

.....
(Original Signature of Member)

117TH CONGRESS
1ST SESSION

H. R. _____

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

IN THE HOUSE OF REPRESENTATIVES

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

A BILL

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

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

3 **SECTION 1. SHORT TITLE.**

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

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

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

Sec. 1. Short title.

Sec. 2. Table of contents.

TITLE I—PUBLIC HEALTH

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

- Sec. 102. National strategy to prevent and respond to pandemics.
- Sec. 103. Pandemic preparedness rare disease support program.
- Sec. 104. Vaccine and immunization programs.
- Sec. 105. Developing antimicrobial innovations.

TITLE II—PATIENTS AND CAREGIVERS

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

TITLE III—FOOD AND DRUG ADMINISTRATION

- Sec. 301. Report on collaboration and alignment in regulating digital health technologies.
- Sec. 302. Grants for novel trial designs and other innovations in drug development.
- Sec. 303. FDA cell and gene therapy.
- Sec. 304. Increasing use of real world evidence.
- Sec. 305. Improving FDA-CMS communication regarding transformative new therapies.
- Sec. 306. Establishment of additional Intercenter Institutes at the Food and Drug Administration.
- Sec. 307. 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 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
25 collaborative with individuals and organizations

1 representing key sectors of the health care com-
2 munity; and

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

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

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

18 (B) each fiscal year thereafter, unless the
19 Secretary determines that the public health and
20 medical knowledge with respect to long COVID
21 has sufficiently advanced to ensure widespread
22 understanding of the characteristics of long
23 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 Health and Human Services may disseminate
6 information under paragraphs (1) and (2) directly or
7 through arrangements with intra-agency initiatives,
8 nonprofit organizations, consumer groups, institu-
9 tions of higher learning (as defined in section 101
10 of the Higher Education Act of 1965 (20 U.S.C.
11 1001)), or Federal, State, or local public private
12 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 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. 3990O. ESTABLISHMENT OF COMMITTEE; SUBSCRIP-**
4 **TION MODEL; ADVISORY GROUP.**

5 “(a) IN GENERAL.—Not later than 60 days after the
6 date of enactment of this part, the Secretary shall estab-
7 lish a Committee on Critical Need Antimicrobials and ap-
8 point 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 enactment of this
16 part and subsequently update the list under this
17 paragraph in accordance with subsection (e).

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

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

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

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

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

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

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

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

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

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

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

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

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

20 “(d) REGULATIONS.—

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

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

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

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

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

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

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

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

16 “(f) TRANSITIONAL SUBSCRIPTION CONTRACTS.—

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

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

14 “(2) REQUIREMENTS.—

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

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

24 “(ii) subject to terms including—

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

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

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

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

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

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

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

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

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

21 “(iii) if—

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

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

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

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

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

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

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

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

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

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

17 “(i) infectious disease specialists; or

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

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

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

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

7 “(5) APPLICABILITY OF 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 re-evaluate the value of a contract
10 to include any new information.

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

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

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

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

3 “(A) shall include—

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

5 and

6 “(ii) the appropriate use of diagnostic

7 tools, where available, such as diagnostic

8 testing for biomarkers related to anti-

9 microbial-resistant pathogens, or other tar-

10 geted diagnostic approaches, to inform use

11 of the drug; and

12 “(B) may be developed in partnership with

13 the Secretary, infectious disease experts, diag-

14 nostic experts or developers, laboratory experts,

15 or another entity.

16 “(2) CONSULTATION.—The Secretary shall con-

17 sult with relevant professional societies and the Crit-

18 ical Need Antimicrobial Advisory Group established

19 under section 39900(g) to ensure that clinical

20 guidelines issued by the Secretary under paragraph

21 (3), with respect to an antimicrobial drug designated

22 under subsection (a), includes the use of appropriate

23 diagnostic approaches, taking into consideration the

24 diagnostic plan submitted by a sponsor under para-

25 graph (1).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

10 “(2) TERMS.—

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

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

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

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

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

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

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

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

22 “(1) REPORTING REQUIREMENT.—

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

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

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

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

1 “(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 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 enactment of this part, the Secretary and
13 the Director of the Centers for Disease Control and
14 Prevention shall coordinate with the Administrator
15 of the Health Resources and Services Administra-
16 tion, the Administrator of the Centers for Medicare
17 & Medicaid Services, the National Coordinator for
18 Health Information Technology, and other relevant
19 agencies, to establish a grant program under the
20 Centers for Disease Control and Prevention to sup-
21 port hospital and other inpatient facility efforts—

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

1 agnostic tools, partnering with academic hos-
2 pitals, increasing health care-associated infec-
3 tion reporting, and monitoring antimicrobial re-
4 sistance; and

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

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

23 “(3) FUNDING.—Of the amounts appropriated
24 under section 399SS, the Secretary shall reserve
25 \$500,000,000 to carry out this subsection.

1 “(b) SURVEILLANCE AND REPORTING OF ANTIBIOTIC
2 USE AND RESISTANCE.—

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

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

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

20 “(2) ANTIBIOTIC USE DATA.—The Secretary,
21 acting through the Director of the Centers for Dis-
22 ease Control and Prevention, shall work with Fed-
23 eral agencies (including the Department of Veterans
24 Affairs, the Department of Defense, the Department
25 of Homeland Security, the Bureau of Prisons, the

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

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

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

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

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

13 **“SEC. 399SS. APPROPRIATIONS.**

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

19 “(b) EMERGENCY DESIGNATION.—

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

24 “(2) DESIGNATION IN SENATE.—In the Senate,
25 this section is designated as an emergency require-

1 ment pursuant to section 4112(a) of H. Con. Res.
2 71 (115th Congress), the concurrent resolution on
3 the budget for fiscal year 2018.

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

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

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

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

6 **“SEC. 399UU. DEFINITIONS.**

7 “In this part—

8 “(1) the term ‘antimicrobial drug’—

9 “(A) means, subject to subparagraph (B),
10 a product that is—

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

17 “(ii) a biological product that acts di-
18 rectly on bacteria or fungi or on the sub-
19 stances produced by such bacteria or fungi;
20 and

21 “(B) does not include—

22 “(i) a drug that achieves the effect de-
23 scribed by subparagraph (A)(i) only at a
24 concentration that cannot reasonably be

1 studied in humans because of its antici-
2 pated toxicity; or

3 “(ii) a vaccine; and

4 “(2) the term ‘Committee’ means the Com-
5 mittee on Critical Need Antimicrobials established
6 under section 39900.”.

7 **TITLE II—PATIENTS AND** 8 **CAREGIVERS**

9 **SEC. 201. EDUCATIONAL PROGRAMS AND TRAINING FOR** 10 **CAREGIVERS.**

11 Part D of title VII of the Public Health Service Act
12 (42 U.S.C. 294 et seq.) is amended by adding at the end
13 the following:

14 **“SEC. 760A. EDUCATIONAL PROGRAMS AND TRAINING FOR** 15 **CAREGIVERS.**

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

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

20 “(2) to complement a clinical visit.

21 “(b) TYPES OF PROGRAMS AND TRAINING.—Edu-
22 cational programs and training funded under subsection
23 (a) may include—

24 “(1) specialized training in medication adher-
25 ence and injections;

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

4 “(3) nutritional compliance;

5 “(4) caregiver psychosocial support (including
6 cognitive-behavioral, supportive, and bereavement
7 counseling);

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

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

10 “(c) NON-DUPLICATION.—The Secretary may not use
11 the same requirements under this section for a grant, con-
12 tract, or cooperative agreement under the Geriatric Work-
13 force Enhancement Program under section 753 of the
14 Public Health Service Act (42 U.S.C. 294c).

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

21 “(e) AUTHORIZATION OF APPROPRIATIONS.—To
22 carry out this section, there is authorized to be appro-
23 priated \$25,000,000 for each of fiscal years 2022 through
24 2024.”.

1 **SEC. 202. INCREASING HEALTH LITERACY TO PROMOTE**
2 **BETTER OUTCOMES FOR PATIENTS.**

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

14 (1) identifying culturally competent, evidence-
15 based interventions that have been proven to im-
16 prove health literacy in populations served by such
17 programs;

18 (2) identifying evidence-based health literacy
19 approaches that can be used by the Medicare pro-
20 gram under title XVIII of the Social Security Act
21 (42 U.S.C. 1395 et seq.), a State plan (or waiver of
22 such plan) under title XIX of such Act (42 U.S.C.
23 1396 et seq.), a State child health plan (or waiver
24 of such plan) under title XXI of such Act (42
25 U.S.C. 1397aa et seq.), or health care providers par-
26 ticipating in such program under such title XVIII,

1 under a State plan (or waiver of such plan) under
2 such title XIX, or under a State child health plan
3 (or waiver of such plan) under such title XXI, and
4 that—

5 (A) have been proven to, or show promise
6 to, reduce costs to individuals enrolled under a
7 State plan (or waiver of such plan) under such
8 title XIX, or under a State child health plan (or
9 waiver of such plan) under such title XXI, re-
10 spectively, and reduce expenditures under such
11 respective titles; or

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

16 (3) how the Centers for Medicare & Medicaid
17 Services can encourage the use of evidence-based
18 health literacy interventions through payment poli-
19 cies under the Medicare program under title XVIII
20 of the Social Security Act (42 U.S.C. 1395 et seq.),
21 a State plan under title XIX of such Act (42 U.S.C.
22 1396 et seq.), a State child health plan under title
23 XXI of such Act (42 U.S.C. 1397 et seq.); and

24 (4) improving patient and family caregiver
25 health literacy with respect to health insurance, in-

1 cluding an understanding of in-network providers,
2 deductibles, co-insurance, co-payments, and dif-
3 ferences between payors.

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

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

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

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

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

24 (1) complete a study—

1 (A) to review how the Department of
2 Health and Human Services addresses barriers
3 to participation by individuals from underrep-
4 resented populations in conducting or sup-
5 porting clinical trials; and

6 (B) to formulate recommendations for ad-
7 dressing such barriers; and

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

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

12 (1) carry out a public awareness campaign to
13 increase awareness and understanding, particularly
14 in minority communities, of—

15 (A) upcoming and ongoing clinical trials;

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

18 (C) the availability of databases and other
19 resources relevant to clinical trial enrollment,
20 such as ClinicalTrials.gov; and

21 (2) in carrying out such campaign, utilize a va-
22 riety of communication channels, including through
23 use of the explanation of Medicare benefits under
24 section 1806 of the Social Security Act (42 U.S.C.
25 1395b–7).

