

117TH CONGRESS
1ST SESSION

H. R. 6000

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

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 17, 2021

Ms. DEGETTE (for herself and Mr. UPTON) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, the Budget, Science, Space, and Technology, Agriculture, Education and Labor, Armed Services, Natural Resources, Veterans' Affairs, Homeland Security, and the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To 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. Accelerating timeline for breakthrough and RMAT designations.
- 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.
- Sec. 310. Recommendations to decentralize clinical trials.

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. Precision Medicine Answers for Kids Today.
- Sec. 408. Medicare coverage for consultations.
- Sec. 409. Prohibiting the use of geographic tracking features and biometrics within Medicaid electronic visit verification systems.
- Sec. 410. Generally accepted standard for electronic prescribing.
- Sec. 411. Meaningful access to Federal health plan claims data.

TITLE V—RESEARCH

- Sec. 501. Advanced Research Projects Agency for Health.

Sec. 502. Research investment to spark the economy.

Sec. 503. Research Policy Board reauthorization.

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 the 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.**—

20 (1) **NATIONAL MEETINGS.**—The Secretary of
21 Health and Human Services shall—

22 (A) convene a series of not less than four
23 national meetings, that may be virtual, to serve
24 as the basis of an ongoing long COVID learning

1 collaborative with individuals and organizations
2 representing key sectors of the health care com-
3 munity; and

4 (B) invite to participate in such meetings
5 individuals who represent the views of health
6 plan representatives, health care providers (in-
7 cluding hospitals, physicians, and nurses), med-
8 ical and scientific researchers, patient and con-
9 sumer advocates, data scientists, health care
10 service providers, providers of workers com-
11 pensation, employers, and developers of diag-
12 nostic and therapeutic products, including clin-
13 ical laboratories.

14 (2) TERMINATION OF MEETINGS.—The Sec-
15 retary shall continue to convene national meetings
16 under paragraph (1) for—

17 (A) not less than 2 years after the date of
18 the enactment of this Act; and

19 (B) each fiscal year thereafter, unless the
20 Secretary determines that the public health and
21 medical knowledge with respect to long COVID
22 has sufficiently advanced to ensure widespread
23 understanding of the characteristics of long
24 COVID, including—

1 (i) the etiology, progression, similarity
2 to other conditions, and duration of long
3 COVID; and

4 (ii) conditions that interact with long
5 COVID.

6 (c) LONG COVID SCIENTIFIC RESEARCH FOR CHIL-
7 DREN.—

8 (1) IN GENERAL.—Beginning not later than
9 180 days after the date of the enactment of this Act,
10 the Director of the National Institutes of Health
11 shall award grants to hospitals for children, pedi-
12 atric researchers, academic medical centers, and
13 other appropriate organizations to research the long-
14 term effects and treatment of COVID–19 in chil-
15 dren, including long COVID.

16 (2) AUTHORIZATION OF APPROPRIATIONS.—Of
17 the amounts made available for research and clinical
18 trials related to long-term studies of COVID–19
19 under the heading “National Institutes of Health—
20 Office of the Director” of title III of the Consoli-
21 dated Appropriations Act, 2021 (Public Law 116–
22 260), there are authorized to be appropriated such
23 sums as may be necessary to carry out this sub-
24 section.

25 (d) STUDY ON DISPARITIES IN LONG COVID.—

1 (1) IN GENERAL.—Not later than 90 days after
2 the date of the enactment of this Act, the Secretary
3 of Health and Human Services shall seek to enter
4 into an arrangement with the National Academy of
5 Medicine under which the Academy conducts a study
6 to evaluate disparities in racial and ethnic minority
7 groups with respect to diagnosis of, severity of
8 symptoms, access to care, and treatment for long
9 COVID.

10 (2) CONTENT.—The study under paragraph (1)
11 shall—

12 (A) with respect to individuals who are
13 Black, Hispanic, American Indian, Alaska Na-
14 tive, or who belong to other racial and ethnic
15 populations—

16 (i) evaluate the prevalence of long
17 COVID;

18 (ii) evaluate the rates of hospitaliza-
19 tion and death from COVID-19; and

20 (iii) evaluate and identify factors that
21 increase the risk of severity of long
22 COVID; and

23 (B) include recommendations to identify
24 and address the disparities described in para-

1 graph (1), including the causes of such dispari-
2 ties.

3 (3) AUTHORIZATION OF APPROPRIATIONS.—

4 There is authorized to be appropriated to carry out
5 this subsection \$5,000,000 for fiscal year 2022, to
6 remain available until expended.

7 (e) EDUCATION AND DISSEMINATION OF INFORMA-
8 TION WITH RESPECT TO LONG-TERM SYMPTOMS OF
9 COVID-19.—

10 (1) LONG COVID PUBLIC EDUCATION PRO-
11 GRAM.—The Secretary of Health and Human Serv-
12 ices, acting through the Director of the Centers for
13 Disease Control and Prevention, shall develop and
14 disseminate to the public information regarding long
15 COVID, including information on—

16 (A) the awareness, incidence, and common
17 symptoms of long COVID; and

18 (B) the availability, as medically appro-
19 priate, of treatment options for long COVID.

20 (2) LONG COVID PROVIDER EDUCATION PRO-
21 GRAM.—The Secretary of Health and Human Serv-
22 ices, acting through the Director of the Centers for
23 Disease Control and Prevention, shall in consulta-
24 tion with communities of individuals diagnosed with
25 long COVID, develop and disseminate to health care

1 providers information on long COVID for the pur-
2 pose of ensuring that such providers remain in-
3 formed about current information on long COVID.

4 (3) ARRANGEMENT AUTHORITY.—The Sec-
5 retary of Health and Human Services may dissemi-
6 nate information under paragraphs (1) and (2) di-
7 rectly or through arrangements with intra-agency
8 initiatives, nonprofit organizations, consumer
9 groups, institutions of higher learning (as defined in
10 section 101 of the Higher Education Act of 1965
11 (20 U.S.C. 1001)), or Federal, State, or local public
12 private partnerships.

13 (4) AUTHORIZATION OF APPROPRIATIONS.—
14 There is authorized to be appropriated to carry out
15 this section \$30,000,000 for fiscal year 2022, which
16 shall remain available until expended.

17 **SEC. 102. NATIONAL STRATEGY TO PREVENT AND RESPOND**
18 **TO PANDEMICS.**

19 (a) IN GENERAL.—Not later than 90 days after the
20 date of the enactment of this Act, the President, acting
21 through the Secretary of Health and Human Services,
22 shall—

23 (1) develop and implement a national strategy
24 to prevent and respond to pandemics and other pub-
25 lic health emergencies for which a declaration is

1 made under section 319 of the Public Health Service
2 Act (42 U.S.C. 247d); and

3 (2) base such strategy on lessons learned, and
4 best practices developed, as a result of the COVID-
5 19 pandemic.

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

9 (1) Strategies for testing (including point-of-
10 care testing and testing at nonmedical sites) to fos-
11 ter expedient results and personalized medical re-
12 sponses for patients and communities, including for
13 medically underserved populations.

14 (2) Methods of data sharing to use testing to
15 inform surveillance and other pandemic monitoring
16 and response efforts.

17 (3) Strategies to enable Americans to continue
18 to work, or return to work, or continue to remain in,
19 or return to, in-person school and childcare settings
20 safely.

21 (4) Modernizing and expanding domestic drug
22 manufacturing, including through the use of contin-
23 uous manufacturing.

24 (5) Developing and administering vaccines,
25 therapeutics, and other medical supplies, including

1 for children, racial and ethnic minorities, and people
2 with disabilities.

3 **SEC. 103. PANDEMIC PREPAREDNESS RARE DISEASE SUP-**
4 **PORT PROGRAM.**

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

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

9 “(a) IN GENERAL.—The Secretary, acting through
10 the Administrator of the Health Resources and Services
11 Administration and in collaboration with the Director of
12 the Centers for Disease Control and Prevention, shall
13 award grants to eligible organizations to develop a pan-
14 demic preparedness plan regarding—

15 “(1) the challenges faced by patients and the
16 family caregivers of such patients served by the re-
17 spective eligible organizations during the COVID–19
18 pandemic;

19 “(2) potential challenges for the respective eligi-
20 ble organizations during future pandemics and other
21 public health emergencies;

22 “(3) how the respective eligible organizations
23 plan to overcome the challenges described in para-
24 graphs (1) and (2), including how the respective or-
25 ganizations plan to support patients, their families,

1 and health care providers to overcome such chal-
2 lenges; and

3 “(4) efforts to partner with local, State, and
4 Federal governments to promote a coordinated re-
5 sponse to future pandemics and other public health
6 emergencies.

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

10 “(c) DEFINITIONS.—In this section:

11 “(1) The term ‘eligible organization’ means an
12 organization that—

13 “(A) is described in section 501(c) of the
14 Internal Revenue Code of 1986 and exempt
15 from tax under section 501(a) of such Code;
16 and

17 “(B) provides support and other resources
18 to patients and their families for accessing and
19 paying for medical care.

20 “(2) The term ‘public health emergency’ means
21 a public health emergency declared under section
22 319.

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

1 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
2 is authorized to be appropriated to carry out this section
3 \$25,000,000 for each of fiscal years 2022 through 2024.”.

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

5 (a) ADDITIONAL FUNDING FOR VACCINE AWARE-
6 NESS.—There are authorized to be appropriated to the
7 Centers for Disease Control and Prevention \$25,000,000
8 for each of fiscal years 2022 through 2024 for the purpose
9 of carrying out an awareness campaign to educate the
10 public with respect to the safety and importance of vac-
11 cines. The amounts authorized by the preceding sentence
12 are in addition to amounts otherwise available for such
13 purpose.

14 (b) STRENGTHENING THE IMMUNIZATION INFORMA-
15 TION SYSTEM.—There are authorized to be appropriated
16 to the Centers for Disease Control and Prevention
17 \$25,000,000 for each of fiscal years 2022 through 2024
18 for the purpose of strengthening immunization informa-
19 tion systems. The amounts authorized by the preceding
20 sentence are in addition to amounts otherwise available
21 for such purpose.

22 **SEC. 105. DEVELOPING ANTIMICROBIAL INNOVATIONS.**

23 Title III of the Public Health Service Act (42 U.S.C.
24 241 et seq.) is amended by adding at the end the fol-
25 lowing:

1 **“PART W—DEVELOPING ANTIMICROBIAL**
 2 **INNOVATIONS**

3 **“SEC. 39900. ESTABLISHMENT OF COMMITTEE; SUBSCRIP-**
 4 **TION MODEL; ADVISORY GROUP.**

5 “(a) IN GENERAL.—Not later than 60 days after the
 6 date of the enactment of this part, the Secretary shall es-
 7 tablish a Committee on Critical Need Antimicrobials and
 8 appoint members to the Committee.

9 “(b) MEMBERS.—

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

19 “(2) CHAIR.—The Secretary shall appoint one
 20 of the members of the Committee to serve as the
 21 Chair of the Committee.

22 “(c) DUTIES.—Not later than 1 year after the ap-
 23 pointment of all initial members of the Committee, the
 24 Secretary, in collaboration with the Committee, and in
 25 consultation with the Critical Need Antimicrobials Advi-

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

20 “(d) REGULATIONS.—

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

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

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

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

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

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

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

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

16 “(f) TRANSITIONAL SUBSCRIPTION CONTRACTS.—

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

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

14 “(2) REQUIREMENTS.—

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

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

24 “(ii) subject to terms including—

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

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

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

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

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

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

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

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

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

21 “(iii) if—

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

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

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

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

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

1 subscription contracts, including eligibility, require-
2 ments, and contract amounts, during the period de-
3 scribed in paragraph (1).

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

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

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

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

17 “(i) infectious disease specialists; or

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

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

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

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

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

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

14 “(a) IN GENERAL.—

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

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

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

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

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

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

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

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

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

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

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

3 “(A) shall include—

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

5 and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

10 “(2) TERMS.—

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

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

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

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

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

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

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

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

22 “(1) REPORTING REQUIREMENT.—

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

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

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

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

1 “(ii) the number of units of such ap-
2 plicable antimicrobial drug paid for under
3 such part D.

4 “(C) MEDICARE PART B PROGRAM.—

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

10 “(I) the per-unit average sales
11 price (as defined in section 1847A(c)
12 of such Act) or the per-unit payment
13 rate under such part B for a sepa-
14 rately paid prescription drug without
15 a reported average sales price; and

16 “(II) the number of units of such
17 applicable antimicrobial drug paid for
18 under such part B.

19 “(ii) UNITS AND ALLOCATED
20 PRICES.—The Secretary shall establish a
21 process for determining the units and the
22 allocated price for purposes of this sub-
23 paragraph for those applicable anti-
24 microbial drugs that are not separately

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

3 “(D) MEDICARE PART A PROGRAM.—

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

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

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

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

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

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

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

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

24 “(I) the product of—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4 “(1) the sponsor—

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

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

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

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

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

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

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

9 “(a) ESTABLISHMENT OF HOSPITAL GRANT PRO-
 10 GRAM.—

11 “(1) IN GENERAL.—Not later than 1 year after
 12 the date of the enactment of this part, the Secretary
 13 and the Director of the Centers for Disease Control
 14 and Prevention shall coordinate with the Adminis-
 15 trator of the Health Resources and Services Admin-
 16 istration, the Administrator of the Centers for Medi-
 17 care & Medicaid Services, the National Coordinator
 18 for Health Information Technology, and other rel-
 19 evant agencies, to establish a grant program under
 20 the Centers for Disease Control and Prevention to
 21 support hospital and other inpatient facility ef-
 22 forts—

23 “(A) to judiciously use antimicrobial drugs,
 24 such as by establishing or implementing appro-
 25 priate use programs, including infectious dis-

1 ease telehealth programs, using appropriate di-
2 agnostic tools, partnering with academic hos-
3 pitals, increasing health care-associated infec-
4 tion reporting, and monitoring antimicrobial re-
5 sistance; and

6 “(B) to participate in the National
7 Healthcare Safety Network Antimicrobial Use
8 and Resistance Module or the Emerging Infec-
9 tions Program Healthcare-Associated Infections
10 Community Interface activity of the Centers for
11 Disease Control and Prevention or a similar re-
12 porting program, as specified by the Secretary,
13 relating to antimicrobial drugs.

14 “(2) PRIORITIZATION.—In awarding grants
15 under paragraph (1), the Secretary shall prioritize
16 hospitals without an existing program to judiciously
17 use antimicrobial drugs, subsection (d) hospitals (as
18 defined in subparagraph (B) of section 1886(d)(2)
19 of the Social Security Act that are located in rural
20 areas (as defined in subparagraph (D) of such sec-
21 tion), critical access hospitals (as defined in section
22 1861(mm)(1) of such Act), hospitals serving Tribal-
23 populations, and safety-net hospitals.

