# [DISCUSSION DRAFT]

117TH CONGRESS
1ST SESSION

# H. R. _____

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

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IN THE HOUSE OF REPRESENTATIVES

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

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# A BILL

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

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE.**

This Act may be cited as the ''Cures 2.0 Act''.

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

The table of contents of this Act is as follows:

# TITLE I—PUBLIC HEALTH

## SEC. 101. FURTHER UNDERSTANDING THE IMPLICATIONS OF LONG COVID.

(a) SOURCES OF COVERAGE SURVEY.—The Secretary of Health and Human Services shall—

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

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

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

(1) convene a series of national virtual meetings to serve as the basis of an ongoing long COVID learning collaborative with individuals and organizations representing key sectors of the health care community; and

(2) invite to participate in such meetings health plan representatives, health care providers (including hospitals, physicians, and nurses), medical and scientific researchers, patient and consumer advocates, data scientists, health care service providers, and developers of diagnostic and therapeutic products.

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

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

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

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

(b) CONTENTS.—The national strategy under subsection (a) shall at a minimum address each of the following:

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

ter expedient results and personalized medical responses for patients and communities, including for medically underserved populations.

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

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

(4) Modernizing and expanding domestic drug manufacturing, including through the use of continuous manufacturing.

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

**SEC. 103. PANDEMIC PREPAREDNESS RARE DISEASE SUPPORT PROGRAM.**

Subtitle B of title XXVIII of the Public Health Service Act (42 U.S.C. 300hh–10 et seq.) is amended by inserting after section 2815 of such Act the following:

**"SEC. 2816. PANDEMIC PREPAREDNESS PLAN.**

''(a) IN GENERAL.—The Secretary, acting through the Administrator of the Health Resources and Services Administration and in collaboration with the Director of the Centers for Disease Control and Prevention, shall award grants to eligible organizations to develop a pandemic preparedness plan regarding—

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

''(2) potential challenges for the respective eligible organizations during future pandemics and other public health emergencies;

''(3) how the respective eligible organizations plan to overcome the challenges described in paragraphs (1) and (2), including how the respective organizations plan to support patients, their families, and health care providers to overcome such challenges; and

''(4) efforts to partner with local, State, and Federal governments to promote a coordinated response to future pandemics and other public health emergencies.

''(b) PRIORITY.—In awarding grants under this section, the Secretary shall give priority to eligible organizations that are rare disease or condition organizations.

''(c) DEFINITIONS.—In this section:

''(1) The term 'eligible organization' means an organization that—

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

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

''(B) provides support and other resources to patients and their families for accessing and paying for medical care.

''(2) The term 'public health emergency' means a public health emergency declared under section 319.

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

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

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

(a) ADDITIONAL FUNDING FOR VACCINE AWARENESS.—There are authorized to be appropriated to the Centers for Disease Control and Prevention $25,000,000 for each of fiscal years 2022 through 2024 for the purpose of carrying out an awareness campaign to educate the public with respect to the safety and importance of vaccines. The amounts authorized by the preceding sentence are in addition to amounts otherwise available for such purpose.

(b) STRENGTHENING THE IMMUNIZATION INFORMATION SYSTEM.—There are authorized to be appropriated to the Centers for Disease Control and Prevention $25,000,000 for each of fiscal years 2022 through 2024 for the purpose of strengthening immunization information systems. The amounts authorized by the preceding sentence are in addition to amounts otherwise available for such purpose.

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

Title III of the Public Health Service Act (42 U.S.C. 241 et seq.) is amended by adding at the end the following:

**"PART W—DEVELOPING ANTIMICROBIAL INNOVATIONS**

**"SEC. 399OO. ESTABLISHMENT OF COMMITTEE; SUBSCRIPTION MODEL; ADVISORY GROUP.**

"(a) IN GENERAL.—Not later than 60 days after the date of enactment of this part, the Secretary shall establish a Committee on Critical Need Antimicrobials and appoint members to the Committee.