1 (d) TASK FORCE FOR MAKING CLINICALTRIALS.GOV
2 MORE USER-FRIENDLY.—

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

8 (2) MEMBERSHIP.—The membership of the
9 task force shall include representatives of—

10 (A) the National Institutes of Health;

11 (B) the Food and Drug Administration;

12 (C) academic researchers; and

13 (D) patient organizations.

14 (e) DEFINITION.—In this section, the term
15 “ClinicalTrials.gov” refers to the data bank described in
16 section 402(i) of the Public Health Service Act (42 U.S.C.
17 282(i)).

18 **SEC. 204. PATIENT EXPERIENCE DATA.**

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

22 (1) by redesignating subsections (b) and (c) as
23 subsections (c) and (d), respectively; and

24 (2) by inserting after subsection (a) the fol-
25 lowing new subsection:

1 “(b) COLLECTION, SUBMISSION, AND USE OF
2 DATA.—

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

4 “(A) for any drug for which an exemption
5 is granted for investigational use under section
6 505(i) of this Act or section 351(a) of the Pub-
7 lic Health Service Act, require the sponsor of
8 the drug to collect standardized patient experi-
9 ence data as part of the clinical trials conducted
10 pursuant to such exemption;

11 “(B) require any application for the ap-
12 proval or licensing of such drug under section
13 505(b) of this Act or section 351(a) of the Pub-
14 lic Health Service Act to include—

15 “(i) the standardized patient experi-
16 ence data so collected; and

17 “(ii) such related information as the
18 Secretary may require; and

19 “(C) consider patient experience data and
20 related information that is submitted pursuant
21 to subparagraph (B) in deciding whether to ap-
22 prove or license, as applicable, the drug in-
23 volved.

24 “(2) APPLICABILITY.—Paragraph (1) applies
25 only with respect to drugs for which a request for

1 an exemption described in paragraph (1)(A) is sub-
2 mitted on or after the date of enactment of the
3 Cures 2.0 Act, or an application under section
4 505(b) of this Act or section 351(a) of the Public
5 Health Service Act is filed, as applicable, on or after
6 the day that is 2 years after the date of enactment
7 of the Cures 2.0 Act.”.

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

14 **SEC. 205. ENSURING COVERAGE FOR CLINICAL TRIALS**
15 **UNDER EXISTING STANDARD OF CARE.**

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

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

24 “(D) The study or investigation is ap-
25 proved or funded (which may include funding

1 through in-kind contributions) by the Patient
2 Centered Outcomes Research Institute estab-
3 lished under section 1181 of the Social Security
4 Act.”.

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

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

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

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

1 **TITLE III—FOOD AND DRUG**
2 **ADMINISTRATION**

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

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

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

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

21 (A) the use of digital endpoints for regu-
22 latory review, including the validation and qual-
23 ification of digital endpoints and digital bio-
24 markers;

25 (B) the acceptance of decentralized trials;

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

3 (D) the use and validation of digital health
4 technology tools;

5 (2) How the Food and Drug Administration co-
6 ordinales with foreign regulators to ensure harmoni-
7 zation on the regulation and use of digital health
8 technologies.

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

20 **SEC. 302. GRANTS FOR NOVEL TRIAL DESIGNS AND OTHER**
21 **INNOVATIONS IN DRUG DEVELOPMENT.**

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

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

8 (2) the collection of patient experience data
9 with respect to drugs and the use of such data and
10 related information in drug development.

11 (b) PRIORITIZATION.—In awarding grants under this
12 section, the Secretary shall prioritize the incorporation of
13 digital health technologies and real world evidence in drug
14 development.

15 (c) DEFINITIONS.—In this section:

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

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

22 (3) The term “real world evidence” has the
23 meaning given to that term in section 505F of the
24 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
25 355g).

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

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

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

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

12 (2) How the Food and Drug Administration
13 will address these challenges.

14 (3) The additional resources and authorities the
15 Food and Drug Administration needs to address
16 these challenges.

17 (4) The current state of cell and gene therapies
18 regulation by the Food and Drug Administration, in-
19 cluding—

20 (A) the amount and nature of the submis-
21 sions filed with the Food and Drug Administra-
22 tion;

23 (B) the status of such applications in the
24 review process; and

1 (C) the therapeutic areas intended to be
2 addressed by the products that are subject to
3 such applications.

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

5 (a) GUIDANCE.—

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

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

23 (A) Special and underrepresented popu-
24 lations.

1 (B) Acceptable endpoints and outcomes
2 measures.

3 (C) Data quality standards.

4 (D) Data transparency requirements.

5 (E) Study design considerations.

6 (b) IDENTIFICATION AND IMPLEMENTATION OF AP-
7 PROACHES.—

8 (1) IDENTIFICATION.—Consistent with the
9 framework established under 505F of the Federal
10 Food, Drug, and Cosmetic Act (21 U.S.C. 355g),
11 the Secretary of Health and Human Services shall,
12 by not later than 1 year after the date of enactment
13 of this Act—

14 (A) identify consistent, clear approaches
15 for the Department of Health and Human
16 Services to use real world evidence (as defined
17 in such section 505F)—

18 (i) in conducting and supporting re-
19 search; and

20 (ii) in regulating, purchasing, and
21 supporting the purchase of health care
22 products and services;

23 (B) include in such approaches rec-
24 ommendations for any additional statutory au-
25 thorities needed;

1 (C) publish such approaches in the Federal
2 Register; and

3 (D) submit a report to the Congress on
4 such approaches.

5 (2) IMPLEMENTATION.—Upon publication
6 under paragraph (1) of the approaches identified
7 pursuant to such paragraph, consistent with the au-
8 thorities vested in the Department of Health and
9 Human Services by other provisions of law, the Sec-
10 retary take such actions as may be appropriate to
11 implement the approaches identified pursuant to
12 paragraph (1).

13 (c) REAL WORLD EVIDENCE TASK FORCE.—

14 (1) ESTABLISHMENT.—The Secretary shall es-
15 tablish a permanent task force, to be known as the
16 Real World Evidence Task Force (in this subsection
17 referred to as the “Task Force”) to coordinate the
18 programs and activities of the Department of Health
19 and Human Services with regard to the collection
20 and use of real world evidence.

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

23 (A) The Secretary (or the Secretary’s des-
24 ignee), who shall serve as the Chair of the Task
25 Force.

1 (B) The Administrator of the Centers for
2 Medicare & Medicaid Services (or the Adminis-
3 trator's designee).

4 (C) The Commissioner of Food and Drugs
5 (or the Commissioner's designee).

6 (D) The Director of the National Insti-
7 tutes of Health (or the Director's designee).

8 (E) Such additional Federal officials (or
9 their designees) as the Secretary determines ap-
10 propriate.

11 (F) Private sector representatives, includ-
12 ing patient group representatives, to be ap-
13 pointed by the Secretary.

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

16 (A) develop and periodically update rec-
17 ommendations on ways to encourage patients
18 to—

19 (i) engage in the generation of real
20 world evidence; and

21 (ii) participate in postapproval clinical
22 trials for the collection of real world evi-
23 dence; and

24 (B) not later than 2 years after the date
25 of enactment of this Act, and every 2 years

1 thereafter, submit a report to the Congress on
2 such recommendations.

3 **SEC. 305. IMPROVING FDA-CMS COMMUNICATION REGARD-**
4 **ING TRANSFORMATIVE NEW THERAPIES.**

5 (a) IN GENERAL.—Upon the designation of a product
6 as a breakthrough therapy, a fast track product, or a
7 product eligible for accelerated approval under subsection
8 (a), (b), or (c), respectively, of section 506 of the Federal
9 Food, Drug, and Cosmetic Act (21 U.S.C. 356), the Com-
10 missioner of Food and Drugs and the Administrator of
11 the Centers for Medicare & Medicaid Services shall—

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

15 (2) share such information with each other as
16 may be appropriate to inform and coordinate such
17 decisions.

18 (b) SEPARATE AND DISTINCT.—In approving or des-
19 ignating a product described in subsection (a), the Com-
20 missioner of Food and Drugs and the Administrator of
21 the Centers for Medicare & Medicaid Services shall ensure
22 that the process for approval or designation remains sepa-
23 rate and distinct.

1 **SEC. 306. ESTABLISHMENT OF ADDITIONAL INTERCENTER**
2 **INSTITUTES AT THE FOOD AND DRUG ADMIN-**
3 **ISTRATION.**

4 (a) ESTABLISHMENT.—Subsection (c) of section
5 1014 of the Federal Food, Drug, and Cosmetic Act (21
6 U.S.C. 399g(c)) is amended to read as follows:

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

14 (b) CRITERIA.—In establishing the focus of the two
15 Institutes referenced in the amendment made by sub-
16 section (a), the Secretary of Health and Human Services
17 shall ensure the following:

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

20 (A) Negatively affects at least one major
21 body system.

22 (B) Represents a major disease burden in
23 the United States.

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

1 (D) According to the National Institutes of
2 Health, affects at least an estimated
3 50,000,000 Americans each year.

4 (E) Contributes to increasing health care
5 (personal, familial, private sector, and govern-
6 mental) expenditures and impacts the United
7 States economy as a whole.

8 (F) For which the SARS-CoV-2 virus ex-
9 acerbates symptoms or causes serious complica-
10 tions.

11 (G) For which medical products are ap-
12 proved by the Food and Drug Administration
13 at a much lower rate than products for other
14 disease areas, including in abbreviated path-
15 ways.

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

18 (A) Affects, individually, fewer than
19 200,000 people in the United States.

20 (B) Over 90 percent of such diseases have
21 no therapy approved by the Food and Drug Ad-
22 ministration.

23 (C) Affects, in total, over 30,000,000
24 Americans.

1 (D) Over 50 percent of patients are chil-
2 dren.

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

12 **SEC. 307. ACCELERATING TIMELINE FOR BREAKTHROUGH**
13 **AND RMAT DESIGNATIONS.**

14 (a) BREAKTHROUGH THERAPIES.—Section
15 506(a)(2) of the Federal Food, Drug, and Cosmetic Act
16 (21 U.S.C. 356(a)(2)) is amended by striking “A request
17 for the designation may be made concurrently with, or at
18 any time after, the submission of an application for the
19 investigation of the drug under section 505(i) or section
20 351(a)(3) of the Public Health Service Act” and inserting
21 “A request for the designation may be made at any point
22 before or after submission of an application for approval
23 of the drug under section 505(b) of this Act or licensure
24 of the drug under section 351(a)(2) of the Public Health
25 Service Act and shall include clinical evidence, including

1 preliminary clinical evidence from clinical trials conducted
2 outside of the United States”.