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

4 “(b) SURVEILLANCE AND REPORTING OF ANTIBIOTIC
5 USE AND RESISTANCE.—

6 “(1) IN GENERAL.—The Secretary, acting
7 through the Director of the Centers for Disease
8 Control and Prevention, shall use the National
9 Healthcare Safety Network and other appropriate
10 surveillance systems to assess—

11 “(A) appropriate conditions, outcomes, and
12 measures causally related to antibacterial resist-
13 ance, including types of infections, the causes
14 for infections, and whether infections are ac-
15 quired in a community or hospital setting, in-
16 creased lengths of hospital stay, increased costs,
17 and rates of mortality; and

18 “(B) changes in bacterial resistance to
19 antimicrobial drugs in relation to patient out-
20 comes, including changes in percent resistance,
21 prevalence of antibiotic-resistant infections, and
22 other such changes.

23 “(2) ANTIBIOTIC USE DATA.—The Secretary,
24 acting through the Director of the Centers for Dis-
25 ease Control and Prevention, shall work with Fed-

1 eral agencies (including the Department of Veterans
2 Affairs, the Department of Defense, the Department
3 of Homeland Security, the Bureau of Prisons, the
4 Indian Health Service, and the Centers for Medicare
5 & Medicaid Services), private vendors, health care
6 organizations, pharmacy benefit managers, and
7 other entities as appropriate to obtain reliable and
8 comparable human antibiotic drug consumption data
9 (including, as available and appropriate, volume an-
10 tibiotic distribution data and antibiotic use data, in-
11 cluding prescription data) by State or metropolitan
12 areas.

13 “(3) ANTIBIOTIC RESISTANCE TREND DATA.—
14 The Secretary, acting through the Director of the
15 Centers for Disease Control and Prevention, shall in-
16 tensify and expand efforts to collect antibiotic resist-
17 ance data and encourage adoption of the Antibiotic
18 Use and Resistance Module within the National
19 Healthcare Safety Network among all health care fa-
20 cilities across the continuum of care, including, as
21 appropriate, acute care hospitals, dialysis facilities,
22 nursing homes, ambulatory surgical centers, and
23 other ambulatory health care settings in which anti-
24 microbial drugs are routinely prescribed. The Sec-
25 retary shall seek to collect such data from electronic

1 medication administration reports and laboratory
2 systems to produce the reports described in para-
3 graph (4).

4 “(4) PUBLIC AVAILABILITY OF DATA.—The
5 Secretary, acting through the Director of the Cen-
6 ters for Disease Control and Prevention, shall, for
7 the purposes of improving the monitoring of impor-
8 tant trends in patient outcomes in relation to anti-
9 bacterial resistance—

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

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

16 **“SEC. 399SS. APPROPRIATIONS.**

17 “(a) IN GENERAL.—To carry out this part, there are
18 hereby appropriated to the Secretary, out of amounts in
19 the Treasury not otherwise appropriated,
20 \$11,000,000,000, for fiscal year 2022, to remain available
21 until expended.

22 “(b) EMERGENCY DESIGNATION.—

23 “(1) IN GENERAL.—The amounts provided by
24 this section are designated as an emergency require-

1 ment pursuant to section 4(g) of the Statutory Pay-
2 As-You-Go Act of 2010.

3 “(2) DESIGNATION IN SENATE.—In the Senate,
4 this section is designated as an emergency require-
5 ment pursuant to section 4112(a) of H. Con. Res.
6 71 (115th Congress), the concurrent resolution on
7 the budget for fiscal year 2018.

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

9 “(a) IN GENERAL.—Not later than 6 years after the
10 date of the enactment of this part, the Comptroller Gen-
11 eral of the United States shall complete a study on the
12 effectiveness of this part in developing priority anti-
13 microbial drugs. Such study shall examine the indications
14 for, usage of, development of resistance with respect to,
15 and private and societal value of critical need anti-
16 microbial drugs, and the impact of the programs under
17 this part on patients and markets of critical need anti-
18 microbial drugs. The Comptroller General shall report to
19 the Committee on Health, Education, Labor, and Pen-
20 sions of the Senate and the Committee on Energy and
21 Commerce of the House of Representatives on the findings
22 of such study.

23 “(b) ANTIBIOTIC USE IN THE UNITED STATES; AN-
24 NUAL REPORTS.—The Director of the Centers for Disease
25 Control and Prevention shall, each year, update the report

1 entitled ‘Antibiotic Use in the United States’ to include
2 updated information on progress and opportunities with
3 respect to data, programs, and resources for prescribers
4 to promote appropriate use of antimicrobial drugs.

5 “(c) REPORT ON ANTIMICROBIAL PROPHYLACTICS.—
6 Not later than 3 years after the date of the enactment
7 of this part, the Director of the Centers for Disease Con-
8 trol and Prevention shall publish a report on antimicrobial
9 prophylactics.

10 **“SEC. 399UU. DEFINITIONS.**

11 “In this part—

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

13 “(A) means, subject to subparagraph (B),
14 a product that is—

15 “(i) a drug that directly inhibits rep-
16 lication of or kills bacteria or fungi rel-
17 evant to the proposed indication at con-
18 centrations likely to be attainable in hu-
19 mans to achieve the intended therapeutic
20 effect; or

21 “(ii) a biological product that acts di-
22 rectly on bacteria or fungi or on the sub-
23 stances produced by such bacteria or fungi;
24 and

25 “(B) does not include—

1 “(i) a drug that achieves the effect de-
2 scribed by subparagraph (A)(i) only at a
3 concentration that cannot reasonably be
4 studied in humans because of its antici-
5 pated toxicity; or

6 “(ii) a vaccine; and

7 “(2) the term ‘Committee’ means the Com-
8 mittee on Critical Need Antimicrobials established
9 under section 39900.”.

10 **TITLE II—PATIENTS AND** 11 **CAREGIVERS**

12 **SEC. 201. EDUCATIONAL PROGRAMS AND TRAINING FOR** 13 **CAREGIVERS.**

14 Part D of title VII of the Public Health Service Act
15 (42 U.S.C. 294 et seq.) is amended by adding at the end
16 the following:

17 **“SEC. 760A. EDUCATIONAL PROGRAMS AND TRAINING FOR** 18 **CAREGIVERS.**

19 “(a) IN GENERAL.—The Secretary may award grants
20 for educational programs and training for caregivers to
21 learn skills to empower them—

22 “(1) to be a member of a care team; and

23 “(2) to complement a clinical visit.

1 “(b) TYPES OF PROGRAMS AND TRAINING.—Edu-
2 cational programs and training funded under subsection
3 (a) may include—

4 “(1) specialized training in medication adher-
5 ence and injections;

6 “(2) complementary strategies to ensure adher-
7 ence to physical, occupational, speech, and
8 habilitative therapy regimens;

9 “(3) nutritional compliance;

10 “(4) caregiver psychosocial support (including
11 cognitive-behavioral, supportive, and bereavement
12 counseling);

13 “(5) caregiver health self-management; and

14 “(6) other services provided in the home.

15 “(c) NON-DUPLICATION.—The Secretary may not
16 use the same requirements under this section for a grant,
17 contract, or cooperative agreement under the Geriatric
18 Workforce Enhancement Program under section 753 of
19 the Public Health Service Act (42 U.S.C. 294c).

20 “(d) CAREGIVER DEFINED.—In this section, the
21 term ‘caregiver’ means an adult family member or other
22 individual who has a significant relationship with, and who
23 provides a broad range of assistance to, an individual with
24 a chronic or other health condition, disability, or func-
25 tional limitation.

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

5 **SEC. 202. INCREASING HEALTH LITERACY TO PROMOTE**
6 **BETTER OUTCOMES FOR PATIENTS.**

7 (a) IN GENERAL.—Not later than one year after the
8 date of the enactment of this Act, the Secretary of Health
9 and Human Services, acting through the Administrator of
10 the Centers for Medicare & Medicaid Services, shall issue
11 a request for information to solicit recommendations on
12 ways the Centers for Medicare & Medicaid Services can
13 work with stakeholders of the Federal health care pro-
14 grams (as defined in section 1128B(f) of the Social Secu-
15 rity Act (42 U.S.C. 1320a–7b(f))) to promote increased
16 patient and family caregiver health literacy, including rec-
17 ommendations for—

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

22 (2) identifying evidence-based health literacy
23 approaches that can be used by the Medicare pro-
24 gram under title XVIII of the Social Security Act
25 (42 U.S.C. 1395 et seq.), a State plan (or waiver of

1 such plan) under title XIX of such Act (42 U.S.C.
2 1396 et seq.), a State child health plan (or waiver
3 of such plan) under title XXI of such Act (42
4 U.S.C. 1397aa et seq.), or health care providers par-
5 ticipating in such program under such title XVIII,
6 under a State plan (or waiver of such plan) under
7 such title XIX, or under a State child health plan
8 (or waiver of such plan) under such title XXI, and
9 that—

10 (A) have been proven to, or show promise
11 to, reduce costs to individuals enrolled under a
12 State plan (or waiver of such plan) under such
13 title XIX, or under a State child health plan (or
14 waiver of such plan) under such title XXI, re-
15 spectively, and reduce expenditures under such
16 respective titles; or

17 (B) have been proven to increase patient
18 and family caregiver satisfaction or improve the
19 quality of care for at-risk populations, including
20 holistic and non-medication-based forms of care;

21 (3) how the Centers for Medicare & Medicaid
22 Services can encourage the use of evidence-based
23 health literacy interventions through payment poli-
24 cies under the Medicare program under title XVIII
25 of the Social Security Act (42 U.S.C. 1395 et seq.),

1 a State plan under title XIX of such Act (42 U.S.C.
2 1396 et seq.), a State child health plan under title
3 XXI of such Act (42 U.S.C. 1397 et seq.); and

4 (4) improving patient and family caregiver
5 health literacy with respect to health insurance, in-
6 cluding an understanding of in-network providers,
7 deductibles, co-insurance, co-payments, and dif-
8 ferences between payors.

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

10 (a) **UPDATED REPORTING ON INCLUSION OF DEMO-**
11 **GRAPHIC SUBGROUPS.**—The Secretary of Health and
12 Human Services, acting through the Commissioner of
13 Food and Drugs, shall—

14 (1) not later than 90 days after the date of the
15 enactment of this Act, submit to the Food and Drug
16 Administration, and provide to the Congress, an up-
17 dated version of the report under section 907(a) of
18 the Food and Drug Administration Safety and Inno-
19 vation Act (Public Law 115–52); and

20 (2) not later than 1 year after the publication
21 of the updated report pursuant to paragraph (1),
22 publish on the website of the Food and Drug Ad-
23 ministration, and provide to the Congress, an up-
24 dated version of the action plan under section
25 907(b) of such Act.

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

5 (1) complete a study—

6 (A) to review how the Department of
7 Health and Human Services addresses barriers
8 to participation by individuals from underrep-
9 resented populations in conducting or sup-
10 porting clinical trials; and

11 (B) to formulate recommendations for ad-
12 dressing such barriers; and

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

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

17 (1) carry out a public awareness campaign to
18 increase awareness and understanding, particularly
19 in minority communities, of—

20 (A) upcoming and ongoing clinical trials;

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

23 (C) the availability of databases and other
24 resources relevant to clinical trial enrollment,
25 such as ClinicalTrials.gov; and

1 (2) in carrying out such campaign, utilize a va-
2 riety of communication channels, including through
3 use of the explanation of Medicare benefits under
4 section 1806 of the Social Security Act (42 U.S.C.
5 1395b-7).

6 (d) TASK FORCE FOR MAKING CLINICALTRIALS.GOV
7 MORE USER-FRIENDLY.—

8 (1) IN GENERAL.—The Secretary of Health and
9 Human Services shall convene a permanent task
10 force to propose, on a biennial basis, recommenda-
11 tions for improving ClinicalTrials.gov by making it
12 more user-friendly, including for patients.

13 (2) MEMBERSHIP.—The membership of the
14 task force shall include representatives of—

- 15 (A) the National Institutes of Health;
16 (B) the Food and Drug Administration;
17 (C) academic researchers; and
18 (D) patient organizations.

19 (e) DEFINITION.—In this section, the term
20 “ClinicalTrials.gov” refers to the data bank described in
21 section 402(i) of the Public Health Service Act (42 U.S.C.
22 282(i)).

1 **SEC. 204. PATIENT EXPERIENCE DATA.**

2 (a) POLICY.—Section 569C of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C. 360bbb–8e) is amend-
4 ed—

5 (1) by redesignating subsections (b) and (c) as
6 subsections (c) and (d), respectively; and

7 (2) by inserting after subsection (a) the fol-
8 lowing new subsection:

9 “(b) COLLECTION, SUBMISSION, AND USE OF
10 DATA.—

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

12 “(A) for any drug for which an exemption
13 is granted for investigational use under section
14 505(i) of this Act or section 351(a) of the Pub-
15 lic Health Service Act, require the sponsor of
16 the drug to collect standardized patient experi-
17 ence data as part of the clinical trials conducted
18 pursuant to such exemption;

19 “(B) require any application for the ap-
20 proval or licensing of such drug under section
21 505(b) of this Act or section 351(a) of the Pub-
22 lic Health Service Act to include—

23 “(i) the standardized patient experi-
24 ence data so collected; and

25 “(ii) such related information as the
26 Secretary may require; and

1 “(C) consider patient experience data and
2 related information that is submitted pursuant
3 to subparagraph (B) in deciding whether to ap-
4 prove or license, as applicable, the drug in-
5 volved.

6 “(2) APPLICABILITY.—Paragraph (1) applies
7 only with respect to drugs for which a request for
8 an exemption described in paragraph (1)(A) is sub-
9 mitted on or after the date of the enactment of the
10 Cures 2.0 Act, or an application under section
11 505(b) of this Act or section 351(a) of the Public
12 Health Service Act is filed, as applicable, on or after
13 the day that is 2 years after the date of the enact-
14 ment of the Cures 2.0 Act.”.

15 (b) REGULATIONS.—Not later than 1 year after the
16 date of the enactment of this Act, the Secretary of Health
17 and Human Services, acting through the Commissioner of
18 Food and Drugs, shall promulgate final regulations to im-
19 plement section 569C(b) of the Federal Food, Drug, and
20 Cosmetic Act, as added by this section.

21 **SEC. 205. ENSURING COVERAGE FOR CLINICAL TRIALS**
22 **UNDER EXISTING STANDARD OF CARE.**

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

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

7 “(D) The study or investigation is ap-
8 proved or funded (which may include funding
9 through in-kind contributions) by the Patient
10 Centered Outcomes Research Institute estab-
11 lished under section 1181 of the Social Security
12 Act.”.

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

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

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

24 (2) EFFECTIVE DATE.—The amendment made
25 by this paragraph shall apply with respect to items

1 and services furnished on or after the date of the en-
2 actment of this Act.

3 **TITLE III—FOOD AND DRUG**
4 **ADMINISTRATION**

5 **SEC. 301. REPORT ON COLLABORATION AND ALIGNMENT IN**
6 **REGULATING DIGITAL HEALTH TECH-**
7 **NOLOGIES.**

8 (a) IN GENERAL.—Not later than 1 year after the
9 date of the enactment of this Act, the Secretary of Health
10 and Human Services, acting through the Commissioner of
11 Food and Drugs, shall submit a report to the Congress
12 on the efforts to ensure collaboration and alignment across
13 the centers and offices of the Food and Drug Administra-
14 tion with respect to the regulation of digital health tech-
15 nologies.