"(b) MEMBERS.—

"(1) IN GENERAL.—The Committee shall consist of at least one representative from each of the National Institute of Allergy and Infectious Diseases, the Centers for Disease Control and Preven-

tion, the Biomedical Advanced Research and Development Authority, the Food and Drug Administration, the Centers for Medicare & Medicaid Services, the Veterans Health Administration, and the Department of Defense.

''(2) CHAIR.—The Secretary shall appoint one of the members of the Committee to serve as the Chair of the Committee.

''(c) DUTIES.—Not later than 1 year after the appointment of all initial members of the Committee, the Secretary, in collaboration with the Committee, and in consultation with the Critical Need Antimicrobials Advisory Group established under subsection (g), shall do the following:

''(1) Develop a list of infections for which new antimicrobial drug development is needed, taking into account organisms, sites of infection, and type of infections for which there is an unmet medical need, findings from the most recent report entitled 'Antibiotic Resistance Threats in the United States' issued by the Centers for Disease Control and Prevention, or an anticipated unmet medical need, including a potential global health security threat. For the list developed under this paragraph, the Secretary, in collaboration with the Committee, may use

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

''(2) Develop regulations, in accordance with subsection (d), outlining favored characteristics of critical need antimicrobial drugs, that are evidence based, clinically focused, and designed to treat the infections described in paragraph (1), and establishing criteria for how each such characteristic will adjust the monetary value of a subscription contract awarded under subsection (f) or section 399QQ. The favored characteristics shall be weighed for purposes of such monetary value such that meeting certain characteristics, or meeting more than one such characteristic, increases the monetary value. Such favored characteristics of an antimicrobial drug shall include—

''(A) treating infections on the list under paragraph (1);

''(B) improving clinical outcomes for patients with multi-drug-resistant infections;

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

life-threatening infection, and, to a lesser extent, second and third drugs that treat such infections;

"(D) route of administration, especially through oral administration;

"(E)(i) containing no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) that has been approved in any other application under section 505(b) of the Federal Food, Drug, and Cosmetic Act or intending to be the subject of a new original biologics license application under section 351(a);

"(ii) being a member of a new class of drugs with a novel target and novel mode of action that are distinctly different from the target or mode of any antimicrobial drug approved under section 505 of such Act or licensed under section 351, including reduced toxicity;

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

"(F) addressing a multi-drug resistant infection through a novel chemical scaffold or mechanism of action;

"(G) having received a transitional subscription contract under subsection (f); and

"(H) any other characteristic the Secretary, in collaboration with the Committee, determines necessary.

"(d) REGULATIONS.—

"(1) IN GENERAL.—Not later than 1 year after the appointment of the initial members of the Committee, the Secretary shall issue proposed regulations which shall include—

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

"(B) how subscription contracts under such section shall be established and paid;

"(C) the favored characteristics under subsection (c)(2), how such characteristics will be weighed, and the minimum number and kind of favored characteristics needed for an antimicrobial drug to be designated a critical need antimicrobial drug; and

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

"(2) DEVELOPMENT OF FINAL REGULATIONS.—Before finalizing the regulations under paragraph (1), the Secretary shall solicit public comment and hold public meetings for the period beginning on the date on which the proposed regulations are issued and ending on the date that is 120 days after such date of issuance. The Secretary shall finalize and publish such regulations not later than 120 days after the close of such period of public comment and meetings.

"(3) SUBSCRIPTION CONTRACT OFFICE.—Not later than 6 months after the date of enactment of this part, the Secretary shall propose an agency or office in the Department of Health and Human Services to manage the establishment and payment of subscription contracts awarded under section 399QQ, including eligibility, requirements, and contract amounts. The Secretary shall solicit public comment and finalize the agency or office no later than 45 days following the proposed agency or office. Such agency or office shall be referred to as the 'Subscription Contract Office'.