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

16 **SEC. 308. GUIDANCE REGARDING DEVELOPMENT AND SUB-**
17 **MISSION OF CHEMISTRY, MANUFACTURING,**
18 **AND CONTROLS INFORMATION FOR EXPE-**
19 **DITED APPROVAL.**

20 (a) IN GENERAL.—The Secretary of Health and
21 Human Services shall—

22 (1) not later than 6 months after the date of
23 enactment of this Act, issue draft revised guidance
24 to provide clarity regarding the development and
25 submission of chemistry, manufacturing, and con-

1 controls information for purposes of subsections (a),
2 (b), (c), and (g) of section 506 of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C. 356; relating to
4 breakthrough therapies, fast track products, acceler-
5 ated approval, and regenerative advanced therapies);
6 and

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

10 (b) CONTENTS.—The guidance under subsection (a)
11 shall address—

12 (1) how the Food and Drug Administration will
13 determine how, and by when, chemistry, manufac-
14 turing, and controls information is required to be
15 submitted throughout development and during the
16 pre- and post-approval phases, taking into consider-
17 ation—

18 (A) how such determinations will reflect
19 the risks and benefits of such information given
20 the seriousness or life-threatening nature of the
21 disease the product is intended to diagnose,
22 cure, mitigate, treat, or prevent;

23 (B) the phase and expedited nature of de-
24 velopment; and

1 (C) the availability of relevant data and in-
2 formation from nonclinical and clinical studies,
3 product applications, and post-approval over-
4 sight; and

5 (2) how the Food and Drug Administration will
6 provide ongoing advice and opportunities for spon-
7 sors to interact with the Food and Drug Administra-
8 tion on, and how the Food and Drug Administration
9 will facilitate, the submission of chemistry, manufac-
10 turing, and controls information throughout the life
11 cycle of the product.

12 **SEC. 309. POST-APPROVAL STUDY REQUIREMENTS FOR AC-**
13 **CCELERATED APPROVAL.**

14 Section 506(c)(2)(A) of the Federal Food, Drug, and
15 Cosmetic Act (21 U.S.C. 356(c)(2)(A)) is amended after
16 “studies” by inserting “, or otherwise submit evidence
17 based on analyses of data in clinical care data repositories,
18 patient registries, or other sources of real world evi-
19 dence,”.

20 **SEC. 310. RECOMMENDATIONS TO DECENTRALIZE CLIN-**
21 **ICAL TRIALS.**

22 (a) IN GENERAL.—Not later than the end of fiscal
23 year 2022, the Secretary of Health and Human Services,
24 acting through the Commissioner of Food and Drugs,
25 shall convene a meeting of covered representatives to rec-

1 commend to the Secretary innovative approaches and in-
2 centives to adopt decentralized clinical trials.

3 (b) DEFINITIONS.—In this section:

4 (1) COVERED REPRESENTATIVE.—The term
5 “covered representative” means a representative of
6 the following:

7 (A) Sponsors of an application for approval
8 of a drug under section 505 of the Federal
9 Food, Drug, and Cosmetic Act (21 U.S.C.
10 355).

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

14 (C) Clinical research organizations.

15 (D) The technology community.

16 (E) The patient community.

17 (2) DECENTRALIZED CLINICAL TRIAL.—The
18 term “decentralized clinical trial” means a clinical
19 trial method that includes the use of telemedicine or
20 digital technologies to allow for the remote collection
21 of clinical trial data from subjects, including in the
22 home or office setting.

1 **TITLE IV—CENTERS FOR MEDI-**
2 **CARE & MEDICAID SERVICES**
3 **Subtitle A**

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

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

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

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

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

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

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

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

22 (b) STUDIES.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 (A) in paragraph (2)(B)—

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

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

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

15 (B) in paragraph (4)(C)—

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

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

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

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

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

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

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

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

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

20 (2) in paragraph (4)(E)—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

13 and

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

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

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

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

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

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

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

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

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

17 “(b) COVERAGE.—

18 “(1) TRANSITIONAL COVERAGE.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

24 “(B) affect the application and approval
25 process for pass-through payment status under

1 section 1833(t)(6) or for an additional payment
2 under section 1886(d)(5)(K) in the case of a
3 medical device that is not approved by the Food
4 and Drug Administration as a breakthrough de-
5 vice; or

6 “(C) prohibit the Secretary from using ex-
7 isting authority under this title to suspend or
8 terminate coverage of a breakthrough device if
9 the Secretary, based on clinical evidence, deter-
10 mines that—

11 “(i) such breakthrough device offers
12 no clinical benefit to Medicare bene-
13 ficiaries; or

14 “(ii) furnishing such breakthrough de-
15 vice to Medicare beneficiaries causes, or
16 may cause, serious harm to Medicare bene-
17 ficiaries.

18 “(c) CODING.—

19 “(1) PROMPT ASSIGNMENT.—Not later than
20 three months after the date of approval or clearance
21 of a breakthrough device by the Food and Drug Ad-
22 ministration, the Secretary shall assign a unique
23 temporary or permanent code or codes for purposes
24 of coverage and payment for such breakthrough de-

1 vice under the applicable payment systems (de-
2 scribed in paragraph (4)).

3 “(2) UPDATES.—

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

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

16 “(C) OTHER PAYMENT SYSTEMS.—The
17 Secretary shall provide for semiannual or quar-
18 terly updates, as the case may be, under the ap-
19 plicable payment systems described in subpara-
20 graphs (C) through (L) of paragraph (4) to rec-
21 ognize the code or codes assigned under para-
22 graph (1).

23 “(3) TRANSPARENCY.—The process for the as-
24 signment of a code or codes under this subsection

1 shall provide for public notice and a meaningful op-
2 portunity for public comment from affected parties.

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

6 “(A) with respect to inpatient hospital
7 services, the prospective payment system for in-
8 patient hospital services established under sec-
9 tion 1886(d);

10 “(B) with respect to outpatient hospital
11 services, the prospective payment system for
12 covered OPD services established under section
13 1833(t);

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

17 “(D) with respect to physicians’ services,
18 the physician fee schedules established under
19 section 1848;

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

23 “(F) with respect to diagnostic laboratory
24 tests, the payment amounts under section

1 1834A and the fee schedules establish under
2 section 1848, as the case may be;

3 “(G) with respect to inpatient hospital
4 services furnished by rehabilitation facilities,
5 the prospective payment system established
6 under section 1886(j);

7 “(H) with respect to inpatient hospital
8 services furnished by long-term care hospitals,
9 the prospective payment system under section
10 1886(m);

11 “(I) with respect to inpatient hospital serv-
12 ices furnished by psychiatric hospitals and psy-
13 chiatric units, the prospective payment system
14 under section 1886(s);

15 “(K) with respect to home health services,
16 the prospective payment system under section
17 1895; and

18 “(L) with respect to items and services, or
19 a provider of services or supplier, not described
20 in subparagraphs (A) through (I), the payment
21 system established under this title for such
22 items and services when furnished by such pro-
23 vider of services or supplier.

24 “(d) PAYMENT.—

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

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

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

22 Nothing in this paragraph shall be construed to af-
23 fect the authority of the Secretary to use claims
24 data to establish new diagnosis or procedure codes
25 for breakthrough devices or to identify appropriate

1 diagnosis-related groups for the assignment of
2 breakthrough devices under annual rulemaking to
3 carry out section 1886(d)(5)(K).

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

11 “(A) except as provided in subparagraph
12 (B), on the date that the Secretary, pursuant to
13 subsection (c)(2)(B), updates the payment sys-
14 tem under section 1833(t) 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)(B) 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 ambulatory payment classifica-
4 tion groups for breakthrough devices or to revise
5 such groups to take into account breakthrough de-
6 vices under annual rulemaking to carry out section
7 1833(t).

8 “(3) OTHER PAYMENT SYSTEMS.—

9 “(A) IN GENERAL.—In the case of break-
10 through device that is furnished and for which
11 payment may be made under the payment sys-
12 tem established under section 1834, 1834A,
13 1848, 1886(j), 1886(m), 1886(s), or 1895 or
14 any other provision of this title (other than sec-
15 tions 1833(i), 1833(t), and 1886(d)), the Sec-
16 retary shall provide for an additional payment
17 for such breakthrough device under such appli-
18 cable payment system or an adjustment to such
19 applicable payment system, as the case may be.
20 The payment basis for such additional payment
21 or adjustment, as the case may be, shall equal
22 an amount that the Secretary determines covers
23 the costs of such breakthrough device.

24 “(B) COST INFORMATION.—In determining
25 the costs of a breakthrough device for purposes

1 of determining an additional payment or pay-
2 ment adjustment under subparagraph (A), the
3 Secretary shall use the most recently available
4 data and information on the costs of such
5 breakthrough device, which may include list
6 prices and invoice prices charged for such
7 breakthrough device.

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

18 “(D) CLINICAL DIAGNOSTIC LABORATORY
19 TESTS.—An additional payment or payment ad-
20 justment under subparagraph (A) for a break-
21 through device under the applicable payment
22 system established in section 1834A may be in
23 the form of an increase to the amount deter-
24 mined for the breakthrough device using cross-
25 walking under section 1834A(c)(1)(A), an ex-

1 tension of the initial period of payment applica-
2 ble to advance diagnostic laboratory tests under
3 section 1834A(d)(1)(A), and in such other form
4 or manner as the Secretary determines reflects
5 the costs for such breakthrough device under
6 the relevant provisions of section 1834A.

7 “(4) PAYMENT FOR BREAKTHROUGH DEVICES
8 AFTER THE TRANSITIONAL COVERAGE PERIOD.—
9 Payment for a breakthrough device that is furnished
10 after the conclusion of the transitional coverage pe-
11 riod under subsection (b)(1) for such device shall be
12 made pursuant to the applicable payment system in-
13 volved, taking into account the additional evidence
14 and data collected under subsection (b)(2).

15 “(e) SPECIAL RULES FOR CERTAIN BREAKTHROUGH
16 DEVICES.—

17 “(1) COVERAGE OF SPECIFIED BREAKTHROUGH
18 DEVICES.—

19 “(A) IN GENERAL.—Subject to the suc-
20 ceeding provisions of this subsection and not-
21 withstanding any other provision of law, the
22 Secretary shall provide for coverage and pay-
23 ment pursuant to this section of a specified
24 breakthrough device (as defined in subpara-
25 graph (B)).