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

18 (1) How the Commissioner of Food and Drugs
19 and the heads of the centers and offices of the Food
20 and Drug Administration collaborate in regulating
21 digital health technologies, including recommenda-
22 tions with respect to—

23 (A) the use of digital endpoints for regu-
24 latory review, including the validation and qual-

1 ification of digital endpoints and digital bio-
2 markers;

3 (B) the acceptance of decentralized trials;

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

6 (D) the use and validation of digital health
7 technology tools;

8 (2) How the Food and Drug Administration co-
9 ordinates with foreign regulators to ensure harmoni-
10 zation on the regulation and use of digital health
11 technologies.

12 (c) DEFINITION.—In this section, the term “digital
13 health technologies” includes those technologies in health
14 care or society that help deliver or provide access to health
15 care products and services such as hardware (for example,
16 wearable sensors, virtual reality headsets, and digitally-en-
17 abled drug delivery devices), advanced analytics (for exam-
18 ple, artificial intelligence, machine learning, and sophisti-
19 cated computation), cloud services (for example, storage,
20 computing, and data processing), and software (for exam-
21 ple, mobile medical applications, and software as a medical
22 device).

1 **SEC. 302. GRANTS FOR NOVEL TRIAL DESIGNS AND OTHER**
2 **INNOVATIONS IN DRUG DEVELOPMENT.**

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

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

13 (2) the collection of patient experience data
14 with respect to drugs and the use of such data and
15 related information in drug development.

16 (b) PRIORITIZATION.—In awarding grants under this
17 section, the Secretary shall prioritize the incorporation of
18 digital health technologies and real world evidence in drug
19 development.

20 (c) DEFINITIONS.—In this section:

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

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

1 (3) The term “real world evidence” has the
2 meaning given to that term in section 505F of the
3 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
4 355g).

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

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

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

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

16 (2) How the Food and Drug Administration
17 will address these challenges.

18 (3) The additional resources and authorities the
19 Food and Drug Administration needs to address
20 these challenges.

21 (4) The current state of cell and gene therapies
22 regulation by the Food and Drug Administration, in-
23 cluding—

1 (A) the amount and nature of the submis-
2 sions filed with the Food and Drug Administra-
3 tion;

4 (B) the status of such applications in the
5 review process; and

6 (C) the therapeutic areas intended to be
7 addressed by the products that are subject to
8 such applications.

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

10 (a) GUIDANCE.—

11 (1) ISSUANCE.—Not later than 6 months after
12 the date of the enactment of this Act, the Secretary
13 of Health and Human Services (in this section re-
14 ferred to as the “Secretary”) shall issue guidance on
15 the use of real world evidence in evaluating the safe-
16 ty and effectiveness of breakthrough devices (devel-
17 oped pursuant to section 515B of the Federal Food,
18 Drug, and Cosmetic Act (21 U.S.C. 360e–3)) and
19 breakthrough drugs subsequent to the approval or li-
20 censing of such drugs pursuant to subsection (a),
21 (b), or (c) of section 506 of the Federal Food, Drug,
22 and Cosmetic Act (21 U.S.C. 356) as a break-
23 through therapy, a fast track product, or a product
24 considered for accelerated approval.

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

4 (A) Special and underrepresented popu-
5 lations.

6 (B) Acceptable endpoints and outcomes
7 measures.

8 (C) Data quality standards.

9 (D) Data transparency requirements.

10 (E) Study design considerations.

11 (b) IDENTIFICATION AND IMPLEMENTATION OF AP-
12 PROACHES.—

13 (1) IDENTIFICATION.—Consistent with the
14 framework established under 505F of the Federal
15 Food, Drug, and Cosmetic Act (21 U.S.C. 355g),
16 the Secretary of Health and Human Services shall,
17 by not later than 1 year after the date of the enact-
18 ment of this Act—

19 (A) identify consistent, clear approaches
20 for the Department of Health and Human
21 Services to use real world evidence (as defined
22 in such section 505F)—

23 (i) in conducting and supporting re-
24 search; and

1 (ii) in regulating, purchasing, and
2 supporting the purchase of health care
3 products and services;

4 (B) include in such approaches rec-
5 ommendations for any additional statutory au-
6 thorities needed;

7 (C) publish such approaches in the Federal
8 Register; and

9 (D) submit a report to the Congress on
10 such approaches.

11 (2) IMPLEMENTATION.—Upon publication
12 under paragraph (1) of the approaches identified
13 pursuant to such paragraph, consistent with the au-
14 thorities vested in the Department of Health and
15 Human Services by other provisions of law, the Sec-
16 retary take such actions as may be appropriate to
17 implement the approaches identified pursuant to
18 paragraph (1).

19 (c) REAL WORLD EVIDENCE TASK FORCE.—

20 (1) ESTABLISHMENT.—The Secretary shall es-
21 tablish a permanent task force, to be known as the
22 Real World Evidence Task Force (in this subsection
23 referred to as the “Task Force”) to coordinate the
24 programs and activities of the Department of Health

1 and Human Services with regard to the collection
2 and use of real world evidence.

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

5 (A) The Secretary (or the Secretary’s des-
6 ignee), who shall serve as the Chair of the Task
7 Force.

8 (B) The Administrator of the Centers for
9 Medicare & Medicaid Services (or the Adminis-
10 trator’s designee).

11 (C) The Commissioner of Food and Drugs
12 (or the Commissioner’s designee).

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

15 (E) Such additional Federal officials (or
16 their designees) as the Secretary determines ap-
17 propriate.

18 (F) Private sector representatives, includ-
19 ing patient group representatives, to be ap-
20 pointed by the Secretary.

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

23 (A) develop and periodically update rec-
24 ommendations on ways to encourage patients
25 to—

1 (i) engage in the generation of real
2 world evidence; and

3 (ii) participate in postapproval clinical
4 trials for the collection of real world evi-
5 dence; and

6 (B) not later than 2 years after the date
7 of the enactment of this Act, and every 2 years
8 thereafter, submit a report to the Congress on
9 such recommendations.

10 **SEC. 305. IMPROVING FDA-CMS COMMUNICATION REGARD-**
11 **ING TRANSFORMATIVE NEW THERAPIES.**

12 (a) IN GENERAL.—Upon the designation of a product
13 as a breakthrough therapy, a fast track product, or a
14 product eligible for accelerated approval under subsection
15 (a), (b), or (c), respectively, of section 506 of the Federal
16 Food, Drug, and Cosmetic Act (21 U.S.C. 356), the Com-
17 missioner of Food and Drugs and the Administrator of
18 the Centers for Medicare & Medicaid Services shall—

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

22 (2) share such information with each other as
23 may be appropriate to inform and coordinate such
24 decisions.

1 (b) SEPARATE AND DISTINCT.—In approving or des-
2 ignating a product described in subsection (a), the Com-
3 missioner of Food and Drugs and the Administrator of
4 the Centers for Medicare & Medicaid Services shall ensure
5 that the process for approval or designation remains sepa-
6 rate and distinct.

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 the enactment of the Cures 2.0 Act
15 or the end of the coronavirus disease 2019 (COVID–19)
16 pandemic public health emergency under section 319 of
17 the 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 the enactment of this
10 Act, 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. ACCELERATING TIMELINE FOR BREAKTHROUGH**
18 **AND RMAT DESIGNATIONS.**

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 the enactment of this Act, issue draft revised guid-
9 ance to provide clarity regarding the development
10 and submission of chemistry, manufacturing, and
11 controls 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 evidence

1 based on analyses of data in clinical care data repositories,
2 patient registries, or other sources of real world evi-
3 dence,”.

4 **SEC. 310. RECOMMENDATIONS TO DECENTRALIZE CLIN-**
5 **ICAL TRIALS.**

6 (a) IN GENERAL.—Not later than the end of fiscal
7 year 2022, the Secretary of Health and Human Services,
8 acting through the Commissioner of Food and Drugs,
9 shall convene a meeting of covered representatives to rec-
10 ommend to the Secretary innovative approaches and in-
11 centives to adopt decentralized clinical trials.

12 (b) DEFINITIONS.—In this section:

13 (1) COVERED REPRESENTATIVE.—The term
14 “covered representative” means a representative of
15 the following:

16 (A) Sponsors of an application for approval
17 of a drug under section 505 of the Federal
18 Food, Drug, and Cosmetic Act (21 U.S.C.
19 355).

20 (B) A manufacturer of a device (as defined
21 in section 201 of the Federal Food, Drug, and
22 Cosmetic Act (21 U.S.C. 321)).

23 (C) Clinical research organizations.

24 (D) The technology community.

25 (E) The patient community.

1 (2) DECENTRALIZED CLINICAL TRIAL.—The
2 term “decentralized clinical trial” means a clinical
3 trial method that includes the use of telemedicine or
4 digital technologies to allow for the remote collection
5 of clinical trial data from subjects, including in the
6 home or office setting.

7 **TITLE IV—CENTERS FOR MEDI-**
8 **CARE & MEDICAID SERVICES**

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

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

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

24 (2) better harmonize and integrate the oper-
25 ating structure of the Medicare program (and the

1 Centers for Medicare & Medicaid Services) to im-
2 prove interagency collaboration and communication.

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

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

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

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

24 (b) STUDIES.—

1 (1) TELEHEALTH IMPACT ON HEALTH CARE
2 ACCESS.—Not later than one year after the date of
3 the enactment of this Act, the Medicaid and CHIP
4 Payment and Access Commission shall conduct a
5 study, with respect to a minimum of 10 States
6 across geographic regions of the United States, and
7 submit to Congress a report, on the impact of tele-
8 health on health care access, utilization, cost, and
9 outcomes, broken down by race, ethnicity, sex, age,
10 disability status, and zip code. Such report shall—

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

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

24 (C) determine the frequency at which out-
25 of-State telehealth is provided to patients en-

1 rolled in the Medicaid program and the poten-
2 tial impact on access to telehealth if State Med-
3 icaid policies were more aligned; and

4 (D) identify and evaluate opportunities for
5 more alignment among such policies to promote
6 access to telehealth across all States, State
7 Medicaid plans under title XIX of the Social
8 Security Act (42 U.S.C. 1396 et seq.), State
9 child health plans under title XXI of such Act
10 (42 U.S.C. 1397aa et seq.), and Medicaid man-
11 aged care organizations, including the potential
12 for regional compacts or reciprocity agreements.

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

1 (A) opportunities for Federal agencies to
2 improve collaboration with respect to such tele-
3 health services; and

4 (B) opportunities for collaboration between
5 Federal agencies to expand telehealth access to
6 such individuals enrolled under the Medicaid or
7 CHIP program, including in early care and
8 education settings.

9 **SEC. 403. EXTENDING MEDICARE TELEHEALTH FLEXIBILI-**
10 **TIES.**

11 (a) EXPANDING ACCESS TO TELEHEALTH SERV-
12 ICES.—

13 (1) IN GENERAL.—Section 1834(m)(4)(C) of
14 the Social Security Act (42 U.S.C. 1395m(m)(4)(C))
15 is amended by adding at the end the following new
16 clause:

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

1 cations system, including the home of an
2 individual.”.

3 (2) CONFORMING AMENDMENTS.—Such section
4 is amended—

5 (A) in paragraph (2)(B)—

6 (i) in clause (i), in the matter pre-
7 ceding subclause (I), by striking “clause
8 (ii)” and inserting “clauses (ii) and (iii)”;
9 and

10 (ii) by adding at the end the following
11 new clause:

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

20 (B) in paragraph (4)(C)—

21 (i) in clause (i), in the matter pre-
22 ceding subclause (I), by inserting “and
23 clause (iii)” after “and (7)”;

24 (ii) in clause (ii)(X), by inserting
25 “prior to the first day after the end of the

1 emergency period described in section
2 1135(g)(1)(B)” before the period;

3 (C) in paragraph (5), 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,”;

7 (D) in paragraph (6)(A), by inserting “and
8 prior to the first day after the end of the emer-
9 gency period described in section
10 1135(g)(1)(B),” after “January 1, 2019,”; and

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

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

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

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

24 (2) in paragraph (4)(E)—

1 (A) by striking “PRACTITIONER.—The
2 term” and inserting “PRACTITIONER.—

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

5 (B) by adding at the end the following new
6 subparagraph:

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

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

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

21 (2) in clause (ii), by striking “The Secretary”
22 and inserting “Subject to clause (iii), the Sec-
23 retary”; and

24 (3) by adding at the end the following new
25 clause:

1 “(iii) RETENTION OF ADDITIONAL
2 SERVICES AND SUBREGULATORY PROCESS
3 FOR MODIFICATIONS FOLLOWING EMER-
4 GENCY PERIOD.—With respect to tele-
5 health services furnished after the last day
6 of the emergency period described in sec-
7 tion 1135(g)(1)(B), the Secretary may—

8 “(I) retain as appropriate the ex-
9 panded list of telehealth services spec-
10 ified in clause (i) pursuant to the
11 waiver authority under section
12 1135(b)(8) during such emergency pe-
13 riod; and

14 “(II) retain the subregulatory
15 process used to modify the services in-
16 cluded on the list of such telehealth
17 services pursuant to clause (ii) during
18 such emergency period.”.

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

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

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

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

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

12 (f) USE OF TELEHEALTH, AS CLINICALLY APPRO-
13 PRIATE, TO CONDUCT FACE-TO-FACE CLINICAL ASSESS-
14 MENTS FOR HOME DIALYSIS.—Clause (iii) of section
15 1881(b)(3)(B) of the Social Security Act (42 U.S.C.
16 1395rr(b)(3)(B)) is amended—

17 (1) by moving such clause 4 ems to the left;
18 and

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

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

1 **SEC. 404. COVERAGE AND PAYMENT FOR BREAKTHROUGH**
2 **DEVICES UNDER THE MEDICARE PROGRAM.**

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

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

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

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

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

17 Such term also includes a breakthrough device that is a
18 specified breakthrough device (as defined in subsection
19 (e)(1)(B)) approved or cleared pursuant to section 510(k),
20 513(f), or 515 of such Act for use in treating an indication
21 on or after March 15, 2021.

22 “(b) COVERAGE.—

23 “(1) TRANSITIONAL COVERAGE.—

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

1 “(i) deemed to be reasonable and nec-
2 essary for purposes of section
3 1862(a)(1)(A);

4 “(ii) deemed to be approved for an ad-
5 ditional payment under section
6 1886(d)(5)(K) (other than with respect to
7 the cost criterion under clause (ii)(I) of
8 such section);

9 “(iii) deemed to be approved for pass-
10 through payment under section 1833(t)(6)
11 and section 1833(i) (other than with re-
12 spect to the cost criterion under section
13 1833(t)(6)(A)(iv)); and

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

1 “(B) TRANSITIONAL COVERAGE PERIOD
2 DEFINED.—As used in this section, the term
3 ‘transitional coverage period’ means, with re-
4 spect to a breakthrough device, the period
5 that—

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

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

23 “(C) DATA USED TO MEET THE NTAP AND
24 PASS-THROUGH COST CRITERIA.—In deter-
25 mining whether a breakthrough device qualifies

1 for an additional payment under section
2 1886(d)(5)(K) or for pass-through payment
3 under section 1833(t)(6) or section 1833(i), the
4 Secretary shall use the most recently available
5 data and information on the costs of such
6 breakthrough device, which may include list
7 prices and invoice prices charged for such
8 breakthrough device.