"(e) LIST OF INFECTIONS.—The Secretary, in collaboration with the Committee, shall update the list of infections under subsection (c)(1) at least every 2 years.

"(f) TRANSITIONAL SUBSCRIPTION CONTRACTS.—

"(1) IN GENERAL.—Not earlier than 30 days after the date of enactment of this part and ending on the date that the Secretary finalizes the subscription contract regulations under subsection (d), the Secretary may use up to $1,000,000,000 of the amount appropriated under section 399SS(a) to engage in transitional subscription contracts of up to 3 years in length with antimicrobial developers, as determined by the Secretary, that have developed antimicrobial drugs treating infections listed in the most recent report entitled 'Antibiotic Resistance Threats in the United States' issued by the Centers for Disease Control and Prevention, and may include antimicrobial drugs that are qualified infectious disease products (as defined in section 505E(g) of the Federal Food, Drug, and Cosmetic Act), innovative biological products, or innovative drugs that achieve a clinical outcome through immunomodulation. Such a contract may authorize the contractor to use funds made available under the contract for completion of

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

''(2) REQUIREMENTS.—

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

''(i) if the Secretary determines that the antimicrobial drug is intended to treat an infection for which there is an unmet clinical need, an anticipated clinical need, or drug resistance;

''(ii) subject to terms including—

''(I) that the Secretary shall cease any payment installments under a transitional subscription contract if the sponsor does not—

''(aa) ensure commercial and Federal availability of the antimicrobial drug within 30 days of receiving first payment under the contract;

''(bb) identify, track, and publicly report drug resistance data and trends using available

data related to the antimicrobial drug;

''(cc) develop and implement education and communications strategies, including communications for individuals with limited English proficiency and individuals with disabilities, for health care professionals and patients about appropriate use of the antimicrobial drug;

''(dd) submit a plan for registering the antimicrobial drug in additional countries where an unmet medical need exists, which such plan may be consistent with the Stewardship and Access Plan (SAP) Development Guide (2021);

''(ee) subject to subparagraph (B), ensure a reliable drug supply chain, thus leading to an interruption of the supply of the antimicrobial drug in the United States for more than 60 days; or

"(ff) make meaningful progress toward completion of Food and Drug Administration-required postmarketing studies, including such studies that are evidence based; and

"(II) other terms as determined by the Secretary; and

"(iii) if—

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

"(II) the antimicrobial drug has been approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act or licensed under section 351(a).

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

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

tional guidance outlining the antimicrobial drugs that are eligible for transitional subscription contracts under paragraph (1), the requirements to enter into a transitional subscription contract under paragraph (2), and the process by which drug developers can enter into transitional subscription contracts with the Secretary under this subsection.

''(4) PAYMENT OFFICE AND MECHANISM.—Not later than 30 days after the date of enactment of this part, the Secretary shall determine the agency or office in the Department of Health and Human Services that will manage the transitional subscription contracts, including eligibility, requirements, and contract amounts, during the period described in paragraph (1).

''(g) CRITICAL NEED ANTIMICROBIAL ADVISORY GROUP.—

''(1) IN GENERAL.—Not later than 30 days after the appointment of all initial members of the Committee, the Secretary, in collaboration with the Committee, shall establish a Critical Need Antimicrobial Advisory Group (referred to in this subsection as the 'Advisory Group') and appoint members to the Advisory Group.

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

''(A) not fewer than 6 individuals who are—

''(i) infectious disease specialists; or

''(ii) other health experts with expertise in researching antimicrobial resistance, health economics, or commercializing antimicrobial drugs; and

''(B) not fewer than 5 patient advocates.

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

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

''(5) APPLICABILITY OF FACA.—Except as otherwise provided in this subsection, the Federal Advisory Committee Act shall apply to the Advisory Group.

