resources, disease models);】

5 【(3) support high-risk exploration that could
6 establish entirely new paradigms; or】

7 【(4) overcome market failures through critical
8 solutions, including financial incentives; or】

9 【(5) complement NIH’s existing research port-
10 folio and mission and the private sector’s research
11 initiatives.】

12 **SEC. 502. RESEARCH INVESTMENT TO SPARK THE ECON-**
13 **OMY.**

14 (a) **AUTHORITY.—**

15 (1) **IN GENERAL.—**Each officer specified in
16 paragraph (2) may exercise the authorities described
17 in paragraph (3).

18 (2) **OFFICERS.—**The officers specified in this
19 paragraph are as follows:

20 (A) The Secretary of Commerce, acting
21 through the Administrator of the National Oce-
22 anic and Atmospheric Administration and the
23 Director of the National Institute of Standards
24 and Technology.

25 (B) The Secretary of Agriculture.

1 (C) The Secretary of Defense.

2 (D) The Secretary of Education.

3 (E) The Secretary of Energy, acting for
4 the Department of Energy (with respect to En-
5 ergy Efficiency and Renewable Energy, Nuclear
6 Energy, and Fossil Research and Development)
7 and through the Office of Science, the Ad-
8 vanced Research Projects Agency–Energy
9 (ARPA–E), and the Office of Electricity.

10 (F) The Secretary of the Interior, acting
11 through the Director of the United States Geo-
12 logical Survey.

13 (G) The Secretary of Health and Human
14 Services, acting through the Director of the Na-
15 tional Institutes of Health.

16 (H) The Secretary of Transportation.

17 (I) The Administrator of the National Aer-
18 onautics and Space Administration.

19 (J) The Administrator of the Environ-
20 mental Protection Agency.

21 (K) The Director of the National Science
22 Foundation.

23 (3) AUTHORITIES.—The officers specified in
24 paragraph (2) may—

1 (A) provide supplemental funding to ex-
2 tend the duration of an award disrupted be-
3 cause of the COVID–19 public health emer-
4 gency to a research institution, Research Lab-
5 oratory, or individual that was awarded before
6 the date of the enactment of this Act, or to ex-
7 pand the purposes of such an award, in order
8 to—

9 (i) enable a postsecondary student or
10 post-doctoral researcher to complete work;

11 (ii) enable research scientists, tech-
12 nical staff, research associates, and prin-
13 cipal investigators to complete work;

14 (iii) extend the training of a postsec-
15 ondary student, or the employment of a
16 post-doctoral researcher, on an ongoing re-
17 search project for up to 2 years because of
18 the disruption of the job market;

19 (iv) create research opportunities for
20 up to 2 years for graduate students and
21 post-doctoral researchers;

22 (v) replace, refurbish, or otherwise
23 make usable laboratory animals, reagents,
24 equipment, or other items required for re-
25 search;

- 1 (vi) facilitate other research (including
2 field work), training, and ongoing con-
3 struction activities, including at institu-
4 tions that are disproportionately affected
5 by the COVID–19 public health emergency
6 (such as minority-serving institutions and
7 2-year institutions of higher education);
- 8 (vii) enable experimental field cam-
9 paigns and maintenance of field infrastruc-
10 ture, including through replacement of dis-
11 rupted experimental data to enable comple-
12 tion of impacted research; and
- 13 (viii) support training in online course
14 delivery and virtual research experiences
15 that will improve quality and access needed
16 to continue undergraduate, graduate, and
17 post-doctoral training;
- 18 (B) issue awards to research institutions,
19 Research Laboratories, or other individuals to
20 conduct research on the effects of the COVID–
21 19 and future potential pandemics, on the ef-
22 fects and effectiveness of responses to such dis-
23 eases, and on improving the prediction of the
24 possible courses of such pandemics; and

1 (C) provide flexibility on an award for
2 funds made available to an agency, by any prior
3 or subsequent Act, by modifying the terms and
4 conditions of the award with a research institu-
5 tion, Research Laboratory, or individual due to
6 facility closures or other limitations during the
7 COVID-19 public health emergency.

8 (4) MODIFICATIONS.—The modifications au-
9 thorized by paragraph (3)(C) include—

10 (A) the provision of supplemental funding
11 to extend the duration of the award concerned;
12 or

13 (B) flexibility on the allowable expenses
14 under such award.

15 (b) PROCEDURES.—The officers specified in sub-
16 section (a)(2) shall each establish procedures to carry out
17 subsection (a).

18 (c) EXPEDITED AWARDS.—Awards under subsection
19 (a) shall be issued as expeditiously as possible.

20 (d) AUTHORIZATIONS OF APPROPRIATIONS.—

21 (1) DEPARTMENT OF COMMERCE.—There is au-
22 thorized to be appropriated for fiscal year 2021 for
23 the Department of Commerce, \$450,000,000 to
24 carry out subsection (a), of which—

1 (A) \$300,000,000 shall be for use by the
2 National Oceanic and Atmospheric Administra-
3 tion; and

4 (B) \$150,000,000 shall be for use by the
5 National Institute of Standards and Tech-
6 nology.