1 “(B) SPECIFIED BREAKTHROUGH DEVICE
2 DEFINED.—In this section, the term ‘specified
3 breakthrough device’ means a breakthrough de-
4 vice with respect to which no Medicare benefit
5 category exists.

6 “(2) PERIOD OF TRANSITIONAL COVERAGE.—

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

24 “(B) REPORT.—

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

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

17 “(II) The impact of the avail-
18 ability of the specified breakthrough
19 device to Medicare beneficiaries, in-
20 cluding impacts on the quality of pa-
21 tient care, patient outcomes, and pa-
22 tient experience.

23 “(III) The impact of the avail-
24 ability of the specified breakthrough

1 device to Medicare beneficiaries on
2 program expenditures under this title.

3 “(IV) Such other information as
4 the Secretary determines to be appro-
5 priate.

6 “(ii) DEADLINE.—

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

14 “(II) EXTENSION TO GENERATE
15 ADDITIONAL DATA.—If the Secretary
16 determines that additional data or evi-
17 dence is required to complete a report
18 required under this subparagraph
19 with respect to a specified break-
20 through device, the deadline under
21 this clause may be extended for an
22 additional two years.

23 “(C) ADDITIONAL PERIOD OF TRANSI-
24 TIONAL COVERAGE TO DEVELOP ADDITIONAL
25 DATA.—Insofar as the Secretary determines

1 that additional data or evidence is required to
2 complete a report required under subparagraph
3 (B) with respect to a specified breakthrough de-
4 vice, the transitional coverage period of cov-
5 erage and payment for such device shall be ex-
6 tended by the lesser of—

7 “(i) two years; or

8 “(ii) the amount of additional time re-
9 quired for the submission of the report
10 with respect to such device.

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

19 “(A) improves the quality of care and pa-
20 tient outcomes;

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

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

24 (b) CONFORMING AMENDMENTS.—

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

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

23 (2) OUTPATIENT PROSPECTIVE PAYMENT SYS-
24 TEM.—Section 1833(t)(6)(C) of such Act (42 U.S.C.

1 13951(t)(6)(C)) is amended by adding at the end the
2 following new clause:

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

17 (c) EFFECTIVE DATE.—This section, and the amend-
18 ments made by this section, shall take effect on the date
19 of the enactment of this Act and, unless otherwise speci-
20 fied in this section (or in an amendment made by this sec-
21 tion), shall apply to breakthrough devices (as defined in
22 section 1899C(a) of the Social Security Act, as added by
23 subsection (a)), approved or cleared on or after July 1,
24 2019, or, in the case of a specified breakthrough device

1 (as defined in such section as so added), approved or
2 cleared on or after December 1, 2018.

3 **SEC. 405. SECRETARY OF HEALTH AND HUMAN SERVICES**
4 **REPORT ON COVERAGE FOR INNOVATIVE**
5 **TECHNOLOGIES.**

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

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

17 (2) establishes a standardized process for deter-
18 mining which technologies satisfy the definition pur-
19 suant to paragraph (1);

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

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

1 **SEC. 406. SECRETARY OF HEALTH AND HUMAN SERVICES**
2 **REPORT ON CMS COMPUTER SYSTEMS.**

3 Not later than one year after the date of the enact-
4 ment of this Act, the Secretary of Health and Human
5 Services shall submit to Congress a report on the fol-
6 lowing:

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

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

16 (A) Replacing or updating such systems
17 identified under paragraph (1).

18 (B) Contractors and other third-parties to
19 solve for deficiencies in such system identified
20 under paragraph (1).

21 **SEC. 407. PRECISION MEDICINE ANSWERS FOR KIDS**
22 **TODAY.**

23 (a) **CENTERS FOR MEDICARE & MEDICAID SERVICES**
24 **GUIDANCE ON THE EARLY AND PERIODIC SCREENING,**
25 **DIAGNOSTIC, AND TREATMENT BENEFIT.**—Not later than
26 6 months after the date of enactment of this Act, the Cen-

1 ters for Medicare & Medicaid Services shall issue guidance
2 to States on authority and requirements under the Med-
3 icaid program under title XIX of the Social Security Act
4 to provide medically necessary health care that falls within
5 the scope of services specified under section 1905(r) of the
6 Social Security Act (42 U.S.C. 1396d(r)) to a child, re-
7 gardless of whether the service is available for adults
8 under the State plan (or waiver of such plan) under such
9 title. The guidance shall—

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

20 (A) have a positive result from a newborn
21 screening program;

22 (B) have one or more neurodevelopmental
23 or congenital anomalies;

24 (C) are experiencing developmental delay
25 or intellectual disability;

1 (D) are having seizures;

2 (E) have been referred or admitted to a
3 pediatric or neonatal intensive care unit for a
4 chronic or undiagnosed disease;

5 (F) have been seen by at least one medical
6 specialist for such chronic or undiagnosed dis-
7 ease; or

8 (G) are suspected by at least one
9 healthcare provider to have a neonatal- or pedi-
10 atric-onset genetic disease;

11 (2) provide education and support to providers
12 to minimize denials of claims for medical assistance
13 under the State plan under title XIX of the Social
14 Security Act resulting from deficient or inadequate
15 paperwork; and

16 (3) ensure that providers and Medicaid-eligible
17 children and the families are aware of the Early and
18 Periodic Screening, Diagnostic and Treatment Ben-
19 efit under title XIX of the Social Security Act and
20 have access to required screenings and necessary
21 treatment services.

22 (b) DEMONSTRATION PROGRAM TO PROVIDE GE-
23 NETIC AND GENOMIC TESTING FOR CERTAIN CHIL-
24 DREN.—

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

16 (2) DEMONSTRATION PROJECT PAYMENT RE-
17 QUIREMENTS.—Under each demonstration project
18 under this section conducted by a State, the fol-
19 lowing shall apply:

20 (A) The State shall provide a health care
21 provider (as defined by the State) with pay-
22 ments for the provision of genetic and genomic
23 testing to any eligible individual. Payments
24 made to a health care provider for such services
25 shall be treated as medical assistance for pur-

1 poses of section 1903(a) of the Social Security
2 Act (42 U.S.C. 1396b(a)), except that the Fed-
3 eral medical assistance percentage applicable to
4 such payments shall be equal to 100 percent.

5 (B) The State shall specify the method-
6 ology the State will use for determining pay-
7 ment for the provision of genetic and genomic
8 testing. Such methodology for determining pay-
9 ment shall be established consistent with section
10 1902(a)(30)(A) of such Act (42 U.S.C.
11 1396a(a)(30)(A)).

12 (3) APPLICATIONS.—

13 (A) IN GENERAL.—A State desiring to
14 enter into an agreement under paragraph (1)
15 with the Secretary for conducting a demonstra-
16 tion project shall submit to the Secretary an
17 application, in accordance with such form and
18 manner, and application priorities, as specified
19 by the Secretary and that at a minimum in-
20 cludes the following:

21 (i) An explanation of how and the ex-
22 tent to which genetic and genomic testing
23 under the demonstration project of the
24 State will provide information and data on

1 how such services improve the diagnosis of
2 eligible individuals.

3 (ii) An explanation of how and the ex-
4 tent to which coverage under the State
5 plan (or waiver) pursuant to the dem-
6 onstration project will increase the use of
7 genetic and genomic testing that may in-
8 crease the use of genetic and genomic test-
9 ing that may improve clinical outcomes for
10 eligible individuals.

11 (iii) Procedures for referring any eligi-
12 ble individual who seeks or needs treat-
13 ment in a hospital emergency department
14 to a health care provider who is qualified
15 (as determined by the State) to provide ge-
16 netic and genomic testing.

17 (iv) An explanation of how genetic
18 and genomic testing may improve health
19 outcomes for all populations in the State,
20 including—

21 (I) individuals with a rare genetic
22 disease, including a metabolic disease,
23 neurologic disorders, or hereditary
24 cancer testing in the presence of a

1 suspected or confirmed cancer diag-
2 nosis; and

3 (II) special populations, including
4 infants and children who are critically
5 ill (non-infectious and non-trauma)
6 patients, transplant patients, individ-
7 uals with cardiac disease, and individ-
8 uals with, or who have a family his-
9 tory of, a birth defect or develop-
10 mental disability.

11 (B) PREFERENCES IN CONSIDERING AP-
12 PPLICATIONS.—In considering applications sub-
13 mitted under subparagraph (A), the Secretary
14 of Health and Human Services shall give pref-
15 erence to States that can demonstrate under-
16 utilization of genetic and genomic sequencing
17 clinical services (with priority given to States
18 that do not cover whole-genome sequencing or
19 do not cover the majority of genetic and
20 genomic clinical services) in pediatric popu-
21 lations under the State plan under title XIX of
22 the Social Security Act (or waiver of such
23 plan).

24 (4) TECHNICAL ASSISTANCE.—The Secretary of
25 Health and Human Services shall provide technical

1 assistance to assist States in planning and designing
2 the demonstration project for purposes of applying
3 for conducting such project under this section.

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

18 (6) REPORTS BY HEALTH CARE PROVIDERS.—
19 As a condition for receiving payment for genetic and
20 genomic testing provided to an eligible individual
21 under a demonstration project conducted by a State
22 under this subsection, a health care provider shall
23 report to the State, in accordance with such require-
24 ments as the Secretary shall specify, on all applica-

1 ble measures for determining the quality and effi-
2 cacy of such services.

3 (7) DEFINITIONS.—In this subsection:

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

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

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

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

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

1 (B) GENETIC AND GENOMIC TESTING.—

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

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

13 (ii) includes—

14 (I) the sequencing of the whole
15 genome, the whole exome, or a panel
16 of genes; and

17 (II) any analysis, interpretation,
18 and data report derived from such se-
19 quencing.