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

16 “(A) IDENTIFICATION OF ADDITIONAL EVI-
17 DENCE.—

18 “(i) IN GENERAL.—With respect to a
19 breakthrough device, not later than 1 year
20 after the date of the approval of such de-
21 vice under section 515 of the Federal
22 Food, Drug, and Cosmetic Act or of the
23 clearance of such device under section
24 510(k) of such Act, as applicable, the Sec-
25 retary shall identify whether any additional

1 data or evidence is required with respect to
2 any indications for such device for pur-
3 poses of the application of such section
4 1862(a)(1)(A) to such device for such indi-
5 cations.

6 “(ii) NON-DUPLICATION OF DATA RE-
7 QUESTS.—In carrying out clause (i) with
8 respect to a breakthrough device, the Sec-
9 retary shall ensure that data or evidence
10 identified—

11 “(I) does not duplicate data re-
12 quired to be collected by the Food and
13 Drug Administration with respect to
14 such breakthrough device;

15 “(II) minimizes the administra-
16 tive burdens of data collection and re-
17 porting on providers of services, sup-
18 pliers, and manufacturers of break-
19 through devices; and

20 “(III) is not otherwise unneces-
21 sary or redundant.

22 “(B) PROPOSAL FOR COVERAGE AFTER
23 THE TRANSITIONAL COVERAGE PERIOD.—Not
24 later than 2 years after the date of the approval
25 or clearance of a breakthrough device by the

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

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

22 “(A) affect the ability of the manufacturer
23 of a breakthrough device to seek approval for
24 pass-through payment status under section
25 1833(t)(6) or to seek approval for an additional

1 payment under section 1886(d)(5)(K) insofar
2 as such breakthrough device does not qualify
3 for transitional coverage under paragraph (1);

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

11 “(C) prohibit the Secretary from using ex-
12 isting authority under this title to suspend or
13 terminate coverage of a breakthrough device if
14 the Secretary, based on clinical evidence, deter-
15 mines that—

16 “(i) such breakthrough device offers
17 no clinical benefit to Medicare bene-
18 ficiaries; or

19 “(ii) furnishing such breakthrough de-
20 vice to Medicare beneficiaries causes, or
21 may cause, serious harm to Medicare bene-
22 ficiaries.

23 “(c) CODING.—

24 “(1) PROMPT ASSIGNMENT.—Not later than
25 three months after the date of approval or clearance

1 of a breakthrough device by the Food and Drug Ad-
2 ministration, the Secretary shall assign a unique
3 temporary or permanent code or codes for purposes
4 of coverage and payment for such breakthrough de-
5 vice under the applicable payment systems (de-
6 scribed in paragraph (4)).

7 “(2) UPDATES.—

8 “(A) IPPS.—The Secretary shall provide
9 for semiannual updates under the applicable
10 payment system described in paragraph (4)(A)
11 (relating to the inpatient hospital prospective
12 payment system) to recognize the code or codes
13 assigned under paragraph (1).

14 “(B) OPPTS.—The Secretary shall provide
15 for quarterly updates under the applicable pay-
16 ment system described in paragraph (4)(B) (re-
17 lating to the outpatient hospital prospective
18 payment system) to recognize the code or codes
19 assigned under paragraph (1).

20 “(C) OTHER PAYMENT SYSTEMS.—The
21 Secretary shall provide for semiannual or quar-
22 terly updates, as the case may be, under the ap-
23 plicable payment systems described in subpara-
24 graphs (C) through (L) of paragraph (4) to rec-

1 ognize the code or codes assigned under para-
2 graph (1).

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

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

10 “(A) with respect to inpatient hospital
11 services, the prospective payment system for in-
12 patient hospital services established under sec-
13 tion 1886(d);

14 “(B) with respect to outpatient hospital
15 services, the prospective payment system for
16 covered OPD services established under section
17 1833(t);

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

21 “(D) with respect to physicians’ services,
22 the physician fee schedules established under
23 section 1848;

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

4 “(F) with respect to diagnostic laboratory
5 tests, the payment amounts under section
6 1834A and the fee schedules establish under
7 section 1848, as the case may be;

8 “(G) with respect to inpatient hospital
9 services furnished by rehabilitation facilities,
10 the prospective payment system established
11 under section 1886(j);

12 “(H) with respect to inpatient hospital
13 services furnished by long-term care hospitals,
14 the prospective payment system under section
15 1886(m);

16 “(I) with respect to inpatient hospital serv-
17 ices furnished by psychiatric hospitals and psy-
18 chiatric units, the prospective payment system
19 under section 1886(s);

20 “(J) with respect to home health services,
21 the prospective payment system under section
22 1895; and

23 “(K) with respect to items and services, or
24 a provider of services or supplier, not described
25 in subparagraphs (A) through (I), the payment

1 system established under this title for such
2 items and services when furnished by such pro-
3 vider of services or supplier.

4 “(d) PAYMENT.—

5 “(1) INPATIENT HOSPITAL PROSPECTIVE PAY-
6 MENT SYSTEM: DEEMED ELIGIBILITY FOR BREAK-
7 THROUGH PAYMENT.—The Secretary shall deem
8 each breakthrough device as approved for an addi-
9 tional payment under section 1886(d)(5)(K) for the
10 4-year period that begins—

11 “(A) except as provided in subparagraph
12 (B), on the date that the Secretary, pursuant to
13 subsection (c)(2)(A), updates the payment sys-
14 tem under section 1886(d) to recognize the
15 unique temporary or permanent code or codes
16 assigned under subsection (c)(1) to such break-
17 through device; or

18 “(B) in the case of a device that has not
19 received approval or clearance as a break-
20 through device by the Food and Drug Adminis-
21 tration before such payment system is updated
22 under subsection (c)(2)(A) to recognize the
23 unique temporary or permanent code or codes
24 assigned under subsection (c)(1) to such device,
25 on the date of such approval or clearance.

1 Nothing in this paragraph shall be construed to af-
2 fect the authority of the Secretary to use claims
3 data to establish new diagnosis or procedure codes
4 for breakthrough devices or to identify appropriate
5 diagnosis-related groups for the assignment of
6 breakthrough devices under annual rulemaking to
7 carry out section 1886(d)(5)(K).

8 “(2) OUTPATIENT PROSPECTIVE PAYMENT SYS-
9 TEM: DEEMED ELIGIBILITY FOR PASS-THROUGH
10 PAYMENT.—The Secretary shall deem each break-
11 through device as approved for pass-through pay-
12 ment under section 1833(t)(6) (including for pur-
13 poses of section 1833(i)(2)(D)) during the 4-year pe-
14 riod that begins—

15 “(A) except as provided in subparagraph
16 (B), on the date that the Secretary, pursuant to
17 subsection (c)(2)(B), updates the payment sys-
18 tem under section 1833(t) to recognize the
19 unique temporary or permanent code or codes
20 assigned under subsection (c)(1) to such break-
21 through device; or

22 “(B) in the case of a device that has not
23 received approval or clearance as a break-
24 through device by the Food and Drug Adminis-
25 tration before such payment system is updated

1 under subsection (c)(2)(B) to recognize the
2 unique temporary or permanent code or codes
3 assigned under subsection (c)(1) to such device,
4 on the date of such approval or clearance.

5 Nothing in this paragraph shall be construed to af-
6 fect the authority of the Secretary to use claims
7 data to establish new ambulatory payment classifica-
8 tion groups for breakthrough devices or to revise
9 such groups to take into account breakthrough de-
10 vices under annual rulemaking to carry out section
11 1833(t).

12 “(3) OTHER PAYMENT SYSTEMS.—

13 “(A) IN GENERAL.—In the case of a
14 breakthrough device that is furnished and for
15 which payment may be made under the pay-
16 ment system established under section 1834,
17 1834A, 1848, 1886(j), 1886(m), 1886(s), or
18 1895 or any other provision of this title (other
19 than sections 1833(i), 1833(t), and 1886(d)),
20 the Secretary shall provide for an additional
21 payment for such breakthrough device under
22 such applicable payment system or an adjust-
23 ment to such applicable payment system, as the
24 case may be. The payment basis for such addi-
25 tional payment or adjustment, as the case may

1 be, shall equal an amount that the Secretary
2 determines covers the costs of such break-
3 through device.

4 “(B) COST INFORMATION.—In determining
5 the costs of a breakthrough device for purposes
6 of determining an additional payment or pay-
7 ment adjustment under subparagraph (A), the
8 Secretary shall use the most recently available
9 data and information on the costs of such
10 breakthrough device, which may include list
11 prices and invoice prices charged for such
12 breakthrough device.

13 “(C) RULE OF CONSTRUCTION.—Nothing
14 in this paragraph shall be construed to affect
15 the authority of the Secretary to use claims
16 data to establish new or modify existing ambu-
17 latory payment classification groups, diagnosis-
18 related groups, level II HCPCS codes or such
19 other groups or codes as the Secretary may es-
20 tablish under the annual rulemaking authority
21 under the provisions referred to in subpara-
22 graph (A).

23 “(D) CLINICAL DIAGNOSTIC LABORATORY
24 TESTS.—An additional payment or payment ad-
25 justment under subparagraph (A) for a break-

1 through device under the applicable payment
2 system established in section 1834A may be in
3 the form of an increase to the amount deter-
4 mined for the breakthrough device using cross-
5 walking under section 1834A(c)(1)(A), an ex-
6 tension of the initial period of payment applica-
7 ble to advance diagnostic laboratory tests under
8 section 1834A(d)(1)(A), and in such other form
9 or manner as the Secretary determines reflects
10 the costs for such breakthrough device under
11 the relevant provisions of section 1834A.

12 “(4) PAYMENT FOR BREAKTHROUGH DEVICES
13 AFTER THE TRANSITIONAL COVERAGE PERIOD.—

14 Payment for a breakthrough device that is furnished
15 after the conclusion of the transitional coverage pe-
16 riod under subsection (b)(1) for such device shall be
17 made pursuant to the applicable payment system in-
18 volved, taking into account the additional evidence
19 and data collected under subsection (b)(2).

20 “(e) SPECIAL RULES FOR CERTAIN BREAKTHROUGH
21 DEVICES.—

22 “(1) COVERAGE OF SPECIFIED BREAKTHROUGH
23 DEVICES.—

24 “(A) IN GENERAL.—Subject to the suc-
25 ceeding provisions of this subsection and not-

1 withstanding any other provision of law, the
2 Secretary shall provide for coverage and pay-
3 ment pursuant to this section of a specified
4 breakthrough device (as defined in subpara-
5 graph (B)).

6 “(B) SPECIFIED BREAKTHROUGH DEVICE
7 DEFINED.—In this section, the term ‘specified
8 breakthrough device’ means a breakthrough de-
9 vice with respect to which no Medicare benefit
10 category exists.

11 “(2) PERIOD OF TRANSITIONAL COVERAGE.—

12 “(A) IN GENERAL.—Subject to subpara-
13 graph (C), the provisions of subsection (b)(1)
14 (relating to the transitional coverage period and
15 payment for breakthrough devices, including the
16 use of the most recently available data and in-
17 formation on costs) shall apply to a specified
18 breakthrough device in the same manner as
19 such provisions apply to a breakthrough device.
20 The Secretary may use methodologies under ex-
21 isting payment systems established under this
22 title, may provide for appropriate adjustments
23 to such methodologies, or may establish a new
24 payment methodology under this title, to pro-
25 vide for payment for a specified breakthrough

1 device to ensure the payment basis for such
2 payment covers costs of the specified break-
3 through device are covered by such payment.

4 “(B) REPORT.—

5 “(i) IN GENERAL.—With respect to
6 each specified breakthrough device, the
7 Secretary shall submit to Congress a re-
8 port on the coverage of and payment for
9 such specified breakthrough device under
10 this section that includes the following in-
11 formation:

12 “(I) The manner in which cov-
13 erage is provided and payment is
14 made for the specified breakthrough
15 device, including how such device was
16 classified (such as an item of durable
17 medical equipment or otherwise) and
18 the payment methodology the Sec-
19 retary applied with respect to such de-
20 vice.

21 “(II) The impact of the avail-
22 ability of the specified breakthrough
23 device to Medicare beneficiaries, in-
24 cluding impacts on the quality of pa-

1 patient care, patient outcomes, and pa-
2 tient experience.

3 “(III) The impact of the avail-
4 ability of the specified breakthrough
5 device to Medicare beneficiaries on
6 program expenditures under this title.

7 “(IV) Such other information as
8 the Secretary determines to be appro-
9 priate.

10 “(ii) DEADLINE.—

11 “(I) IN GENERAL.—Except as
12 provided in subclause (II), the Sec-
13 retary shall submit a report required
14 under this subparagraph no later than
15 the end of the transitional period of
16 coverage and payment applicable to
17 such specified breakthrough device.

18 “(II) EXTENSION TO GENERATE
19 ADDITIONAL DATA.—If the Secretary
20 determines that additional data or evi-
21 dence is required to complete a report
22 required under this subparagraph
23 with respect to a specified break-
24 through device, the deadline under

1 this clause may be extended for an
2 additional two years.

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

12 “(i) two years; or

13 “(ii) the amount of additional time re-
14 quired for the submission of the report
15 with respect to such device.

16 “(3) COVERAGE AND PAYMENT AFTER THE
17 TRANSITIONAL PERIOD.—The Secretary may con-
18 tinue to provide for coverage of and payment for a
19 specified breakthrough device after the end of the
20 transitional period of coverage and payment for
21 breakthrough devices through the national coverage
22 determination process if the Secretary determines
23 that the specified breakthrough device—

24 “(A) improves the quality of care and pa-
25 tient outcomes;

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

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

4 (b) CONFORMING AMENDMENTS.—

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

9 “(x) Effective for discharges occurring on
10 or after October 1, 2019, in the case of a new
11 medical service or technology that is a break-
12 through device (as defined in section
13 1899C(a)), the additional payment established
14 for such breakthrough device under this sub-
15 paragraph shall be made for the 4-year period
16 applicable to such breakthrough device under
17 section 1899C(d)(1). In determining the
18 amount of the additional payment for a break-
19 through device under this subparagraph during
20 such 4-year period, the Secretary shall apply
21 section 412.88(b) of title 42, Code of Federal
22 Regulations, as in effect on the date of the en-
23 actment of this clause, except as if the ref-
24 erence in such section to ‘65 percent’ were a

1 reference to ‘65 percent (or such greater per-
2 cent specified by the Secretary)’.”.