**"SEC. 399PP. CRITICAL NEED ANTIMICROBIAL DRUG APPLICATION AND PAYMENT THROUGH SUBSCRIPTION CONTRACTS.**

''(a) IN GENERAL.—

''(1) SUBMISSION OF REQUEST.—The sponsor of an application under section 505(b) of the Federal Food, Drug, and Cosmetic Act or section 351(a) for an antimicrobial drug may request that the Secretary designate the drug as a critical need antimicrobial. A request for such designation may be submitted after the Secretary grants for such drug an investigational new drug exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act or section 351(a)(3), and shall be submitted not later than 5 years after the date of approval under section 505(c) of the Federal Food, Drug, and Cosmetic Act or licensure under section 351(a).

''(2) CONTENT OF REQUEST.—A request under paragraph (1) shall include information, such as clinical, preclinical and postmarketing data, a list of the favorable characteristics described in section 399OO(c)(2), and any other material that the Secretary in consultation with the Committee requires.

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

application components, and determine if the antimicrobial drug is likely to meet the favorable characteristics identified in the application upon the completion of clinical development. After review, the Secretary shall approve or deny each request for designation not later than 90 days after receiving a request. If the Secretary approves a request, it shall publish the value of the contract that the critical need antimicrobial developer would be eligible to receive if such developer successfully demonstrates that the drug meets the maximum value of the favored characteristics listed in the application.

''(4) LENGTH OF DESIGNATION PERIOD.—A designation granted under this section shall be in effect for a period of 10 years after the date that the designation is approved, and shall remain in effect for such period even if the infection treated by such drug is later removed from the list of infections under section 399OO(c)(1).

''(5) SUBSEQUENT REVIEWS.—No sooner than 2 years after a designation approval or denial under subsection (3), the sponsor may request a subsequent review to re-evaluate the value of a contract to include any new information.

''(b) DEVELOPMENT OF DESIGNATED DRUGS.—If a critical need antimicrobial designation is granted during clinical development of an antimicrobial drug, the Secretary may work with the sponsor to maximize the opportunity for the sponsor to successfully demonstrate that the antimicrobial drug possesses the favored characteristics of high-monetary valued products identified under section 399OO(c)(2).

''(c) APPROPRIATE USE OF CRITICAL NEED ANTIMICROBIAL.—

''(1) IN GENERAL.—The sponsor of an antimicrobial drug that receives designation under subsection (a) shall within 90 days of such designation, submit to the Secretary a plan for appropriate use of diagnostics, in order for the Secretary and Committee to consider such plan in developing clinical guidelines. An appropriate use plan—

''(A) shall include—

''(i) the appropriate use of the drug; and

''(ii) the appropriate use of diagnostic tools, where available, such as diagnostic testing for biomarkers related to antimicrobial-resistant pathogens, or other tar-

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

"(B) may be developed in partnership with the Secretary, infectious disease experts, diagnostic experts or developers, laboratory experts, or another entity.

"(2) CONSULTATION.—The Secretary shall consult with relevant professional societies and the Critical Need Antimicrobial Advisory Group established under section 399OO(g) to ensure that clinical guidelines issued by the Secretary under paragraph (3), with respect to an antimicrobial drug designated under subsection (a), includes the use of appropriate diagnostic approaches, taking into consideration the diagnostic plan submitted by a sponsor under paragraph (1).

"(3) PUBLICATION OF CLINICAL GUIDELINES.—Not later than 1 year after the Secretary makes the first designation under subsection (a), and not less than every 3 years thereafter, the Secretary shall publish clinical guidelines in consultation with relevant professional societies with respect to each antimicrobial drug that has been approved or licensed as described in subsection (a)(1) and that has been designated under subsection (a), which guidelines shall

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

**"SEC. 399QQ. SUBSCRIPTION CONTRACTS.**

"(a) APPLICATION FOR A SUBSCRIPTION CONTRACT.—

"(1) SUBMISSION OF APPLICATIONS.—After approval under section 505(c) of the Federal Food, Drug, and Cosmetic Act or licensure under section 351(a), the sponsor of an antimicrobial drug designated as a critical need antimicrobial under section 399PP may submit an application for a subscription contract with the Secretary, under a procedure established by the Secretary.