20 (c) NATIONAL ACADEMY OF MEDICINE STUDY.—

21 (1) IN GENERAL.—Not later than one year
22 after the date of the enactment of this Act, the Sec-
23 retary of Health and Human Services shall enter
24 into an arrangement with the National Academy of

1 Medicine under which the Academy agrees to
2 study—

3 (A) how genetic and genomic testing may
4 improve preventative care and precision medi-
5 cine;

6 (B) disparities in access to precision
7 diagnostics and associated therapeutics;

8 (C) how genetic and genomic testing may
9 be used to reduce health disparities in
10 marginalized communities;

11 (D) how the Federal Government may help
12 to reduce barriers to genetic and genomic test-
13 ing, including—

14 (i) encouraging the expansion of
15 health insurance coverage of genetic and
16 genomic testing, including diagnostic, pre-
17 dictive, and presymptomatic testing, and
18 genetic and genomic testing (as defined in
19 subsection (b)(7)(B));

20 (ii) supporting the collection of evi-
21 dence for the clinical utility and appro-
22 priate use of genetic and genomic tests;
23 and

24 (iii) improving access to genetic coun-
25 selors, pathologists, and other relevant pro-

1 fessions, including strengthening related
2 workforce education and training efforts;

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

10 (ii) the extent to which coverage provided
11 pursuant to subsection (a) increased the use of
12 genetic and genomic testing and improved clin-
13 ical outcomes for beneficiaries; and

14 (iii) how the Centers for Medicare & Med-
15 icaid Services may make coverage determina-
16 tions that better suit a precision medicine ap-
17 proach to treatment; and

18 (F) how genetic and genomic testing may
19 improve health outcomes for all pediatric popu-
20 lations in the United States, including—

21 (i) children with a rare disease, in-
22 cluding a metabolic disease, neurologic dis-
23 order, or hereditary cancer testing in the
24 presence of a suspected or confirmed can-
25 cer diagnosis; and

- 1 (ii) special populations, including—
2 (I) critically ill (non-infectious
3 and non-trauma) patients;
4 (II) transplant patients;
5 (III) individuals with cardiac dis-
6 ease; and
7 (IV) individuals with, or who
8 have a family history of, a birth defect
9 or developmental disability.

10 (2) REPORT.—

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

- 17 (i) the Secretary of Health and
18 Human Services;
19 (ii) the Committee on Ways and
20 Means and the Committee on Energy and
21 Commerce of the House of Representa-
22 tives; and
23 (iii) the Committee on Finance and
24 the Committee on Health, Education,
25 Labor, and Pensions of the Senate.

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

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

19 (d) CENTERS FOR MEDICARE & MEDICAID SERVICES
20 REPORT ON MEDICAID COVERAGE FOR GENETIC AND
21 GENOMIC TESTING.—Not later than one year after the
22 date of the enactment of this Act, and annually thereafter
23 for the subsequent 3 years, the Centers for Medicare &
24 Medicaid Services shall submit to the Secretary of Health
25 and Human Services, the Committees on Ways and Means

1 and on Energy and Commerce of the House of Represent-
2 atives, and the Committees on Finance and Health, Edu-
3 cation, Labor, and Pensions of the Senate a report on the
4 extent to which each of the 50 States provide coverage
5 under the State plan under title XIX of the Social Secu-
6 rity Act (or waiver of such plan) of genetic and genomic
7 testing (as defined in subsection (b)(7)(B)) (including
8 whole exome, whole genome, gene panels, single gene tests,
9 Chromosomal microarray analysis, Fluorescence in situ
10 hybridization, and other genetic and genomic tests), in-
11 cluding information on—

12 (1) how often genetic and genomic diagnostic
13 testing services are covered and reimbursed;

14 (2) the frequency of denials for coverage and
15 the rationale for denying coverage;

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

18 (4) how often test genetic counseling is covered
19 pre- and post- genetic and genomic diagnostic test-
20 ing;

21 (5) the turn-around time for prior authorization
22 requests; and

23 (6) any barriers to coverage of genetic and
24 genomic testing services identified.

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

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

5 (1) in subsection (s)(2)—

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

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

10 (C) by adding at the end the following new
11 subparagraph:

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

16 (2) by adding at the end the following new sub-
17 section:

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

19 “(1) PHARMACOGENETIC CONSULTATION.—The
20 term ‘pharmacogenetic consultation’ means, with re-
21 spect to a genetic or genomic test furnished to an
22 individual, a consultation with respect to such test
23 requested by the physician treating such individual
24 to provide such physician with advice and rec-
25 ommendations regarding the dosage, safety, and effi-
26 cacy of particular drugs, biologicals, and other treat-

1 ments based on the individual’s pharmacogenetic re-
2 sult.

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

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

8 “(B) in the case of an individual practicing
9 in a State that does not license genetic coun-
10 selors, meets such other criteria as the Sec-
11 retary establishes.

12 “(3) QUALIFIED CLINICAL PHARMACIST.—The
13 term ‘qualified clinical pharmacist’ means an indi-
14 vidual—

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

16 “(B) who is licensed as a pharmacist in
17 the State in which such individual furnishes
18 consultations;

19 “(C) has appropriate pharmacy specialty
20 certifications or appropriate training, as deter-
21 mined by the Secretary; and

22 “(D) meets other qualifications as specified
23 by the Secretary.”.

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

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

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

8 (3) by adding at the end the following new sub-
9 paragraph:

10 “(K) pharmacogenetic consultations (as
11 defined in subsection (lll)).”.

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

16 **SEC. 409. PROHIBITING THE USE OF GEOGRAPHIC TRACK-**
17 **ING FEATURES AND BIOMETRICS WITHIN**
18 **MEDICAID ELECTRONIC VISIT VERIFICATION**
19 **SYSTEMS.**

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

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

4 **SEC. 410. GENERALLY ACCEPTED STANDARD FOR ELEC-**
5 **TRONIC PRESCRIBING.**

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

9 “(8) GENERALLY ACCEPTED STANDARDS.—

10 “(A) DESIGNATION OF STANDARDS MAIN-
11 TENANCE ORGANIZATION TO RECOGNIZE GEN-
12 ERALLY ACCEPTED STANDARDS.—Not later
13 than 6 months after the date of the enactment
14 of this paragraph, the Secretary shall designate
15 through rulemaking a standards maintenance
16 organization with the authority to establish,
17 maintain, and modify generally accepted stand-
18 ards for electronic prescribing and electronic
19 prior authorization. The standards maintenance
20 organization named by the Secretary shall be a
21 standard setting body that—

22 “(i) is a not-for-profit;

23 “(ii) has established a multi-stake-
24 holder forum for development and approval

1 of electronic prescribing and electronic
2 prior authorization standards;

3 “(iii) is a standards development or-
4 ganization accredited by the American Na-
5 tional Standards Institute; and

6 “(iv) includes in its membership phar-
7 macies, prescribers, prescription drug
8 plans, health information technology devel-
9 opers, and representatives from the Cen-
10 ters for Medicare & Medicaid Services and
11 the Food and Drug Administration.

12 In providing the standards maintenance organi-
13 zation with the authority to establish, maintain,
14 and modify generally accepted standards, the
15 Secretary shall permit the standards mainte-
16 nance organization to recognize up to two
17 versions of a standard as being generally ac-
18 cepted to facilitate the testing of newer stand-
19 ards and to allow a smooth transition from one
20 standard to another.

21 “(B) ADOPTION OF GENERALLY ACCEPTED
22 STANDARDS.—Not later than six months after
23 making the designation under paragraph (8),
24 the Secretary shall require prescriptions and
25 other information described in paragraph

1 (2)(A) for covered Part D drugs prescribed for
2 Part D eligible individuals that are transmitted
3 electronically to be transmitted only in accord-
4 ance with generally accepted standards, as des-
5 ignated by the standards maintenance organiza-
6 tion named by the Secretary under subpara-
7 graph (A), under an electronic prescription
8 drug program that meets the requirements of
9 paragraph (2).”.

10 **Subtitle B**

11 **SEC. 411. MEANINGFUL ACCESS TO FEDERAL HEALTH** 12 **PLAN CLAIMS DATA.**

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

14 (1) Clinician-led clinical data registries serve an
15 important role in promoting, facilitating, and con-
16 ducting medical research and improving quality of
17 healthcare by providing timely and actionable feed-
18 back to practitioners on their performance in rela-
19 tion to other practitioners and best clinical practices.

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

24 (3) While the Centers for Medicare and Med-
25 icaid Services has established programs for providing

1 access to claims data, those programs fail to provide
2 clinician-led clinical data registries with meaningful
3 access to such data.

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

11 (b) ENSURING MEANINGFUL ACCESS TO CLAIMS
12 DATA.—

13 (1) ESTABLISHMENT OF A NEW PROGRAM.—
14 The Secretary shall establish a new program (sepa-
15 rate from any existing data access programs, includ-
16 ing, without limitation, the Centers for Medicare and
17 Medicaid Services Qualified Entity (in this section,
18 referred to as “QE”) Program (42 U.S.C.
19 1395kk(e), 1395kk-2) (in this section, referred to as
20 the “Medicare Data Sharing for Performance Meas-
21 urement Program”) and the Research Data Assist-
22 ance Center (in this section, referred to as the
23 “ResDAC”) process) under which the Secretary
24 shall, at the request of a clinician-led clinical data
25 registry, provide timely, broad, and continuous ac-

1 cess to a database of claims data to such clinician-
2 led clinical data registry for purposes of research,
3 quality of care measurement and reporting to health
4 care providers, linking such data with clinical data
5 and performing risk-adjusted, scientifically valid
6 analyses and research to support quality improve-
7 ment or patient safety, and other purposes and uses
8 described herein or approved by the Secretary. Ac-
9 cess to a database of claims data pursuant to this
10 subsection shall not be more restrictive than access
11 to data provided under the QE Program or the
12 ResDAC process.

13 (2) STREAMLINED APPLICATION PROCESS.—

14 (A) INITIAL AND RECERTIFICATION APPLI-
15 CATION.—Prior to gaining access to a database
16 of claims data under the program established in
17 subsection (a), a clinician-led clinical data reg-
18 istry shall submit to the Secretary an applica-
19 tion demonstrating that it is qualified (as deter-
20 mined by the Secretary) to use claims data.
21 Upon the Secretary's approval of a clinician-led
22 clinical data registry's application described in
23 this subparagraph, the Secretary shall provide
24 access to a database of claims data to such cli-
25 nician-led clinical data registry for a period of

1 at least 5 years. After the expiration of the time
2 period described in this subparagraph, the clini-
3 cian-led clinical data registry shall reapply to
4 access the database of claims data under the
5 program established in subsection (a).

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

19 (3) APPEAL RIGHTS.—

20 (A) OPPORTUNITY TO APPEAL.—The Sec-
21 retary shall develop and maintain a process by
22 which a clinician-led clinical data registry may
23 appeal—

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

1 (ii) the Secretary's failure to approve
2 or deny the clinician-led clinical data reg-
3 istry's application described in paragraph
4 (2) within a reasonable time frame estab-
5 lished by the Secretary.