3 (2) OUTPATIENT PROSPECTIVE PAYMENT SYS-
4 TEM.—Section 1833(t)(6)(C) of such Act (42 U.S.C.
5 1395l(t)(6)(C)) is amended by adding at the end the
6 following new clause:

7 “(iii) SPECIAL RULE FOR BREAK-
8 THROUGH DEVICES.—Notwithstanding
9 clause (i) or (ii), or any other provision of
10 this paragraph to the contrary, in the case
11 of a breakthrough device (as defined in
12 section 1899C(a)) that is furnished on or
13 after January 1, 2020, payment under this
14 paragraph for such breakthrough device
15 shall be made for the 4-year period appli-
16 cable to such breakthrough device under
17 section 1899C(d)(2). The provisions of this
18 clause shall also apply for purposes of
19 transitional pass-through payment under
20 section 1833(i)(2)(D).”.

21 (c) EFFECTIVE DATE.—This section, and the amend-
22 ments made by this section, shall take effect on the date
23 of the enactment of this Act and, unless otherwise speci-
24 fied in this section (or in an amendment made by this sec-
25 tion), shall apply to breakthrough devices (as defined in

1 section 1899C(a) of the Social Security Act, as added by
2 subsection (a)), approved or cleared on or after July 1,
3 2019, or, in the case of a specified breakthrough device
4 (as defined in such section as so added), approved or
5 cleared on or after December 1, 2018.

6 **SEC. 405. SECRETARY OF HEALTH AND HUMAN SERVICES**
7 **REPORT ON COVERAGE FOR INNOVATIVE**
8 **TECHNOLOGIES.**

9 Not later than 1 year after the date of the enactment
10 of this Act, the Secretary of Health and Human Services,
11 in collaboration with the Administrator of the Centers for
12 Medicare & Medicaid Services, and following a request for
13 information, shall submit to Congress a report containing
14 a proposal that—

15 (1) specifies, for purposes of payment and cov-
16 erage under title XVIII of the Social Security Act,
17 a definition for digital alternatives to treatment and
18 therapies, including wearables and digital applica-
19 tions and platforms;

20 (2) establishes a standardized process for deter-
21 mining which technologies satisfy the definition pur-
22 suant to paragraph (1);

23 (3) establishes a standardized process for deter-
24 mining coverage under such title of digital alter-

1 natives as defined pursuant to paragraph (1) that
2 are prescribed by a physician; and

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

5 **SEC. 406. SECRETARY OF HEALTH AND HUMAN SERVICES**
6 **REPORT ON CMS COMPUTER SYSTEMS.**

7 Not later than one year after the date of the enact-
8 ment of this Act, the Secretary of Health and Human
9 Services shall submit to Congress a report on the fol-
10 lowing:

11 (1) The current state of computer systems of
12 the Centers for Medicare & Medicaid Services, in-
13 cluding an analysis of the capabilities and defi-
14 ciencies of such systems in helping to managing the
15 operations of the programs administered by the Cen-
16 ters for Medicare & Medicaid Services.

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

20 (A) Replacing or updating such systems
21 identified under paragraph (1).

22 (B) Contractors and other third parties to
23 solve for deficiencies in such system identified
24 under paragraph (1).

1 **SEC. 407. PRECISION MEDICINE ANSWERS FOR KIDS**
2 **TODAY.**

3 (a) CENTERS FOR MEDICARE & MEDICAID SERVICES
4 GUIDANCE ON THE EARLY AND PERIODIC SCREENING,
5 DIAGNOSTIC, AND TREATMENT BENEFIT.—Not later than
6 6 months after the date of the enactment of this Act, the
7 Centers for Medicare & Medicaid Services shall issue guid-
8 ance to States on authority and requirements under the
9 Medicaid program under title XIX of the Social Security
10 Act to provide medically necessary health care that falls
11 within the scope of services specified under section
12 1905(r) of the Social Security Act (42 U.S.C. 1396d(r))
13 to a child, regardless of whether the service is available
14 for adults under the State plan (or waiver of such plan)
15 under such title. The guidance shall—

16 (1) include technical and educational assistance
17 on how to increase the frequency of coverage under
18 the State plan (or waiver) pursuant to paragraphs
19 (4) and (16) of section 1905(a) of such Act (42
20 U.S.C. 1396d(a)) for genetic and genomic testing di-
21 agnostic services, including whole exome sequencing,
22 whole genome sequencing, and gene panels when rec-
23 ommended by a qualified treating provider as a first-
24 or second-tier test for pediatric patients, including
25 those who—

1 (A) have a positive result from a newborn
2 screening program;

3 (B) have one or more neurodevelopmental
4 or congenital anomalies;

5 (C) are experiencing developmental delay
6 or intellectual disability;

7 (D) are having seizures;

8 (E) have been referred or admitted to a
9 pediatric or neonatal intensive care unit for a
10 chronic or undiagnosed disease;

11 (F) have been seen by at least one medical
12 specialist for such chronic or undiagnosed dis-
13 ease; or

14 (G) are suspected by at least one
15 healthcare provider to have a neonatal- or pedi-
16 atric-onset genetic disease;

17 (2) provide education and support to providers
18 to minimize denials of claims for medical assistance
19 under the State plan under title XIX of the Social
20 Security Act resulting from deficient or inadequate
21 paperwork; and

22 (3) ensure that providers and Medicaid-eligible
23 children and the families are aware of the Early and
24 Periodic Screening, Diagnostic and Treatment Ben-
25 efit under title XIX of the Social Security Act and

1 have access to required screenings and necessary
2 treatment services.

3 (b) DEMONSTRATION PROGRAM TO PROVIDE GE-
4 NETIC AND GENOMIC TESTING FOR CERTAIN CHIL-
5 DREN.—

6 (1) IN GENERAL.—The Secretary of Health and
7 Human Services shall enter into agreements with up
8 to 15 States submitting applications under para-
9 graph (3) for the purpose of conducting, in accord-
10 ance with this subsection, demonstration projects
11 under section 1115 of the Social Security Act (42
12 U.S.C. 1315) in such States during the 3-year pe-
13 riod beginning on the first date of the first fiscal
14 quarter than begins on or after the date of the en-
15 actment of this subsection to test and evaluate the
16 provision of medical assistance under the State plans
17 under title XIX of such Act (or waivers of such
18 plans) to eligible individuals for purposes of pro-
19 viding such individuals with genetic and genomic
20 testing.

21 (2) DEMONSTRATION PROJECT PAYMENT RE-
22 QUIREMENTS.—Under each demonstration project
23 under this section conducted by a State, the fol-
24 lowing shall apply:

1 (A) The State shall provide a health care
2 provider (as defined by the State) with pay-
3 ments for the provision of genetic and genomic
4 testing to any eligible individual. Payments
5 made to a health care provider for such services
6 shall be treated as medical assistance for pur-
7 poses of section 1903(a) of the Social Security
8 Act (42 U.S.C. 1396b(a)), except that the Fed-
9 eral medical assistance percentage applicable to
10 such payments shall be equal to 100 percent.

11 (B) The State shall specify the method-
12 ology the State will use for determining pay-
13 ment for the provision of genetic and genomic
14 testing. Such methodology for determining pay-
15 ment shall be established consistent with section
16 1902(a)(30)(A) of such Act (42 U.S.C.
17 1396a(a)(30)(A)).

18 (3) APPLICATIONS.—

19 (A) IN GENERAL.—A State desiring to
20 enter into an agreement under paragraph (1)
21 with the Secretary for conducting a demonstra-
22 tion project shall submit to the Secretary an
23 application, in accordance with such form and
24 manner, and application priorities, as specified

1 by the Secretary and that at a minimum in-
2 cludes the following:

3 (i) An explanation of how and the ex-
4 tent to which genetic and genomic testing
5 under the demonstration project of the
6 State will provide information and data on
7 how such services improve the diagnosis of
8 eligible individuals.

9 (ii) An explanation of how and the ex-
10 tent to which coverage under the State
11 plan (or waiver) pursuant to the dem-
12 onstration project will increase the use of
13 genetic and genomic testing that may in-
14 crease the use of genetic and genomic test-
15 ing that may improve clinical outcomes for
16 eligible individuals.

17 (iii) Procedures for referring any eligi-
18 ble individual who seeks or needs treat-
19 ment in a hospital emergency department
20 to a health care provider who is qualified
21 (as determined by the State) to provide ge-
22 netic and genomic testing.

23 (iv) An explanation of how genetic
24 and genomic testing may improve health

1 outcomes for all populations in the State,
2 including—

3 (I) individuals with a rare genetic
4 disease, including a metabolic disease,
5 neurologic disorders, or hereditary
6 cancer testing in the presence of a
7 suspected or confirmed cancer diag-
8 nosis; and

9 (II) special populations, including
10 infants and children who are critically
11 ill (non-infectious and non-trauma)
12 patients, transplant patients, individ-
13 uals with cardiac disease, and individ-
14 uals with, or who have a family his-
15 tory of, a birth defect or develop-
16 mental disability.

17 (B) PREFERENCES IN CONSIDERING AP-
18 PPLICATIONS.—In considering applications sub-
19 mitted under subparagraph (A), the Secretary
20 of Health and Human Services shall give pref-
21 erence to States that can demonstrate under-
22 utilization of genetic and genomic sequencing
23 clinical services (with priority given to States
24 that do not cover whole-genome sequencing or
25 do not cover the majority of genetic and

1 genomic clinical services) in pediatric popu-
2 lations under the State plan under title XIX of
3 the Social Security Act (or waiver of such
4 plan).

5 (4) TECHNICAL ASSISTANCE.—The Secretary of
6 Health and Human Services shall provide technical
7 assistance to assist States in planning and designing
8 the demonstration project for purposes of applying
9 for conducting such project under this section.

10 (5) REPORTS BY STATES.—Not later than one
11 year after the date on which a State enters into an
12 agreement under paragraph (1) with the Secretary
13 for conducting a demonstration project, the State
14 shall submit a report to the Administrator of the
15 Centers for Medicare & Medicaid Services and the
16 Administrator of the Health Resources and Services
17 Administration on the extent to which genetic and
18 genomic testing improved outcomes and reduced
19 health disparities. Such report shall include informa-
20 tion on the number of patients receiving genetic and
21 genomic testing, the types of services provided, and
22 such other information as the Secretary shall pre-
23 scribe.

24 (6) REPORTS BY HEALTH CARE PROVIDERS.—
25 As a condition for receiving payment for genetic and

1 genomic testing provided to an eligible individual
2 under a demonstration project conducted by a State
3 under this subsection, a health care provider shall
4 report to the State, in accordance with such require-
5 ments as the Secretary shall specify, on all applica-
6 ble measures for determining the quality and effi-
7 cacy of such services.

8 (7) DEFINITIONS.—In this subsection:

9 (A) ELIGIBLE INDIVIDUAL.—The term “el-
10 igible individual” means, with respect to a
11 State, an individual who—

12 (i) is eligible for medical assistance
13 under the State plan under title XIX of
14 the Social Security Act (or a waiver of
15 such plan);

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

23 (iii) has been referred or admitted to
24 an intensive care unit, or has been seen by

1 at least one medical specialist, for a sus-
2 pected genetic or undiagnosed disease; or

3 (iv) is suspected by at least one med-
4 ical specialist to have a neonatal-onset or
5 pediatric-onset genetic disease.

6 (B) GENETIC AND GENOMIC TESTING.—

7 The term “genetic and genomic testing”, with
8 respect to an eligible individual—

9 (i) means the determination of a se-
10 quence of deoxyribonucleic acid bases in
11 the genome of such individual, and, if for
12 the sole benefit of the individual, a biologi-
13 cal parent of such individual for the pur-
14 pose of determining whether one or more
15 potentially disease-causing genetic variants
16 are present in the genome of such indi-
17 vidual or such biological parent; and

18 (ii) includes—

19 (I) the sequencing of the whole
20 genome, the whole exome, or a panel
21 of genes; and

22 (II) any analysis, interpretation,
23 and data report derived from such se-
24 quencing.

25 (c) NATIONAL ACADEMY OF MEDICINE STUDY.—

1 (1) IN GENERAL.—Not later than one year
2 after the date of the enactment of this Act, the Sec-
3 retary of Health and Human Services shall enter
4 into an arrangement with the National Academy of
5 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) disparities in access to precision
11 diagnostics and associated therapeutics;

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 genetic and genomic testing (as defined in
23 subsection (b)(7)(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 pediatric popu-
24 lations in the United States, including—

1 (i) children with a rare disease, in-
2 cluding a metabolic disease, neurologic dis-
3 order, or hereditary cancer testing in the
4 presence of a suspected or confirmed can-
5 cer diagnosis; and

6 (ii) special populations, including—

7 (I) critically ill (non-infectious
8 and non-trauma) patients;

9 (II) transplant patients;

10 (III) individuals with cardiac dis-
11 ease; and

12 (IV) individuals with, or who
13 have a family history of, a birth defect
14 or developmental disability.

15 (2) REPORT.—

16 (A) IN GENERAL.—The arrangement
17 under paragraph (1) shall provide for the Na-
18 tional Academy of Medicine to submit, not later
19 than 2 years after the date of the enactment of
20 this Act, a report on the results of the study
21 under paragraph (1) to—

22 (i) the Secretary of Health and
23 Human Services;

24 (ii) the Committee on Ways and
25 Means and the Committee on Energy and

1 Commerce of the House of Representa-
2 tives; and

3 (iii) the Committee on Finance and
4 the Committee on Health, Education,
5 Labor, and Pensions of the Senate.

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

18 (C) USE OF INFORMATION.—The National
19 Academy of Medicine shall, to the extent pos-
20 sible, in conducting the study under paragraph
21 (1), utilize information included in the reports
22 submitted pursuant to subsections (f) and (g)
23 of section 2.

24 (d) CENTERS FOR MEDICARE & MEDICAID SERVICES
25 REPORT ON MEDICAID COVERAGE FOR GENETIC AND

1 GENOMIC TESTING.—Not later than one year after the
2 date of the enactment of this Act, and annually thereafter
3 for the subsequent 3 years, the Centers for Medicare &
4 Medicaid Services shall submit to the Secretary of Health
5 and Human Services, the Committees on Ways and Means
6 and on Energy and Commerce of the House of Represent-
7 atives, and the Committees on Finance and Health, Edu-
8 cation, Labor, and Pensions of the Senate a report on the
9 extent to which each of the 50 States provide coverage
10 under the State plan under title XIX of the Social Secu-
11 rity Act (or waiver of such plan) of genetic and genomic
12 testing (as defined in subsection (b)(7)(B)) (including
13 whole exome, whole genome, gene panels, single gene tests,
14 Chromosomal microarray analysis, Fluorescence in situ
15 hybridization, and other genetic and genomic tests), in-
16 cluding information on—

17 (1) how often genetic and genomic diagnostic
18 testing services are covered and reimbursed;

19 (2) the frequency of denials for coverage and
20 the rationale for denying coverage;

21 (3) an analysis of which genetic and genomic
22 diagnostic tests are being approved or denied;

23 (4) how often test genetic counseling is covered
24 pre- and post-genetic and genomic diagnostic test-
25 ing;

1 (5) the turn-around time for prior authorization
2 requests; and

3 (6) any barriers to coverage of genetic and
4 genomic testing services identified.