7 (2) DEPARTMENT OF AGRICULTURE.—There is
8 authorized to be appropriated for fiscal year 2021
9 for the Department of Agriculture, \$380,000,000 to
10 carry out subsection (a).

11 (3) DEPARTMENT OF DEFENSE.—There is au-
12 thorized to be appropriated for fiscal year 2021 for
13 the Department of Defense, \$3,000,000,000 to carry
14 out subsection (a).

15 (4) DEPARTMENT OF EDUCATION.—There is
16 authorized to be appropriated for fiscal year 2021
17 for the Department of Education, \$200,000,000 to
18 carry out subsection (a), which shall be for use by
19 the Institute for Education Sciences.

20 (5) DEPARTMENT OF ENERGY.—There is au-
21 thorized to be appropriated for fiscal year 2021 for
22 the Department of Energy, \$5,000,000,000 to carry
23 out subsection (a), of which—

24 (A) not less than \$3,000,000,000 shall be
25 for use by the Office of Science;

1 (B) not less than \$900,000,000 shall be
2 for Energy Efficiency and Renewable Energy;

3 (C) not less than \$450,000,000 shall be
4 for Nuclear Energy;

5 (D) not less than \$300,000,000 shall be
6 for Fossil Research and Development;

7 (E) not less than \$150,000,000 shall be
8 for use by the Advanced Research Projects
9 Agency–Energy; and

10 (F) not less than \$100,000,000 shall be
11 for use by the Office of Electricity.

12 (6) DEPARTMENT OF THE INTERIOR.—There is
13 authorized to be appropriated for fiscal year 2021
14 for the Department of the Interior, \$300,000,000 to
15 carry out subsection (a), which shall be for use by
16 the United States Geological Survey.

17 (7) DEPARTMENT OF HEALTH AND HUMAN
18 SERVICES.—There is authorized to be appropriated
19 for fiscal year 2021 for the Department of Health
20 and Human Services, \$10,000,000,000 to carry out
21 subsection (a), which shall be for use by the Na-
22 tional Institutes of Health.

23 (8) DEPARTMENT OF TRANSPORTATION.—
24 There is authorized to be appropriated for fiscal
25 year 2021 for the Department of Transportation,

1 \$300,000,000 to carry out subsection (a), of which
2 not less than \$130,000,000 shall be for use by the
3 Federal Aviation Administration.

4 (9) NATIONAL AERONAUTICS AND SPACE AD-
5 MINISTRATION.—There is authorized to be appro-
6 priated for fiscal year 2021 for the National Aero-
7 nautics and Space Administration, \$2,000,000,000
8 to carry out subsection (a).

9 (10) ENVIRONMENTAL PROTECTION AGENCY.—
10 There is authorized to be appropriated for fiscal
11 year 2021 for the Environmental Protection Agency,
12 \$200,000,000 to carry out subsection (a).

13 (11) NATIONAL SCIENCE FOUNDATION.—There
14 is authorized to be appropriated for fiscal year 2021
15 for the National Science Foundation,
16 \$3,000,000,000 to carry out subsection (a).

17 (12) AVAILABILITY OF FUNDS FOR ADMINIS-
18 TRATION.—

19 (A) IN GENERAL.—Amounts authorized to
20 be appropriated by this subsection may be used
21 for the payment of indirect costs of Federal
22 awards under subsection (a), up to the limit
23 otherwise allowable by law and subject to the
24 requirements of part 200 of title 2, Code of
25 Federal Regulations.

1 (B) LIMITATION.—Not more than 5 per-
2 cent of each of the amounts appropriated pur-
3 suant to this subsection may be used for admin-
4 istration of awards under subsection (a).

5 (13) DURATION OF AVAILABILITY.—Amounts
6 authorized to be appropriated by this subsection
7 shall be available for the purposes described in this
8 subsection through fiscal year 2021.

9 (e) DEFINITIONS.—In this section:

10 (1) AWARD.—The term “award” includes a
11 grant, cooperative agreement, or other financial as-
12 sistance.

13 (2) COVID–19 PUBLIC HEALTH EMERGENCY.—
14 The term “COVID–19 public health emergency”
15 means the public health emergency declared by the
16 Secretary of Health and Human Services under sec-
17 tion 319 of the Public Health Service Act (42
18 U.S.C. 247d) on January 31, 2020, with respect to
19 coronavirus disease 2019 (COVID–19).

20 (3) RESEARCH INSTITUTION.—The term “re-
21 search institution” means the following:

22 (A) An institution of higher education (as
23 defined in section 101(a) of the Higher Edu-
24 cation Act of 1965 (20 U.S.C. 1001(a))).

1 (B) A Tribal College or University (as de-
2 fined in section 316 of the Higher Education
3 Act of 1965 (20 U.S.C. 1059e)).

4 (C) A nonprofit entity that conducts feder-
5 ally funded research.

6 (4) RESEARCH LABORATORY.—The term “Re-
7 search Laboratory” means the following:

8 (A) A National Laboratory (as defined in
9 section 2 of the Energy Policy Act of 2005 (42
10 U.S.C. 15801)).

11 (B) A Federally Funded Research and De-
12 velopment Center for purposes of section
13 3.5.017 of title 48, Code of Federal Regula-
14 tions.