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

16 (4) BROAD AND TIMELY ACCESS TO DATA.—
17 The Secretary shall structure its database of claims
18 data to allow for various data set queries, including,
19 but not limited to, provider-specific claims data, clin-
20 ical specialty-specific claims data, state-specific
21 claims data, and nationwide claims data. The Sec-
22 retary shall promptly make available to a clinician-
23 led clinical data registry access to claims data re-
24 quested by such clinician-led clinical data registry
25 within a reasonable timeframe, not to exceed 30 cal-

1 endar days, after the Secretary approves the request
2 from the clinician-led clinical data registry.

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

5 (1) make available to the public reports evalu-
6 ating the performance of providers of services and
7 suppliers using the claims data provided to such cli-
8 nician-led clinical data registry under subsection (a)
9 in combination with registry data;

10 (2) use claims data received under subsection
11 (a) combined with registry data to conduct addi-
12 tional nonpublic analyses and provide or charge an
13 access fee for such analyses to authorized users for
14 nonpublic use;

15 (3) provide or charge an access fee for data sets
16 that link claims data received under subsection (a)
17 with registry data to authorized users for nonpublic
18 use; and

19 (4) provide or charge an access fee for claims
20 data received under subsection (a) to authorized
21 users for nonpublic use.

22 (d) FEES.—

23 (1) CLAIMS DATA PROVIDED TO CLINICIAN-LED
24 CLINICAL DATA REGISTRIES.—Claims data shall be
25 provided to a clinician-led clinical data registry

1 under subsection (a) at a reasonable fee based on
2 the cost of providing such data to the clinician-led
3 clinical data registry. Such fee shall be based at
4 least in part on the number of patients included in
5 the claims data provided to such clinician-led clinical
6 data registry. Any fee collected pursuant to the pre-
7 ceding sentences shall be deposited in the Centers
8 for Medicare and Medicaid Services Program Man-
9 agement Account.

10 (2) ANALYSES AND DATA PROVIDED TO AU-
11 THORIZED USERS.—A clinician-led clinical data reg-
12 istry may charge a reasonable, cost-based fee for
13 providing to authorized users claims data, data sets
14 linking claims data with registry data, or analyses
15 described in subsection (b).

16 (e) PROTECTION OF INFORMATION.—

17 (1) PRIVACY, SECURITY, AND DISCLOSURE
18 LAWS.—The Secretary shall provide access to a
19 database of claims data pursuant to subsection (a)
20 in accordance with applicable information, privacy,
21 security, and disclosure laws, including, without limi-
22 tation, the Health Insurance Portability and Ac-
23 countability Act of 1996 (Public Law 104–191) as
24 amended by the privacy and security provisions set
25 forth in section 13400 of the Health Information

1 Technology for Economic and Clinical Health Act
2 (Public Law 111–5), the regulations promulgated
3 thereunder codified at parts 160 and 164 of title 45,
4 Code of Federal Regulations, and subparagraphs (A)
5 through (B) of section 105(a)(3) of the Medicare
6 Access and CHIP Reauthorization Act of 2015 (42
7 U.S.C. 1395kk–2(a)(3)).

8 (2) PROHIBITION ON USING ANALYSES OR DATA
9 FOR MARKETING PURPOSES.—An authorized user
10 shall not use analyses or data provided or sold under
11 paragraphs (2) through (4) of subsection (b) for
12 marketing purposes.

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

19 (4) OPPORTUNITY FOR PROVIDERS OF SERV-
20 ICES AND SUPPLIERS TO REVIEW.—Prior to a clini-
21 cian-led clinical data registry using, providing, or
22 charging an access fee for claims data, data sets
23 linking claims data with registry data, or analyses
24 described in subsection (b), to the extent that such
25 data, data sets, or analyses would individually iden-

1 tify a provider of services or supplier who is not
2 being provided or sold such data, data sets, or anal-
3 yses, such clinician-led clinical data registry shall
4 confidentially make available such data, data sets, or
5 analyses to such provider of services or supplier and
6 provide such provider of services or supplier with the
7 opportunity to appeal and correct errors.

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

19 (g) ASSESSMENT FOR A BREACH.—

20 (1) IN GENERAL.—In the case of a breach of a
21 data use agreement described in subsection (e), the
22 Secretary shall impose an assessment on the clini-
23 cian-led clinical data registry and the authorized
24 user.

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

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

13 (h) DISCOVERY OR ADMISSION AS EVIDENCE.—
14 Claims data released to a clinician-led clinical data reg-
15 istry under subsection (a) shall not be subject to discovery
16 or admission as evidence in judicial or administrative pro-
17 ceedings without consent of the applicable provider of
18 services or supplier.

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

24 (j) DEFINITIONS.—In this subtitle:

1 (1) AUTHORIZED USER.—The term “authorized
2 user” has the meaning given such term in section
3 105(a)(9)(A) of the Medicare Access and CHIP Re-
4 authorization Act of 2015 (42 U.S.C. 1395kk–
5 2(a)(9)(A)), as well as a government agency or other
6 governmental entity, researchers, entities that seek
7 data for purposes of complying with regulations or
8 other requirements of the Federal Food and Drug
9 Administration, and other entities approved by the
10 Secretary.

11 (2) CLAIMS DATA.—The term “claims data”
12 has the meaning given to the term “data” in section
13 105(b)(1)(B) of the Medicare Access and CHIP Re-
14 authorization Act of 2015 (42 U.S.C. 1395kk–
15 2(b)(1)(B)).

16 (3) CLINICIAN-LED CLINICAL DATA REG-
17 ISTRY.—The term “clinician-led clinical data reg-
18 istry” has the meaning given such term in section
19 4005(b) of the 21st Century Cures Act.

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

22 (A) promoting, facilitating, and conducting
23 medical research, assisting providers of services
24 and suppliers to improve patient safety, and to
25 develop and participate in quality and patient

1 care improvement activities, including devel-
2 oping new models of care;

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

6 (C) educating a government agency or
7 other governmental entity; and

8 (D) supporting clinical trials and other ac-
9 tivities necessary to comply with pre- or post-
10 market approval or adverse event reporting re-
11 quirements or conditions imposed by the Food
12 and Drug Administration, and other purpose
13 approved by the Secretary.

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

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

21 (k) REGULATIONS.—Not later than 1 year after the
22 date of the enactment of this Act, the Secretary of Health
23 and Human Services shall promulgate final regulations to
24 implement the provisions of the preceding sections of this
25 subtitle.

1 **TITLE V—RESEARCH**

2 **SEC. 501. ADVANCED RESEARCH PROJECTS AGENCY FOR**
3 **HEALTH.**

4 (a) ESTABLISHMENT.—The Secretary of Health and
5 Human Services, acting through the Director of the Na-
6 tional Institutes of Health, shall establish the Advanced
7 Research Projects Agency for Health (to be referred to
8 in this Act as “ARPA–H”) to transform and improve im-
9 portant areas of medicine and health for the wellbeing of
10 all individuals in the United States.

11 (b) GOALS.—

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

15 (A) accelerate the discovery and applica-
16 tion of transformational innovations in health
17 and medical product development; and

18 (B) reduce the human and economic cost
19 of disease.

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

23 (A) Promoting high-risk, high-reward inno-
24 vation.

1 (B) Identifying and promoting revolu-
2 tionary advances in biomedical and health re-
3 search that enable new paradigms in health.

4 (C) Accelerating transformational health
5 advances in areas that the relevant industries
6 by themselves are not likely to undertake be-
7 cause of technical, financial, or other uncer-
8 tainty.

9 (D) Prioritizing project investments based
10 on scientific opportunity and uniqueness of fit
11 to ARPA–H strategies and operating practice,
12 together with the prospective impact on disease
13 burden (regardless of disease prevalence), both
14 human and fiscal, including the health care fis-
15 cal liability of the Federal government.

16 (E) Partnering with, and providing fund-
17 ing to, a broad range of institutions, including
18 universities, national laboratories, public sector
19 organizations, private companies, nonprofit or-
20 ganizations, and foreign institutions.

21 (c) DIRECTOR.—

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

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

3 (A) be an individual who, by reason of pro-
4 fessional background and experience, is quali-
5 fied to advise the Secretary on, and manage re-
6 search programs addressing, matters pertaining
7 to long-term and high-risk barriers to the devel-
8 opment of health innovation;

9 (B) have authority to execute contracts de-
10 veloped by in-house program managers who se-
11 lect external performers, and maintain, enhance
12 or terminate projects based on performance
13 against explicit milestones; and

14 (C) have a time-limited appointment of 5
15 years with the opportunity, at the discretion of
16 the President, of one extension.

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

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

22 (B) approve all new programs within
23 ARPA–H;

24 (C) have final funding authority to initiate
25 and terminate program funding;

1 (D) establish criteria for funding and as-
2 ssuming the success of programs through the es-
3 tablishment of technical milestones;

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

7 (F) designate employees to serve as pro-
8 gram managers to carry out the duties de-
9 scribed in subsection (e) for each of the pro-
10 grams established pursuant to the responsibil-
11 ities established for ARPA–H.

12 (4) AUTHORITY.—The Director of ARPA–H is
13 authorized to—

14 (A) acquire (by purchase, lease, condemna-
15 tion, or otherwise), construct, improve, repair,
16 operate, and maintain such real and personal
17 property as are necessary to carry out this sec-
18 tion; and

19 (B) lease an interest in property for not
20 more than 20 years, notwithstanding section
21 1341(a)(1) of title 31, United States Code.

22 (d) PERSONNEL MANAGEMENT AUTHORITY.—

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

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

13 (B) hire personnel under section 207(f) of
14 the Public Health Service Act (42 U.S.C.
15 209(f)) and establish governing criteria to re-
16 cruit, appoint, and compensate personnel under
17 this section notwithstanding section 202 of De-
18 partment of Health and Human Services Ap-
19 propriations Act, 1993 (Public Law 102–394)
20 or any provision of title 5, United States Code,
21 governing the rates of pay or classification of
22 employees in the Executive branch;

23 (C) make additional appointments of sci-
24 entific, medical, and professional personnel
25 under this section without regard to any provi-

1 sion in title 5, United States Code, governing
2 appointments under the civil service laws and
3 fix the compensation of such personnel at a rate
4 to be determined by the Director, up to the
5 amount of annual compensation (excluding ex-
6 penses) specified in section 102 of title 3,
7 United States Code, notwithstanding section
8 202 of Department of Health and Human Serv-
9 ices Appropriations Act, 1993 (Public Law
10 102–394) or any provision of title 5, United
11 States Code, governing the rates of pay or clas-
12 sification of employees in the Executive branch;
13 and

14 (D) recruit and retain a diverse workforce,
15 including individuals underrepresented in
16 science and medicine and racial and ethnic mi-
17 norities.