5 **SEC. 408. MEDICARE COVERAGE FOR CONSULTATIONS.**

6 (a) INCLUSION OF CONSULTATIONS AS A MEDICARE
7 BENEFIT.—Section 1861 of the Social Security Act (42
8 U.S.C. 1395x) is amended—

9 (1) in subsection (s)(2)—

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

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

14 (C) by adding at the end the following new
15 subparagraph:

16 “(II) pharmacogenetic consultations pro-
17 vided by a qualified clinical pharmacist, genetic
18 counselor, or pathologist (as such terms are de-
19 fined in subsection (lll)).”; and

20 (2) by adding at the end the following new sub-
21 section:

22 “(lll) DEFINITIONS.—In this section:

23 “(1) PHARMACOGENETIC CONSULTATION.—The
24 term ‘pharmacogenetic consultation’ means, with re-
25 spect to a genetic or genomic test furnished to an

1 individual, a consultation with respect to such test
2 requested by the physician treating such individual
3 to provide such physician with advice and rec-
4 ommendations regarding the dosage, safety, and effi-
5 cacy of particular drugs, biologicals, and other treat-
6 ments based on the individual's pharmacogenetic re-
7 sult.

8 “(2) GENETIC COUNSELOR.—The term ‘genetic
9 counselor’ means an individual who—

10 “(A) is licensed as a genetic counselor by
11 the State in which the individual furnishes ge-
12 netic counseling services; or

13 “(B) in the case of an individual practicing
14 in a State that does not license genetic coun-
15 selors, meets such other criteria as the Sec-
16 retary establishes.

17 “(3) QUALIFIED CLINICAL PHARMACIST.—The
18 term ‘qualified clinical pharmacist’ means an indi-
19 vidual—

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

21 “(B) who is licensed as a pharmacist in
22 the State in which such individual furnishes
23 consultations;

1 “(C) has appropriate pharmacy specialty
2 certifications or appropriate training, as deter-
3 mined by the Secretary; and

4 “(D) meets other qualifications as specified
5 by the Secretary.”.

6 (b) PAYMENT FOR PHARMACOGENETIC CONSULTA-
7 TION.—Section 1832(a)(2) of the Social Security Act (42
8 U.S.C. 1395k(a)(2)) is amended—

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

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

13 (3) by adding at the end the following new sub-
14 paragraph:

15 “(K) pharmacogenetic consultations (as
16 defined in subsection (lll)).”.

17 (c) EFFECTIVE DATE.—The amendments made by
18 subsections (a) and (b) shall apply to consultations fur-
19 nished during a cost reporting period beginning on or after
20 the date of the enactment of such subsections.

1 **SEC. 409. PROHIBITING THE USE OF GEOGRAPHIC TRACK-**
2 **ING FEATURES AND BIOMETRICS WITHIN**
3 **MEDICAID ELECTRONIC VISIT VERIFICATION**
4 **SYSTEMS.**

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

9 (b) EFFECTIVE DATE.—The amendment made by
10 subsection (a) shall apply with respect to calendar quar-
11 ters beginning on or after June 1, 2022.

12 **SEC. 410. GENERALLY ACCEPTED STANDARD FOR ELEC-**
13 **TRONIC PRESCRIBING.**

14 Section 1860D–4(e) of the Social Security Act (42
15 U.S.C. 1395w–104(e)) is amended by adding at the end
16 the following new paragraph:

17 “(8) GENERALLY ACCEPTED STANDARDS.—

18 “(A) DESIGNATION OF STANDARDS MAIN-
19 TENANCE ORGANIZATION TO RECOGNIZE GEN-
20 ERALLY ACCEPTED STANDARDS.—Not later
21 than 6 months after the date of the enactment
22 of this paragraph, the Secretary shall designate
23 through rulemaking a standards maintenance
24 organization with the authority to establish,
25 maintain, and modify generally accepted stand-
26 ards for electronic prescribing and electronic

1 prior authorization. The standards maintenance
2 organization named by the Secretary shall be a
3 standard setting body that—

4 “(i) is a not-for-profit;

5 “(ii) has established a multi-stake-
6 holder forum for development and approval
7 of electronic prescribing and electronic
8 prior authorization standards;

9 “(iii) is a standards development or-
10 ganization accredited by the American Na-
11 tional Standards Institute; and

12 “(iv) includes in its membership phar-
13 macies, prescribers, prescription drug
14 plans, health information technology devel-
15 opers, and representatives from the Cen-
16 ters for Medicare & Medicaid Services and
17 the Food and Drug Administration.

18 In providing the standards maintenance organi-
19 zation with the authority to establish, maintain,
20 and modify generally accepted standards, the
21 Secretary shall permit the standards mainte-
22 nance organization to recognize up to two
23 versions of a standard as being generally ac-
24 cepted to facilitate the testing of newer stand-

1 ards and to allow a smooth transition from one
2 standard to another.

3 “(B) ADOPTION OF GENERALLY ACCEPTED
4 STANDARDS.—Not later than six months after
5 making the designation under paragraph (8),
6 the Secretary shall require prescriptions and
7 other information described in paragraph
8 (2)(A) for covered Part D drugs prescribed for
9 Part D eligible individuals that are transmitted
10 electronically to be transmitted only in accord-
11 ance with generally accepted standards, as des-
12 ignated by the standards maintenance organiza-
13 tion named by the Secretary under subpara-
14 graph (A), under an electronic prescription
15 drug program that meets the requirements of
16 paragraph (2).”.

17 **SEC. 411. MEANINGFUL ACCESS TO FEDERAL HEALTH**
18 **PLAN CLAIMS DATA.**

19 (a) FINDINGS.—Congress finds as follows:

20 (1) Clinician-led clinical data registries serve an
21 important role in promoting, facilitating, and con-
22 ducting medical research and improving quality of
23 healthcare by providing timely and actionable feed-
24 back to practitioners on their performance in rela-
25 tion to other practitioners and best clinical practices.

1 (2) Clinician-led clinical data registries are hin-
2 dered in their ability to promote medical research
3 and quality improvement by their lack of meaningful
4 access to claims data.

5 (3) While the Centers for Medicare & Medicaid
6 Services has established programs for providing ac-
7 cess to claims data, those programs fail to provide
8 clinician-led clinical data registries with meaningful
9 access to such data.

10 (4) Ensuring clinician-led clinical data reg-
11 istries meaningful access to claims data will enable
12 such entities to better track patient outcomes over
13 time, expand their ability to assess the safety and ef-
14 fectiveness of medical treatments, and provide them
15 with the information necessary to assess the cost-ef-
16 fectiveness of therapies.

17 (b) ENSURING MEANINGFUL ACCESS TO CLAIMS
18 DATA.—

19 (1) ESTABLISHMENT OF A NEW PROGRAM.—
20 The Secretary shall establish a new program (sepa-
21 rate from any existing data access programs, includ-
22 ing, without limitation, the Centers for Medicare &
23 Medicaid Services Qualified Entity (in this section,
24 referred to as “QE”) Program (42 U.S.C.
25 1395kk(e), 1395kk–2) (in this section, referred to as

1 the “Medicare Data Sharing for Performance Meas-
2 urement Program”) and the Research Data Assist-
3 ance Center (in this section, referred to as the
4 “ResDAC”) process) under which the Secretary
5 shall, at the request of a clinician-led clinical data
6 registry, provide timely, broad, and continuous ac-
7 cess to a database of claims data to such clinician-
8 led clinical data registry for purposes of research,
9 quality of care measurement and reporting to health
10 care providers, linking such data with clinical data
11 and performing risk-adjusted, scientifically valid
12 analyses and research to support quality improve-
13 ment or patient safety, and other purposes and uses
14 described herein or approved by the Secretary. Ac-
15 cess to a database of claims data pursuant to this
16 subsection shall not be more restrictive than access
17 to data provided under the QE Program or the
18 ResDAC process.

19 (2) STREAMLINED APPLICATION PROCESS.—

20 (A) INITIAL AND RECERTIFICATION APPLI-
21 CATION.—Prior to gaining access to a database
22 of claims data under the program established in
23 subsection (a), a clinician-led clinical data reg-
24 istry shall submit to the Secretary an applica-
25 tion demonstrating that it is qualified (as deter-

1 mined by the Secretary) to use claims data.
2 Upon the Secretary's approval of a clinician-led
3 clinical data registry's application described in
4 this subparagraph, the Secretary shall provide
5 access to a database of claims data to such cli-
6 nician-led clinical data registry for a period of
7 at least 5 years. After the expiration of the time
8 period described in this subparagraph, the clini-
9 cian-led clinical data registry shall reapply to
10 access the database of claims data under the
11 program established in subsection (a).

12 (B) PROCESS.—The Secretary shall estab-
13 lish a streamlined initial application and recer-
14 tification application process under which the
15 Secretary shall approve or deny the clinician-led
16 clinical data registry's application described in
17 subparagraph (2)(A) within 60 calendar days
18 after receiving the application unless the Sec-
19 retary demonstrates a compelling reason for
20 needing additional time to complete the process.
21 If the clinician-led clinical data registry's appli-
22 cation described in subparagraph (2)(A) is de-
23 nied, the Secretary shall provide the reason(s)
24 for denial.

25 (3) APPEAL RIGHTS.—

1 (A) OPPORTUNITY TO APPEAL.—The Sec-
2 retary shall develop and maintain a process by
3 which a clinician-led clinical data registry may
4 appeal—

5 (i) the Secretary’s decision to deny an
6 application described in paragraph (2); and

7 (ii) the Secretary’s failure to approve
8 or deny the clinician-led clinical data reg-
9 istry’s application described in paragraph
10 (2) within a reasonable time frame estab-
11 lished by the Secretary.

12 (B) DEADLINE FOR DECISION.—The Sec-
13 retary shall render a decision with respect to an
14 appeal filed by a clinician-led clinical data reg-
15 istry pursuant to subparagraph (A) in a timely
16 manner, not to exceed 60 calendar days after
17 the Secretary receives the clinician-led clinical
18 data registry’s request for an appeal. Notice of
19 such decision shall be provided to the clinician-
20 led clinical data registry filing the appeal before
21 the conclusion of such 60-day period.

22 (4) BROAD AND TIMELY ACCESS TO DATA.—

23 The Secretary shall structure its database of claims
24 data to allow for various data set queries, including,
25 but not limited to, provider-specific claims data, clin-

1 ical specialty-specific claims data, state-specific
2 claims data, and nationwide claims data. The Sec-
3 retary shall promptly make available to a clinician-
4 led clinical data registry access to claims data re-
5 quested by such clinician-led clinical data registry
6 within a reasonable timeframe, not to exceed 30 cal-
7 endar days, after the Secretary approves the request
8 from the clinician-led clinical data registry.

9 (c) PERMISSIBLE USES OF CLAIMS DATA.—Clini-
10 cian-led clinical data registries may—

11 (1) make available to the public reports evalu-
12 ating the performance of providers of services and
13 suppliers using the claims data provided to such cli-
14 nician-led clinical data registry under subsection (a)
15 in combination with registry data;

16 (2) use claims data received under subsection
17 (a) combined with registry data to conduct addi-
18 tional nonpublic analyses and provide or charge an
19 access fee for such analyses to authorized users for
20 nonpublic use;

21 (3) provide or charge an access fee for data sets
22 that link claims data received under subsection (a)
23 with registry data to authorized users for nonpublic
24 use; and

1 (4) provide or charge an access fee for claims
2 data received under subsection (a) to authorized
3 users for nonpublic use.

4 (d) FEES.—

5 (1) CLAIMS DATA PROVIDED TO CLINICIAN-LED
6 CLINICAL DATA REGISTRIES.—Claims data shall be
7 provided to a clinician-led clinical data registry
8 under subsection (a) at a reasonable fee based on
9 the cost of providing such data to the clinician-led
10 clinical data registry. Such fee shall be based at
11 least in part on the number of patients included in
12 the claims data provided to such clinician-led clinical
13 data registry. Any fee collected pursuant to the pre-
14 ceding sentences shall be deposited in the Centers
15 for Medicare & Medicaid Services Program Manage-
16 ment Account.

17 (2) ANALYSES AND DATA PROVIDED TO AU-
18 THORIZED USERS.—A clinician-led clinical data reg-
19 istry may charge a reasonable, cost-based fee for
20 providing to authorized users claims data, data sets
21 linking claims data with registry data, or analyses
22 described in subsection (b).

23 (e) PROTECTION OF INFORMATION.—

24 (1) PRIVACY, SECURITY, AND DISCLOSURE
25 LAWS.—The Secretary shall provide access to a

1 database of claims data pursuant to subsection (a)
2 in accordance with applicable information, privacy,
3 security, and disclosure laws, including, without limi-
4 tation, the Health Insurance Portability and Ac-
5 countability Act of 1996 (Public Law 104–191) as
6 amended by the privacy and security provisions set
7 forth in section 13400 of the Health Information
8 Technology for Economic and Clinical Health Act
9 (Public Law 111–5), the regulations promulgated
10 thereunder codified at parts 160 and 164 of title 45,
11 Code of Federal Regulations, and subparagraphs (A)
12 through (B) of section 105(a)(3) of the Medicare
13 Access and CHIP Reauthorization Act of 2015 (42
14 U.S.C. 1395kk–2(a)(3)).

15 (2) PROHIBITION ON USING ANALYSES OR DATA
16 FOR MARKETING PURPOSES.—An authorized user
17 shall not use analyses or data provided or sold under
18 paragraphs (2) through (4) of subsection (b) for
19 marketing purposes.

20 (3) NO REDISCLOSURE OF ANALYSES OR
21 DATA.—An authorized user in receipt of an analysis
22 or datum provided or sold under paragraphs (2)
23 through (4) of subsection (b) shall comply with sec-
24 tion 105(a)(5) of Medicare Access and CHIP Reau-
25 thorization Act of 2015 (42 U.S.C. 1395kk–2(a)(5)).

1 (4) OPPORTUNITY FOR PROVIDERS OF SERV-
2 ICES AND SUPPLIERS TO REVIEW.—Prior to a clini-
3 cian-led clinical data registry using, providing, or
4 charging an access fee for claims data, data sets
5 linking claims data with registry data, or analyses
6 described in subsection (b), to the extent that such
7 data, data sets, or analyses would individually iden-
8 tify a provider of services or supplier who is not
9 being provided or sold such data, data sets, or anal-
10 yses, such clinician-led clinical data registry shall
11 confidentially make available such data, data sets, or
12 analyses to such provider of services or supplier and
13 provide such provider of services or supplier with the
14 opportunity to appeal and correct errors.

15 (f) DATA USE AGREEMENT.—A clinician-led clinical
16 data registry and an authorized user shall enter into a
17 data use agreement regarding the use or disclosure of any
18 claims data or data sets that link claims data with registry
19 data that the clinician-led clinical data registry is pro-
20 viding or charging an access fee to the authorized user
21 under paragraphs (3) through (4) of subsection (b). Such
22 agreement shall include the requirements and prohibitions
23 described in section 105(a)(4) of the Medicare Access and
24 CHIP Reauthorization Act of 2015 (42 U.S.C. 1395kk–
25 2(a)(4)).

1 (g) ASSESSMENT FOR A BREACH.—

2 (1) IN GENERAL.—In the case of a breach of a
3 data use agreement described in subsection (e), the
4 Secretary shall impose an assessment on the clini-
5 cian-led clinical data registry and the authorized
6 user.