"(2) REVIEW OF APPLICATIONS.—The Secretary shall, in consultation with the Committee—

"(A) review all applications for subscription contracts under paragraph (1) and assess all required application components;

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

drug that meets none of such characteristics; and

''(C) assign a monetary value to the contract based on the regulations developed under section 399OO(d).

''(b) CRITERIA.—To qualify for a subscription contract under this section, the sponsor of an antimicrobial drug designated as a critical need antimicrobial shall agree to—

''(1) ensure commercial and Federal availability of the antimicrobial drug within 30 days of receiving first payment under the contract, and sufficient supply for susceptibility device manufacturers;

''(2) identify, track, and publicly report drug resistance data and trends using available data related to the antimicrobial drug;

''(3) develop and implement education and communications strategies, including communications for individuals with limited English proficiency and individuals with disabilities, for health care professionals and patients about appropriate use of the antimicrobial drug;

''(4) submit an appropriate use assessment to the Secretary, Committee, Food and Drug Administration, and Centers for Disease Control and Pre-

vention every 2 years regarding use of the antimicrobial drug, including how the drug is being marketed;

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

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

''(7) complete any postmarketing studies required by the Food and Drug Administration in a timely manner;

''(8) produce the drug at a reasonable volume determined with the Secretary to ensure patient access to the drug;

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

''(10) abide by the manufacturing and environmental best practices in the supply chain to ensure that there is no discharge into, or contamination of, the environment by antimicrobial agents or products as a result of the manufacturing process; and

''(11) abide by other terms as the Secretary may require.

''(c) AMOUNT AND TERMS OF CONTRACTS.—

''(1) AMOUNTS.—A subscription contract under this section shall be for the sale to the Secretary of any quantity of the antimicrobial drug needed over the term of the contract under paragraph (2), at an agreed upon price, for a total projected amount determined by the Secretary that is not less than $750,000,000 and not more than $3,000,000,000, adjusted for inflation, accounting for the favored characteristics of the drug, as determined by the Secretary, in consultation with the Committee, under subsection (a)(2), and shall be allocated from the amount made available under section 399SS(a). Not later than 6 months after the subscription contract is granted under subsection (a), the Secretary shall provide payments for purchased drugs in installments established by the Secretary in consultation with the sponsor of the antimicrobial drug and in accordance with subsection (d)(3). Funds received by the sponsor shall be used to support criteria qualification under subsection (b), the completion of post-marketing clinical studies, manufacturing, other pre-clinical and clinical activities, or other activities agreed to by the Secretary and sponsor in the contract.

''(2) TERMS.—

"(A) INITIAL TERM.—The initial term of a contract under this subsection shall be no less than 5 years or greater than the greater of 10 years or the remaining period of time during which the sponsor has patent protections or a remaining exclusivity period with respect to the antimicrobial drug in the United States, as listed in the publication of the Food and Drug Administration entitled 'Approved Drug Products with Therapeutic Equivalence Evaluations'. Payments may be in equal annual installments with the option to redeem 50 percent of the last year's reimbursement in year 1 of the contract in order to offset costs of establishing manufacturing capacity, or another subscription arrangement to which the Secretary and sponsor agree. Subscription contracts shall remain in effect for such period even if the infection treated by such antimicrobial drug is later removed from the list of infections under section 399OO(c)(1).

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

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

''(C) MODIFICATION OF CONTRACTS.—The Secretary or sponsor, 1 year after the start of the contract period under this subsection and every 2 years thereafter, may request a modification of the amount of the contract based on information that adjusts favored characteristics in section 399OO(c)(2).