18 (2) ADDITIONAL STAFF.—The Director of
19 ARPA–H may use all authorities in existence on the
20 date of enactment of this Act that are provided to
21 the Secretary to hire administrative, financial, infor-
22 mation technology staff, and any other staff the Di-
23 rector of ARPA–H determines are necessary to
24 carry out this section.

25 (3) LIMITATION ON TERM.—

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

6 (B) EXTENSION.—The Director of ARPA–
7 H may, in the case of a particular employee, ex-
8 tend the period to which service is limited under
9 subparagraph (A) by up to 3 years if the Direc-
10 tor determines that such action is necessary to
11 promote the efficiency of ARPA–H.

12 (4) LIMITATION ON ADDITIONAL PAYMENTS.—
13 The total amount of the additional payments paid to
14 an employee under paragraph (1)(C) for any 12-
15 month period may not exceed the least of the fol-
16 lowing amounts:

17 (A) \$25,000.

18 (B) The amount equal to 25 percent of the
19 employee’s annual rate of basic pay.

20 (C) The amount of the limitation that is
21 applicable for a calendar year under section
22 5307(a)(1) of title 5, United States Code.

23 (e) PROGRAM MANAGERS.—An employee designated
24 as a program manager pursuant to subsection (c)(3)(F)
25 shall—

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

4 (2) track progress and course-correct projects
5 when needed;

6 (3) recommend, as necessary, the restructuring
7 or termination of projects supported by ARPA-H;
8 and

9 (4) select, on the basis of merit and need, each
10 of the projects to be supported under the program
11 involved after considering—

12 (A) the novelty and scientific and technical
13 merit of the proposed projects;

14 (B) the demonstrated capabilities of the
15 applicants to successfully carry out the pro-
16 posed project;

17 (C) the consideration by the applicant of
18 future commercial applications of the project;

19 or

20 (D) the unmet need within patient popu-
21 lations.

22 (f) REPORTS.—

23 (1) STRATEGIC VISION.—Not later than 180
24 days after the date of the enactment of this Act, the
25 Director of ARPA-H shall provide to the Committee

1 on Energy and Commerce and the Committee on
2 Appropriations of the House of Representatives and
3 the Committee on Health, Education, Labor and
4 Pensions and the Committee on Appropriations of
5 the Senate a report describing the strategic vision
6 that ARPA–H will use to guide the choices of
7 ARPA–H for future health investments over the fol-
8 lowing 3 fiscal years beginning on or after the date
9 of the enactment of this Act.

10 (2) ANNUAL BUDGET REQUEST.—As part of
11 the annual budget request submitted for each fiscal
12 year, the Director of ARPA–H shall provide to the
13 congressional committees specified in paragraph (1)
14 a report describing—

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

17 (i) the transition of projects’ outcomes
18 to clinical practice;

19 (ii) the impact on clinical outcome;
20 and

21 (iii) the creation of biomedical capa-
22 bilities; and

23 (B) successes and barriers to scientific
24 interchanges;

25 (C) rapid knowledge transfer;

1 (D) resource optimization; and

2 (E) heightened investment impact among
3 collaborators.

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

14 (A) A general description of the coopera-
15 tive agreement or other transaction (as the case
16 may be), including the innovations for which
17 advanced research is provided for under such
18 agreement or transaction.

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

21 (C) The reasons for not using a contract
22 or grant to provide support for such advanced
23 research.

24 (D) The amount of the payments, if any,
25 referred to in subsection (i)(2) that were re-

1 ceived by the Federal Government in connection
2 with such cooperative agreement or other trans-
3 action during the fiscal year covered by the re-
4 port.

5 (E) The amount of the payments reported
6 under subparagraph (D), if any, that were cred-
7 ited to the account established under subsection
8 (i)(7).

9 (g) COORDINATION AND NONDUPLICATION.—

10 (1) IN GENERAL.—The Director of ARPA–H
11 shall ensure effective, early, and frequent coordina-
12 tion between ARPA–H and the heads of the re-
13 search, public health, and regulatory agencies of the
14 Department of Health and Human Services, includ-
15 ing—

16 (A) the Director of the National Institutes
17 of Health;

18 (B) the Commissioner of Food and Drugs;

19 (C) the Administrator of the Centers for
20 Medicare and Medicaid Services;

21 (D) the Director of the Centers for Disease
22 Control and Prevention; and

23 (E) the Assistant Secretary for Prepared-
24 ness and Response.

1 (F) The Director of the National Science
2 Foundation.

3 (G) The Director of the Office of Science
4 of the Department of Energy.

5 (2) COORDINATION.—The Director shall also
6 coordinate among the full set of advanced research
7 project agencies including—

8 (A) the Defense Advanced Research
9 Project Agency;

10 (B) the Advanced Research Project Agen-
11 cy-Energy; and

12 (C) others as they may be established.

13 (h) ADVICE.—

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

16 (A) any advisory committee that, as of the
17 date of the enactment of this Act, is providing
18 advice to the Secretary of Health and Human
19 Services (or any head of a research, public
20 health, or regulatory agency of the Department
21 of Health and Human Services); and

22 (B) an advisory committee established on
23 or after such date of enactment to support the
24 programs of ARPA–H and to provide advice
25 and assistance on—

1 (i) specific program tasks; or

2 (ii) overall direction of ARPA–H.

3 (2) ADDITIONAL SOURCES.—In addition to the
4 advisory committees specified in paragraph (1), the
5 Director of ARPA–H may seek advice and review
6 from—

7 (A) the President’s Committee of Advisors
8 on Science and Technology;

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

12 (C) representatives of patient communities.

13 (i) COOPERATIVE AGREEMENTS AND OTHER TRANS-
14 ACTIONS.—

15 (1) IN GENERAL.—The Director of ARPA–H,
16 in carrying out advanced research projects through
17 ARPA–H, may enter into grants, contracts, coopera-
18 tive agreements, cash prizes, and other transactions
19 (as defined in section 319L(a) of the Public Health
20 Service Act (42 U.S.C. 247d–7e(a))) with any per-
21 son, any agency or instrumentality of the United
22 States, any unit of State or local government, and
23 any other entity institutions, including universities,
24 national laboratories, public sector organizations,

1 private companies, nonprofit organizations, and for-
2 eign institutions.

3 (2) TERMS.—

4 (A) REQUIRED PROVISIONS.—The Director
5 of ARPA–H shall ensure that, in entering into
6 cooperative agreements and other transactions
7 under paragraph (1)—

8 (i) to the extent the Director of
9 ARPA–H determines practicable, the Fed-
10 eral funds provided under the cooperative
11 agreement or other transaction do not ex-
12 ceed the total amount provided by other
13 parties to the cooperative agreement or
14 other transaction; and

15 (ii) the authority under paragraph (1)
16 is used only when the use of standard con-
17 tracts or grants is not feasible or appro-
18 priate.

19 (B) OPTIONAL PROVISION.—Cooperative
20 agreements and other transactions entered into
21 by the Director of ARPA–H under paragraph
22 (1) may include a clause that requires a person
23 or other entity to make payments to ARPA–H
24 (or any other department or agency of the Fed-
25 eral Government) as a condition for receiving

1 support under the agreement or other trans-
2 action.

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

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

21 (5) MULTI-YEAR CONTRACTS.—

22 (A) IN GENERAL.—The Director of
23 ARPA–H may enter into a multi-year contract
24 if—

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

7 (ii) the Director determines that a
8 multiyear contract will serve the best inter-
9 ests of the Federal Government in carrying
10 out this section; and

11 (iii) the contract includes a provision
12 that the contract shall be terminated if
13 funds are not made available for the con-
14 tinuation of the contract in a fiscal year
15 covered by the contract.

16 (B) TERMINATION COSTS.—A provision re-
17 ferred to in subparagraph (A)(iii) shall provide
18 that funds available for paying termination
19 costs shall remain available for that purpose
20 until the costs associated with termination of
21 the contract are paid.

22 (6) APPLICATION OF OTHER PROVISIONS.—The
23 authority provided under paragraph (1) may be ex-
24 ercised without regard to section 3324 of title 31,
25 United States Code.

1 (7) ACCOUNT.—There is hereby established on
2 the books of the Treasury an account for support of
3 advanced research projects provided for in coopera-
4 tive agreements and other transactions entered into
5 under paragraph (1). Funds in such account shall be
6 available for the payment of such support.

7 (8) PRIZE COMPETITIONS.—The Director of
8 ARPA–H may carry out prize competitions in ac-
9 cordance with section 24 of the Stevenson-Wydler
10 Technology Innovation Act of 1980 (15 U.S.C.
11 3719)) in support of the goals specified in sub-
12 section (b).

13 (9) NONAPPLICABILITY OF CERTAIN PROVI-
14 SIONS.—Research funded pursuant to this section
15 shall not be subject to—

16 (A) advisory council approval under section
17 405(b)(2) of the Public Health Service Act (42
18 U.S.C. 284(b)(2));

19 (B) advisory council review under section
20 406(a)(3)(A)(ii) of such Act (42 U.S.C.
21 284a(a)(3)(A)(ii)); or

22 (C) the peer review requirements under
23 section 492 of such Act (42 U.S.C. 284(b)(2),
24 289a).

25 (j) CONFIDENTIALITY.—

1 (1) IN GENERAL.—The information specified in
2 paragraph (2) shall be exempt from disclosure under
3 section 552 of title 5, United States Code (com-
4 monly referred to as the Freedom of Information
5 Act).

6 (2) INFORMATION.—The information specified
7 in this paragraph is information collected by ARPA-
8 H from recipients of financial assistance awards, in-
9 cluding the following:

10 (A) Plans for commercialization of tech-
11 nologies developed under the award, including
12 business plans, technology-to-market plans,
13 market studies, and cost and performance mod-
14 els.

15 (B) Investments provided to an awardee
16 from third parties (such as venture capital
17 firms, hedge funds, and private equity firms),
18 including the amounts and the percentage of
19 ownership of the awardee provided in return for
20 the investments.

21 (k) EXPEDITING BREAKTHROUGHS THROUGH CO-
22 OPERATION WITH FOOD AND DRUG ADMINISTRATION.—

23 (1) IN GENERAL.—The Secretary of Health and
24 Human Services, acting through the Commissioner
25 of Food and Drugs and in consultation with the Di-

1 rector of ARPA–H, may take actions to facilitate
2 transformation of biomedical breakthroughs into
3 tangible solutions for patients and to expedite devel-
4 opment of medical products, including through any
5 of the following means:

6 (A) Helping to ensure that medical prod-
7 uct development programs, in as efficient a
8 manner as possible, gather the nonclinical and
9 clinical data necessary to advancing the devel-
10 opment of such products and to obtaining their
11 approval, licensure, or clearance, as applicable,
12 by the Food and Drug Administration under
13 sections 505, 510(k), and 515 of such Act (21
14 U.S.C. 355, 360(k), 360) and section 351 of
15 the Public Health Service Act (42 U.S.C. 262).