7 (2) ASSESSMENT.—The assessment under para-
8 graph (1) shall be in an amount up to \$100 for each
9 individual entitled to, or enrolled for, benefits under
10 part A of title XVIII of the Social Security Act or
11 enrolled for benefits under part B of such title for
12 whom the clinician-led clinical data registry provided
13 data on to the authorized user.

14 (3) DEPOSIT OF AMOUNTS COLLECTED.—Any
15 amounts collected pursuant to this subsection shall
16 be deposited in the Federal Supplementary Medical
17 Insurance Trust Fund under section 1841 of the So-
18 cial Security Act (42 U.S.C. 1395t).

19 (h) DISCOVERY OR ADMISSION AS EVIDENCE.—
20 Claims data released to a clinician-led clinical data reg-
21 istry under subsection (a) shall not be subject to discovery
22 or admission as evidence in judicial or administrative pro-
23 ceedings without consent of the applicable provider of
24 services or supplier.

1 (i) REPORT TO CONGRESS.—Not later than 2 years
2 after the date of the enactment of this Act, and annually
3 thereafter, the Secretary shall submit to Congress a report
4 on the extent to which clinician-led clinical data registries
5 are afforded meaningful access to claims data.

6 (j) DEFINITIONS.—In this subtitle:

7 (1) AUTHORIZED USER.—The term “authorized
8 user” has the meaning given such term in section
9 105(a)(9)(A) of the Medicare Access and CHIP Re-
10 authorization Act of 2015 (42 U.S.C. 1395kk-
11 2(a)(9)(A)), as well as a government agency or other
12 governmental entity, researchers, entities that seek
13 data for purposes of complying with regulations or
14 other requirements of the Federal Food and Drug
15 Administration, and other entities approved by the
16 Secretary.

17 (2) CLAIMS DATA.—The term “claims data”
18 has the meaning given to the term “data” in section
19 105(b)(1)(B) of the Medicare Access and CHIP Re-
20 authorization Act of 2015 (42 U.S.C. 1395kk-
21 2(b)(1)(B)).

22 (3) CLINICIAN-LED CLINICAL DATA REG-
23 ISTRY.—The term “clinician-led clinical data reg-
24 istry” has the meaning given such term in section
25 4005(b) of the 21st Century Cures Act.

1 (4) NONPUBLIC USE.—The term “nonpublic
2 use” means a use for the purpose of—

3 (A) promoting, facilitating, and conducting
4 medical research, assisting providers of services
5 and suppliers to improve patient safety, and to
6 develop and participate in quality and patient
7 care improvement activities, including devel-
8 oping new models of care;

9 (B) assisting clinician-led clinical data reg-
10 istries in developing and reporting quality meas-
11 ures to health care providers quality measures;

12 (C) educating a government agency or
13 other governmental entity; and

14 (D) supporting clinical trials and other ac-
15 tivities necessary to comply with pre- or post-
16 market approval or adverse event reporting re-
17 quirements or conditions imposed by the Food
18 and Drug Administration, and other purpose
19 approved by the Secretary.

20 (5) PROVIDER OF SERVICES.—The term “pro-
21 vider of services” has the meaning given such term
22 in section 1861(u) of the Social Security Act (42
23 U.S.C. 1395x(u)).

1 (6) SUPPLIER.—The term “supplier” has the
2 meaning given such term in section 1861(d) of the
3 Social Security Act (42 U.S.C. 1395x(d)).

4 (k) REGULATIONS.—Not later than 1 year after the
5 date of the enactment of this Act, the Secretary of Health
6 and Human Services shall promulgate final regulations to
7 implement the provisions of the preceding sections of this
8 subtitle.

9 **TITLE V—RESEARCH**

10 **SEC. 501. ADVANCED RESEARCH PROJECTS AGENCY FOR** 11 **HEALTH.**

12 (a) ESTABLISHMENT.—The Secretary of Health and
13 Human Services, acting through the Director of the Na-
14 tional Institutes of Health, shall establish the Advanced
15 Research Projects Agency for Health (to be referred to
16 in this Act as “ARPA–H”) to transform and improve im-
17 portant areas of medicine and health for the well-being
18 of all individuals in the United States.

19 (b) GOALS.—

20 (1) IN GENERAL.—The goals of ARPA–H shall
21 be to deliver breakthrough capabilities through tech-
22 nologies, systems, and platforms that—

23 (A) accelerate the discovery and applica-
24 tion of transformational innovations in health
25 and medical product development; and

1 (B) reduce the human and economic cost
2 of disease.

3 (2) MEANS.—ARPA–H may achieve the estab-
4 lished goals under paragraph (1), including by any
5 of the following means:

6 (A) Promoting high-risk, high-reward inno-
7 vation.

8 (B) Identifying and promoting revolu-
9 tionary advances in biomedical and health re-
10 search that enable new paradigms in health.

11 (C) Accelerating transformational health
12 advances in areas that the relevant industries
13 by themselves are not likely to undertake be-
14 cause of technical, financial, or other uncer-
15 tainty.

16 (D) Prioritizing project investments based
17 on scientific opportunity and uniqueness of fit
18 to ARPA–H strategies and operating practice,
19 together with the prospective impact on disease
20 burden (regardless of disease prevalence), both
21 human and fiscal, including the health care fis-
22 cal liability of the Federal government.

23 (E) Partnering with, and providing fund-
24 ing to, a broad range of institutions, including
25 universities, national laboratories, public sector

1 organizations, private companies, nonprofit or-
2 ganizations, and foreign institutions.

3 (c) DIRECTOR.—

4 (1) IN GENERAL.— ARPA–H shall be headed
5 by a Director, who shall be appointed by and serve
6 at the pleasure of the President (referred to in this
7 section as the “Director of ARPA–H”).

8 (2) SELECTION.—The Director of ARPA–H
9 shall—

10 (A) be an individual who, by reason of pro-
11 fessional background and experience, is quali-
12 fied to advise the Secretary on, and manage re-
13 search programs addressing, matters pertaining
14 to long-term and high-risk barriers to the devel-
15 opment of health innovation;

16 (B) have authority to execute contracts de-
17 veloped by in-house program managers who se-
18 lect external performers, and maintain, enhance
19 or terminate projects based on performance
20 against explicit milestones; and

21 (C) have a time-limited appointment of 5
22 years with the opportunity, at the discretion of
23 the President, of one extension.

24 (3) DUTIES.—The duties of the Director of
25 ARPA–H shall be to—

1 (A) set national research priorities to ad-
2 vance the mission of the agency as informed by
3 a multi-sectoral board of advisors;

4 (B) approve all new programs within
5 ARPA–H;

6 (C) have final funding authority to initiate
7 and terminate program funding;

8 (D) establish criteria for funding and as-
9 ssuming the success of programs through the es-
10 tablishment of technical milestones;

11 (E) appoint the personnel necessary, con-
12 sistent with subsection (d), to successfully exe-
13 cute the goals of ARPA–H; and

14 (F) designate employees to serve as pro-
15 gram managers to carry out the duties de-
16 scribed in subsection (e) for each of the pro-
17 grams established pursuant to the responsibil-
18 ities established for ARPA–H.

19 (4) AUTHORITY.—The Director of ARPA–H is
20 authorized to—

21 (A) acquire (by purchase, lease, condemna-
22 tion, or otherwise), construct, improve, repair,
23 operate, and maintain such real and personal
24 property as are necessary to carry out this sec-
25 tion; and

1 (B) lease an interest in property for not
2 more than 20 years, notwithstanding section
3 1341(a)(1) of title 31, United States Code.

4 (d) PERSONNEL MANAGEMENT AUTHORITY.—

5 (1) SPECIAL PERSONNEL MANAGEMENT AU-
6 THORITY.—The Director of ARPA–H may—

7 (A) make appointments to positions of ad-
8 ministration or management of ARPA–H with-
9 out regard to any provision in title 5, United
10 States Code, governing appointments under the
11 civil service laws and fix the compensation of
12 such positions at a rate not to exceed the
13 amount of annual compensation (excluding ex-
14 penses) specified in section 102 of title 3,
15 United States Code, notwithstanding section
16 202 of Department of Health and Human Serv-
17 ices Appropriations Act, 1993 (Public Law
18 102–394);

19 (B) hire personnel under section 207(f) of
20 the Public Health Service Act (42 U.S.C.
21 209(f)) and establish governing criteria to re-
22 cruit, appoint, and compensate personnel under
23 this section notwithstanding section 202 of De-
24 partment of Health and Human Services Ap-
25 propriations Act, 1993 (Public Law 102–394)

1 or any provision of title 5, United States Code,
2 governing the rates of pay or classification of
3 employees in the Executive branch;

4 (C) make additional appointments of sci-
5 entific, medical, and professional personnel
6 under this section without regard to any provi-
7 sion in title 5, United States Code, governing
8 appointments under the civil service laws and
9 fix the compensation of such personnel at a rate
10 to be determined by the Director, up to the
11 amount of annual compensation (excluding ex-
12 penses) specified in section 102 of title 3,
13 United States Code, notwithstanding section
14 202 of Department of Health and Human Serv-
15 ices Appropriations Act, 1993 (Public Law
16 102–394) or any provision of title 5, United
17 States Code, governing the rates of pay or clas-
18 sification of employees in the Executive branch;
19 and

20 (D) recruit and retain a diverse workforce,
21 including individuals underrepresented in
22 science and medicine and racial and ethnic mi-
23 norities.

24 (2) ADDITIONAL STAFF.—The Director of
25 ARPA–H may use all authorities in existence on the

1 date of enactment of this Act that are provided to
2 the Secretary to hire administrative, financial, infor-
3 mation technology staff, and any other staff the Di-
4 rector of ARPA-H determines are necessary to
5 carry out this section.

6 (3) LIMITATION ON TERM.—

7 (A) IN GENERAL.—Except as provided in
8 subparagraph (B), the service of an employee
9 under an appointment under paragraph (1)(A)
10 in the position of a program manager may not
11 exceed 3 years.

12 (B) EXTENSION.—The Director of ARPA-
13 H may, in the case of a particular employee, ex-
14 tend the period to which service is limited under
15 subparagraph (A) by up to 3 years if the Direc-
16 tor determines that such action is necessary to
17 promote the efficiency of ARPA-H.

18 (4) LIMITATION ON ADDITIONAL PAYMENTS.—

19 The total amount of the additional payments paid to
20 an employee under paragraph (1)(C) for any 12-
21 month period may not exceed the least of the fol-
22 lowing amounts:

23 (A) \$25,000.

24 (B) The amount equal to 25 percent of the
25 employee's annual rate of basic pay.

1 (C) The amount of the limitation that is
2 applicable for a calendar year under section
3 5307(a)(1) of title 5, United States Code.

4 (e) PROGRAM MANAGERS.—An employee designated
5 as a program manager pursuant to subsection (c)(3)(F)
6 shall—

7 (1) define the research and development goals
8 and milestones of the program involved, in line with
9 guidance from the Director;

10 (2) track progress and course-correct projects
11 when needed;

12 (3) recommend, as necessary, the restructuring
13 or termination of projects supported by ARPA-H;
14 and

15 (4) select, on the basis of merit and need, each
16 of the projects to be supported under the program
17 involved after considering—

18 (A) the novelty and scientific and technical
19 merit of the proposed projects;

20 (B) the demonstrated capabilities of the
21 applicants to successfully carry out the pro-
22 posed project;

23 (C) the consideration by the applicant of
24 future commercial applications of the project;

25 or

1 (D) the unmet need within patient popu-
2 lations.

3 (f) REPORTS.—

4 (1) STRATEGIC VISION.—Not later than 180
5 days after the date of the enactment of this Act, the
6 Director of ARPA–H shall provide to the Committee
7 on Energy and Commerce and the Committee on
8 Appropriations of the House of Representatives and
9 the Committee on Health, Education, Labor, and
10 Pensions and the Committee on Appropriations of
11 the Senate a report describing the strategic vision
12 that ARPA–H will use to guide the choices of
13 ARPA–H for future health investments over the fol-
14 lowing 3 fiscal years beginning on or after the date
15 of the enactment of this Act.

16 (2) ANNUAL BUDGET REQUEST.—As part of
17 the annual budget request submitted for each fiscal
18 year, the Director of ARPA–H shall provide to the
19 congressional committees specified in paragraph (1)
20 a report describing—

21 (A) projects supported by ARPA–H during
22 the previous fiscal year, including—

23 (i) the transition of projects' outcomes
24 to clinical practice;

- 1 (ii) the impact on clinical outcome;
2 and
3 (iii) the creation of biomedical capa-
4 bilities; and
5 (B) successes and barriers to scientific
6 interchanges;
7 (C) rapid knowledge transfer;
8 (D) resource optimization; and
9 (E) heightened investment impact among
10 collaborators.

11 (3) REPORT ON COOPERATIVE AGREEMENTS
12 AND OTHER TRANSACTION.—Not later than 90 days
13 after the end of each fiscal year, the Director of
14 ARPA–H shall submit to the congressional commit-
15 tees specified in paragraph (1) a report on all coop-
16 erative agreements and other transactions (other
17 than contracts and grants) entered into under this
18 subsection during such fiscal year. The report shall
19 contain, with respect to such cooperative agreement
20 and transaction, the following:

- 21 (A) A general description of the coopera-
22 tive agreement or other transaction (as the case
23 may be), including the innovations for which
24 advanced research is provided for under such
25 agreement or transaction.

1 (B) The potential clinical and, if any, com-
2 mercial utility of such innovations.

3 (C) The reasons for not using a contract
4 or grant to provide support for such advanced
5 research.

6 (D) The amount of the payments, if any,
7 referred to in subsection (i)(2) that were re-
8 ceived by the Federal Government in connection
9 with such cooperative agreement or other trans-
10 action during the fiscal year covered by the re-
11 port.

12 (E) The amount of the payments reported
13 under subparagraph (D), if any, that were cred-
14 ited to the account established under subsection
15 (i)(7).

16 (g) COORDINATION AND NONDUPLICATION.—

17 (1) IN GENERAL.—The Director of ARPA–H
18 shall ensure effective, early, and frequent coordina-
19 tion between ARPA–H and the heads of the re-
20 search, public health, and regulatory agencies of the
21 Department of Health and Human Services, includ-
22 ing—

23 (A) the Director of the National Institutes
24 of Health;

25 (B) the Commissioner of Food and Drugs;

1 (C) the Administrator of the Centers for
2 Medicare & Medicaid Services;

3 (D) the Director of the Centers for Disease
4 Control and Prevention; and

5 (E) the Assistant Secretary for Prepared-
6 ness and Response.

7 (F) The Director of the National Science
8 Foundation.

9 (G) The Director of the Office of Science
10 of the Department of Energy.

11 (2) COORDINATION.—The Director shall also
12 coordinate among the full set of advanced research
13 project agencies including—

14 (A) the Defense Advanced Research
15 Project Agency;

16 (B) the Advanced Research Project Agen-
17 cy-Energy; and

18 (C) others as they may be established.