16 (B) Expediting review of investigational
17 new drug applications under section 505(i) of
18 the Federal Food, Drug, and Cosmetic Act (21
19 U.S.C. 355(i)), review of investigational device
20 exemptions under section 520(g) of such Act
21 (21 U.S.C. 360j(g)), and review of applications
22 for approval, licensure, and clearance of medical
23 products under sections 505, 510(k), and 515
24 of such Act (21 U.S.C. 355, 360(k), 360) and

1 section 351 of the Public Health Service Act
2 (42 U.S.C. 262).

3 (C) Meeting at appropriate intervals with
4 the Director of ARPA–H and any other appro-
5 priate medical product development partners,
6 such as the Director of the Biomedical Ad-
7 vanced Research and Development Authority to
8 discuss the development status of medical prod-
9 ucts and projects that are the highest priorities
10 to ARPA–H, unless the Director of ARPA–H
11 and the Commissioner of Food and Drugs de-
12 termine that any such meetings are not nec-
13 essary.

14 (2) RELATION TO OTHERWISE AUTHORIZED AC-
15 TIVITIES OF THE FDA.—The authority specified in
16 paragraph (1) shall not be construed as limiting the
17 authority of the Secretary of Health and Human
18 Services, acting through the Commissioner of Food
19 and Drugs with respect to the review and approval,
20 clearance, authorization for emergency use, or licen-
21 sure of a medical product under the Federal Food,
22 Drug and Cosmetic Act (21 U.S.C. 321 et seq.) or
23 section 351 of the Public Health Service Act (42
24 U.S.C. 262).

1 (3) REIMBURSEMENT.—Utilizing interagency
2 agreements or other appropriate resource allocation
3 mechanisms available, the Director of ARPA–H,
4 using funds made available to ARPA–H, shall reim-
5 burse the Food and Drug Administration for ex-
6 penditures made by the Food and Drug Administra-
7 tion for activities carried out under this section that
8 have been identified by the Commissioner of Food
9 and Drugs and the Director of ARPA–H as being
10 carried out by the Food and Drug Administration.

11 (4) MEDICAL PRODUCT DEFINED.—In this sec-
12 tion, the term “medical product” means a drug (as
13 defined in section 201 of the Federal Food, Drug,
14 and Cosmetic Act (21 U.S.C. 321)), a device (as de-
15 fined in such section 201), or a biological product
16 (as defined in section 351 of the Public Health Serv-
17 ice Act (42 U.S.C. 262)).

18 (1) AUTHORIZATION OF APPROPRIATIONS AND BY-
19 PASS BUDGET AUTHORITY.—

20 (1) AUTHORIZATION OF APPROPRIATIONS.—
21 There is authorized to be appropriated to carry out
22 this section \$6,500,000,000 for fiscal year 2022, to
23 remain available until expended.

24 (2) BYPASS BUDGET AUTHORITY.—The budget
25 of ARPA–H shall be a separate line item in the an-

1 and through the Office of Science, the Ad-
2 vanced Research Projects Agency–Energy
3 (ARPA–E), and the Office of Electricity.

4 (F) The Secretary of the Interior, acting
5 through the Director of the United States Geo-
6 logical Survey.

7 (G) The Secretary of Health and Human
8 Services, acting through the Director of the Na-
9 tional Institutes of Health.

10 (H) The Secretary of Transportation.

11 (I) The Administrator of the National Aer-
12 onautics and Space Administration.

13 (J) The Administrator of the Environ-
14 mental Protection Agency.

15 (K) The Director of the National Science
16 Foundation.

17 (3) AUTHORITIES.—The officers specified in
18 paragraph (2) may—

19 (A) provide supplemental funding to ex-
20 tend the duration of an award disrupted be-
21 cause of the COVID–19 public health emer-
22 gency to a research institution, Research Lab-
23 oratory, or individual that was awarded before
24 the date of the enactment of this Act, or to ex-

1 pand the purposes of such an award, in order
2 to—

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

5 (ii) enable research scientists, tech-
6 nical staff, research associates, and prin-
7 cipal investigators to complete work;

8 (iii) extend the training of a postsec-
9 ondary student, or the employment of a
10 post-doctoral researcher, on an ongoing re-
11 search project for up to 2 years because of
12 the disruption of the job market;

13 (iv) create research opportunities for
14 up to 2 years for graduate students and
15 post-doctoral researchers;

16 (v) replace, refurbish, or otherwise
17 make usable laboratory animals, reagents,
18 equipment, or other items required for re-
19 search;

20 (vi) facilitate other research (including
21 field work), training, and ongoing con-
22 struction activities, including at institu-
23 tions that are disproportionately affected
24 by the COVID–19 public health emergency

1 (such as minority-serving institutions and
2 2-year institutions of higher education);

3 (vii) enable experimental field cam-
4 paigns and maintenance of field infrastruc-
5 ture, including through replacement of dis-
6 rupted experimental data to enable comple-
7 tion of impacted research; and

8 (viii) support training in online course
9 delivery and virtual research experiences
10 that will improve quality and access needed
11 to continue undergraduate, graduate, and
12 post-doctoral training;

13 (B) issue awards to research institutions,
14 Research Laboratories, or other individuals to
15 conduct research on the effects of the COVID-
16 19 and future potential pandemics, on the ef-
17 fects and effectiveness of responses to such dis-
18 eases, and on improving the prediction of the
19 possible courses of such pandemics; and

20 (C) provide flexibility on an award for
21 funds made available to an agency, by any prior
22 or subsequent Act, by modifying the terms and
23 conditions of the award with a research institu-
24 tion, Research Laboratory, or individual due to

1 facility closures or other limitations during the
2 COVID–19 public health emergency.

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

5 (A) the provision of supplemental funding
6 to extend the duration of the award concerned;
7 or

8 (B) flexibility on the allowable expenses
9 under such award.

10 (b) PROCEDURES.—The officers specified in sub-
11 section (a)(2) shall each establish procedures to carry out
12 subsection (a).

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

15 (d) AUTHORIZATIONS OF APPROPRIATIONS.—

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

20 (A) \$300,000,000 shall be for use by the
21 National Oceanic and Atmospheric Administra-
22 tion; and

23 (B) \$150,000,000 shall be for use by the
24 National Institute of Standards and Tech-
25 nology.

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

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

9 (4) DEPARTMENT OF EDUCATION.—There is
10 authorized to be appropriated for fiscal year 2021
11 for the Department of Education, \$200,000,000 to
12 carry out subsection (a), which shall be for use by
13 the Institute for Education Sciences.

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

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

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

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

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

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

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

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

11 (7) DEPARTMENT OF HEALTH AND HUMAN
12 SERVICES.—There is authorized to be appropriated
13 for fiscal year 2021 for the Department of Health
14 and Human Services, \$10,000,000,000 to carry out
15 subsection (a), which shall be for use by the Na-
16 tional Institutes of Health.

17 (8) DEPARTMENT OF TRANSPORTATION.—
18 There is authorized to be appropriated for fiscal
19 year 2021 for the Department of Transportation,
20 \$300,000,000 to carry out subsection (a), of which
21 not less than \$130,000,000 shall be for use by the
22 Federal Aviation Administration.

23 (9) NATIONAL AERONAUTICS AND SPACE AD-
24 MINISTRATION.—There is authorized to be appro-
25 priated for fiscal year 2021 for the National Aero-

1 nautics and Space Administration, \$2,000,000,000
2 to carry out subsection (a).

3 (10) ENVIRONMENTAL PROTECTION AGENCY.—

4 There is authorized to be appropriated for fiscal
5 year 2021 for the Environmental Protection Agency,
6 \$200,000,000 to carry out subsection (a).

7 (11) NATIONAL SCIENCE FOUNDATION.—There

8 is authorized to be appropriated for fiscal year 2021
9 for the National Science Foundation,
10 \$3,000,000,000 to carry out subsection (a).

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

13 (A) IN GENERAL.—Amounts authorized to
14 be appropriated by this subsection may be used
15 for the payment of indirect costs of Federal
16 awards under subsection (a), up to the limit
17 otherwise allowable by law and subject to the
18 requirements of part 200 of title 2, Code of
19 Federal Regulations.

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

24 (13) DURATION OF AVAILABILITY.—Amounts
25 authorized to be appropriated by this subsection

1 shall be available for the purposes described in this
2 subsection through fiscal year 2021.

3 (e) DEFINITIONS.—In this section:

4 (1) AWARD.—The term “award” includes a
5 grant, cooperative agreement, or other financial as-
6 sistance.

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

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

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

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

22 (C) A nonprofit entity that conducts feder-
23 ally funded research.

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

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

4 (B) A Federally Funded Research and De-
5 velopment Center for purposes of section
6 3.5.017 of title 48, Code of Federal Regula-
7 tions.

8 **SEC. 503. RESEARCH POLICY BOARD REAUTHORIZATION.**

9 (a) EXTENSION OF SUNSET.—Section 2034(f)(6) of
10 the 21st Century Cures Act (42 U.S.C. 3501 note) is
11 amended by striking “September 30, 2021” and inserting
12 “September 30, 2026”.

13 (b) PARTICIPATION BY DIRECTOR OF NIH.—

14 (1) INCLUSION AS MEMBER.—Section
15 2034(f)(2)(A) of the 21st Century Cures Act (42
16 U.S.C. 3501 note) is amended—

17 (A) by redesignating clause (v) as clause
18 (vi);

19 (B) by inserting after clause (iv) the fol-
20 lowing:

21 “(iv) The Director of the National In-
22 stitutes of Health.”.

23 (2) LIMITATIONS RELATING TO INDIRECT
24 COSTS.—Section 2034(f)(2) of the 21st Century

1 Cures Act (42 U.S.C. 3501 note) is amended by
2 adding at the end the following:

3 “(C) LIMITATIONS RELATING TO INDIRECT
4 COSTS.—Notwithstanding any other provision
5 of law, the Director of the National Institutes
6 of Health may participate in the activities of
7 the Board, including the formulation of rec-
8 ommendations, without regard to limitations re-
9 lating to indirect costs in part 75 of title 45,
10 Code of Federal Regulations (or any successor
11 regulations).”.