19 (h) ADVICE.—

20 (1) IN GENERAL.—The Director of ARPA–H
21 may seek advice on any aspect of ARPA–H from—

22 (A) any advisory committee that, as of the
23 date of the enactment of this Act, is providing
24 advice to the Secretary of Health and Human
25 Services (or any head of a research, public

1 health, or regulatory agency of the Department
2 of Health and Human Services); and

3 (B) an advisory committee established on
4 or after such date of the enactment to support
5 the programs of ARPA–H and to provide advice
6 and assistance on—

7 (i) specific program tasks; or

8 (ii) overall direction of ARPA–H.

9 (2) ADDITIONAL SOURCES.—In addition to the
10 advisory committees specified in paragraph (1), the
11 Director of ARPA–H may seek advice and review
12 from—

13 (A) the President’s Committee of Advisors
14 on Science and Technology;

15 (B) any professional or scientific organiza-
16 tion with expertise in specific processes or tech-
17 nologies under development by ARPA–H; and

18 (C) representatives of patient communities.

19 (i) COOPERATIVE AGREEMENTS AND OTHER TRANS-
20 ACTIONS.—

21 (1) IN GENERAL.—The Director of ARPA–H,
22 in carrying out advanced research projects through
23 ARPA–H, may enter into grants, contracts, coopera-
24 tive agreements, cash prizes, and other transactions
25 (as defined in section 319L(a) of the Public Health

1 Service Act (42 U.S.C. 247d-7e(a))) with any per-
2 son, any agency or instrumentality of the United
3 States, any unit of State or local government, and
4 any other entity institutions, including universities,
5 national laboratories, public sector organizations,
6 private companies, nonprofit organizations, and for-
7 eign institutions.

8 (2) TERMS.—

9 (A) REQUIRED PROVISIONS.—The Director
10 of ARPA-H shall ensure that, in entering into
11 cooperative agreements and other transactions
12 under paragraph (1)—

13 (i) to the extent the Director of
14 ARPA-H determines practicable, the Fed-
15 eral funds provided under the cooperative
16 agreement or other transaction do not ex-
17 ceed the total amount provided by other
18 parties to the cooperative agreement or
19 other transaction; and

20 (ii) the authority under paragraph (1)
21 is used only when the use of standard con-
22 tracts or grants is not feasible or appro-
23 priate.

24 (B) OPTIONAL PROVISION.—Cooperative
25 agreements and other transactions entered into

1 by the Director of ARPA–H under paragraph
2 (1) may include a clause that requires a person
3 or other entity to make payments to ARPA–H
4 (or any other department or agency of the Fed-
5 eral Government) as a condition for receiving
6 support under the agreement or other trans-
7 action.

8 (3) DUPLICATIVE RESEARCH.—The Director of
9 ARPA–H shall ensure that to the maximum extent
10 practicable, a cooperative agreement or other trans-
11 action under this section does not provide for re-
12 search that duplicates research being conducted
13 under existing programs carried out by the Depart-
14 ment of Health and Human Services, the Depart-
15 ment of Defense, or other Federal Government enti-
16 ties.

17 (4) AMOUNT OF PAYMENTS.—The amount of
18 any payment received by the Federal Government
19 pursuant to a requirement imposed under paragraph
20 (1) may be credited, to the extent authorized by the
21 Director of ARPA–H, to the account established
22 under paragraph (7). Amounts so credited shall be
23 merged with other funds in the account and shall be
24 available for the same purposes and the same period
25 for which other funds in such account are available.

1 (5) MULTI-YEAR CONTRACTS.—

2 (A) IN GENERAL.—The Director of
3 ARPA–H may enter into a multi-year contract
4 if—

5 (i) funds are available and obligated
6 for the contract for the full period of the
7 contract, or for the first fiscal year in
8 which the contract is in effect, and for the
9 estimated costs associated with a necessary
10 termination of the contract;

11 (ii) the Director determines that a
12 multiyear contract will serve the best inter-
13 ests of the Federal Government in carrying
14 out this section; and

15 (iii) the contract includes a provision
16 that the contract shall be terminated if
17 funds are not made available for the con-
18 tinuation of the contract in a fiscal year
19 covered by the contract.

20 (B) TERMINATION COSTS.—A provision re-
21 ferred to in subparagraph (A)(iii) shall provide
22 that funds available for paying termination
23 costs shall remain available for that purpose
24 until the costs associated with termination of
25 the contract are paid.

1 (6) APPLICATION OF OTHER PROVISIONS.—The
2 authority provided under paragraph (1) may be ex-
3 ercised without regard to section 3324 of title 31,
4 United States Code.

5 (7) ACCOUNT.—There is hereby established on
6 the books of the Treasury an account for support of
7 advanced research projects provided for in coopera-
8 tive agreements and other transactions entered into
9 under paragraph (1). Funds in such account shall be
10 available for the payment of such support.

11 (8) PRIZE COMPETITIONS.—The Director of
12 ARPA–H may carry out prize competitions in ac-
13 cordance with section 24 of the Stevenson-Wydler
14 Technology Innovation Act of 1980 (15 U.S.C.
15 3719)) in support of the goals specified in sub-
16 section (b).

17 (9) NONAPPLICABILITY OF CERTAIN PROVI-
18 SIONS.—Research funded pursuant to this section
19 shall not be subject to—

20 (A) advisory council approval under section
21 405(b)(2) of the Public Health Service Act (42
22 U.S.C. 284(b)(2));

23 (B) advisory council review under section
24 406(a)(3)(A)(ii) of such Act (42 U.S.C.
25 284a(a)(3)(A)(ii)); or

1 (C) the peer review requirements under
2 section 492 of such Act (42 U.S.C. 284(b)(2),
3 289a).

4 (j) CONFIDENTIALITY.—

5 (1) IN GENERAL.—The information specified in
6 paragraph (2) shall be exempt from disclosure under
7 section 552 of title 5, United States Code (com-
8 monly referred to as the Freedom of Information
9 Act).

10 (2) INFORMATION.—The information specified
11 in this paragraph is information collected by ARPA-
12 H from recipients of financial assistance awards, in-
13 cluding the following:

14 (A) Plans for commercialization of tech-
15 nologies developed under the award, including
16 business plans, technology-to-market plans,
17 market studies, and cost and performance mod-
18 els.

19 (B) Investments provided to an awardee
20 from third parties (such as venture capital
21 firms, hedge funds, and private equity firms),
22 including the amounts and the percentage of
23 ownership of the awardee provided in return for
24 the investments.

1 (k) EXPEDITING BREAKTHROUGHS THROUGH CO-
2 OPERATION WITH FOOD AND DRUG ADMINISTRATION.—

3 (1) IN GENERAL.—The Secretary of Health and
4 Human Services, acting through the Commissioner
5 of Food and Drugs and in consultation with the Di-
6 rector of ARPA–H, may take actions to facilitate
7 transformation of biomedical breakthroughs into
8 tangible solutions for patients and to expedite devel-
9 opment of medical products, including through any
10 of the following means:

11 (A) Helping to ensure that medical prod-
12 uct development programs, in as efficient a
13 manner as possible, gather the nonclinical and
14 clinical data necessary to advancing the devel-
15 opment of such products and to obtaining their
16 approval, licensure, or clearance, as applicable,
17 by the Food and Drug Administration under
18 sections 505, 510(k), and 515 of such Act (21
19 U.S.C. 355, 360(k), 360) and section 351 of
20 the Public Health Service Act (42 U.S.C. 262).

21 (B) Expediting review of investigational
22 new drug applications under section 505(i) of
23 the Federal Food, Drug, and Cosmetic Act (21
24 U.S.C. 355(i)), review of investigational device
25 exemptions under section 520(g) of such Act

1 (21 U.S.C. 360j(g)), and review of applications
2 for approval, licensure, and clearance of medical
3 products under sections 505, 510(k), and 515
4 of such Act (21 U.S.C. 355, 360(k), 360) and
5 section 351 of the Public Health Service Act
6 (42 U.S.C. 262).

7 (C) Meeting at appropriate intervals with
8 the Director of ARPA–H and any other appro-
9 priate medical product development partners,
10 such as the Director of the Biomedical Ad-
11 vanced Research and Development Authority to
12 discuss the development status of medical prod-
13 ucts and projects that are the highest priorities
14 to ARPA–H, unless the Director of ARPA–H
15 and the Commissioner of Food and Drugs de-
16 termine that any such meetings are not nec-
17 essary.

18 (2) RELATION TO OTHERWISE AUTHORIZED AC-
19 TIVITIES OF THE FDA.—The authority specified in
20 paragraph (1) shall not be construed as limiting the
21 authority of the Secretary of Health and Human
22 Services, acting through the Commissioner of Food
23 and Drugs with respect to the review and approval,
24 clearance, authorization for emergency use, or licen-
25 sure of a medical product under the Federal Food,

1 Drug and Cosmetic Act (21 U.S.C. 321 et seq.) or
2 section 351 of the Public Health Service Act (42
3 U.S.C. 262).

4 (3) REIMBURSEMENT.—Utilizing interagency
5 agreements or other appropriate resource allocation
6 mechanisms available, the Director of ARPA–H,
7 using funds made available to ARPA–H, shall reim-
8 burse the Food and Drug Administration for ex-
9 penditures made by the Food and Drug Administra-
10 tion for activities carried out under this section that
11 have been identified by the Commissioner of Food
12 and Drugs and the Director of ARPA–H as being
13 carried out by the Food and Drug Administration.

14 (4) MEDICAL PRODUCT DEFINED.—In this sec-
15 tion, the term “medical product” means a drug (as
16 defined in section 201 of the Federal Food, Drug,
17 and Cosmetic Act (21 U.S.C. 321)), a device (as de-
18 fined in such section 201), or a biological product
19 (as defined in section 351 of the Public Health Serv-
20 ice Act (42 U.S.C. 262)).

21 (l) AUTHORIZATION OF APPROPRIATIONS AND BY-
22 PASS BUDGET AUTHORITY.—

23 (1) AUTHORIZATION OF APPROPRIATIONS.—
24 There is authorized to be appropriated to carry out

1 this section \$6,500,000,000 for fiscal year 2022, to
2 remain available until expended.

3 (2) **BYPASS BUDGET AUTHORITY.**—The budget
4 of ARPA–H shall be a separate line item in the an-
5 nual budget request submitted by the President to
6 the Congress. ARPA–H shall have the authority to
7 submit its annual budget request directly to Con-
8 gress concurrently with its submission to the Office
9 of Management and Budget.

10 **SEC. 502. RESEARCH INVESTMENT TO SPARK THE ECON-**
11 **OMY.**

12 (a) **AUTHORITY.**—

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

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

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

23 (B) The Secretary of Agriculture.

24 (C) The Secretary of Defense.

25 (D) The Secretary of Education.

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

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

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

14 (H) The Secretary of Transportation.

15 (I) The Administrator of the National Aer-
16 onautics and Space Administration.

17 (J) The Administrator of the Environ-
18 mental Protection Agency.

19 (K) The Director of the National Science
20 Foundation.

21 (3) AUTHORITIES.—The officers specified in
22 paragraph (2) may—

23 (A) provide supplemental funding to ex-
24 tend the duration of an award disrupted be-
25 cause of the COVID–19 public health emer-

1 agency to a research institution, Research Lab-
2 oratory, or individual that was awarded before
3 the date of the enactment of this Act, or to ex-
4 pand the purposes of such an award, in order
5 to—

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

8 (ii) enable research scientists, tech-
9 nical staff, research associates, and prin-
10 cipal investigators to complete work;

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

16 (iv) create research opportunities for
17 up to 2 years for graduate students and
18 post-doctoral researchers;

19 (v) replace, refurbish, or otherwise
20 make usable laboratory animals, reagents,
21 equipment, or other items required for re-
22 search;

23 (vi) facilitate other research (including
24 field work), training, and ongoing con-
25 struction activities, including at institu-

1 tions that are disproportionately affected
2 by the COVID–19 public health emergency
3 (such as minority-serving institutions and
4 2-year institutions of higher education);

5 (vii) enable experimental field cam-
6 paigns and maintenance of field infrastruc-
7 ture, including through replacement of dis-
8 rupted experimental data to enable comple-
9 tion of impacted research; and

10 (viii) support training in online course
11 delivery and virtual research experiences
12 that will improve quality and access needed
13 to continue undergraduate, graduate, and
14 post-doctoral training;

15 (B) issue awards to research institutions,
16 Research Laboratories, or other individuals to
17 conduct research on the effects of the COVID–
18 19 and future potential pandemics, on the ef-
19 fects and effectiveness of responses to such dis-
20 eases, and on improving the prediction of the
21 possible courses of such pandemics; and

22 (C) provide flexibility on an award for
23 funds made available to an agency, by any prior
24 or subsequent Act, by modifying the terms and
25 conditions of the award with a research institu-

1 tion, Research Laboratory, or individual due to
2 facility closures or other limitations during the
3 COVID–19 public health emergency.

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

6 (A) the provision of supplemental funding
7 to extend the duration of the award concerned;
8 or

9 (B) flexibility on the allowable expenses
10 under such award.

11 (b) PROCEDURES.—The officers specified in sub-
12 section (a)(2) shall each establish procedures to carry out
13 subsection (a).

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

16 (d) AUTHORIZATIONS OF APPROPRIATIONS.—

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

21 (A) \$300,000,000 shall be for use by the
22 National Oceanic and Atmospheric Administra-
23 tion; and

1 (B) \$150,000,000 shall be for use by the
2 National Institute of Standards and Tech-
3 nology.

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

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

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

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

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

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

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

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

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

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

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

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

21 (8) DEPARTMENT OF TRANSPORTATION.—
22 There is authorized to be appropriated for fiscal
23 year 2021 for the Department of Transportation,
24 \$300,000,000 to carry out subsection (a), of which

1 not less than \$130,000,000 shall be for use by the
2 Federal Aviation Administration.

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

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

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

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

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

15 **SEC. 503. RESEARCH POLICY BOARD REAUTHORIZATION.**

16 (a) EXTENSION OF SUNSET.—Section 2034(f)(6) of
17 the 21st Century Cures Act (42 U.S.C. 3501 note) is
18 amended by striking “September 30, 2021” and inserting
19 “September 30, 2026”.

20 (b) PARTICIPATION BY DIRECTOR OF NIH.—

21 (1) INCLUSION AS MEMBER.—Section
22 2034(f)(2)(A) of the 21st Century Cures Act (42
23 U.S.C. 3501 note) is amended—

24 (A) by redesignating clause (v) as clause
25 (vi);

1 (B) by inserting after clause (iv) the fol-
2 lowing:

3 “(iv) The Director of the National In-
4 stitutes of Health.”.

5 (2) LIMITATIONS RELATING TO INDIRECT
6 COSTS.—Section 2034(f)(2) of the 21st Century
7 Cures Act (42 U.S.C. 3501 note) is amended by
8 adding at the end the following:

9 “(C) LIMITATIONS RELATING TO INDIRECT
10 COSTS.—Notwithstanding any other provision
11 of law, the Director of the National Institutes
12 of Health may participate in the activities of
13 the Board, including the formulation of rec-
14 ommendations, without regard to limitations re-
15 lating to indirect costs in part 75 of title 45,
16 Code of Federal Regulations (or any successor
17 regulations).”.

○