''(3) ADJUSTMENT.—In the case of an antimicrobial drug that received a transitional subscription contract under section 399OO(f), the amount of a subscription contract for such drug under this section shall be reduced by the amount of the transitional subscription contract under such section 399OO(f) for such drug.

''(4) CONTRACTS FOR GENERIC AND BIOSIMILAR VERSIONS.—Notwithstanding any other provision in this part, the Secretary may award a subscription contract under this section to a manufacturer of a generic or biosimilar version of an antimicrobial drug for which a subscription contract has been awarded under this section. Such contracts shall be awarded in accordance with a procedure, including for determining the terms and amounts of such contracts, established by the Secretary.

''(d) ANNUAL ANTIMICROBIAL DRUG SPONSOR REVENUE LIMITATIONS.—

''(1) REPORTING REQUIREMENT.—

''(A) IN GENERAL.—Not later than a date determined appropriate by the Secretary following the end of each calendar year, and not earlier than 6 months after the end of each calendar year, the head (or a designee of such head) of each Federal agency carrying out a specified government program shall, in accordance with this paragraph, report to the Subscription Contract Office established under section 399OO(d)(3) the total prescription drug sales for each applicable antimicrobial drug

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

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

''(i) the per-unit ingredient cost, as reported to the Secretary by prescription drug plans and Medicare Advantage prescription drug plans, minus any per-unit rebate, discount, or other price concession provided by the sponsor of such applicable antimicrobial drug, as reported to the Secretary by the prescription drug plans and the Medicare Advantage prescription drug plans; and

''(ii) the number of units of such applicable antimicrobial drug paid for under such part D.

''(C) MEDICARE PART B PROGRAM.—

''(i) IN GENERAL.—For purposes of subparagraph (A), the Secretary shall report, for each applicable antimicrobial drug

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

"(I) the per-unit average sales price (as defined in section 1847A(c) of such Act) or the per-unit payment rate under such part B for a separately paid prescription drug without a reported average sales price; and

"(II) the number of units of such applicable antimicrobial drug paid for under such part B.

"(ii) UNITS AND ALLOCATED PRICES.—The Secretary shall establish a process for determining the units and the allocated price for purposes of this subparagraph for those applicable antimicrobial drugs that are not separately payable or for which National Drug Codes are not reported.

"(D) MEDICARE PART A PROGRAM.—

"(i) IN GENERAL.—For purposes of subparagraph (A), the Secretary shall report, for each applicable antimicrobial drug covered under part A of title XVIII of the Social Security Act, the product of—

"(I) the per-unit price under such part A for the antimicrobial drug; and

"(II) the number of units of such antimicrobial drug paid for under such part A.

"(ii) SPECIAL RULE.—For purposes of clause (i), the Secretary shall establish a process for determining the units and the allocated price for those prescription drugs that are not separately payable or for which National Drug Codes are not reported in the diagnosis-related groups.

"(E) MEDICAID PROGRAM.—Under the authority of section 1902(a)(6) of the Social Security Act, the Secretary shall require each State that makes medical assistance available under the State plan under title XIX of such Act (or any waiver of such plan) for an applicable antimicrobial drug (including, if applicable, any such drug which is a covered outpatient drug under a rebate agreement entered into under section 1927 of such Act) to report, in a form consistent with a standard reporting format es-

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

"(i) information on the total number of units of each dosage form and strength and package size of each applicable antimicrobial drug dispensed during the preceding calendar year under such State plan or waiver (including any such drugs dispensed to an individual enrolled with a medicaid managed care organization or other specified entity (as such terms are defined in section 1903(m) of such Act)); and

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

"(I) the product of—

"(aa) the total number of units dispensed under the State plan or waiver during the preceding calendar year (as determined under clause (i)); and

"(bb) the per-unit ingredient cost paid by the State for each such unit; minus

"(II) any discounts or other price concessions provided and rebates paid to the State with respect to the dosage form and strength and package size of such drug and such calendar year (including rebates paid under a rebate agreement under section 1927 of such Act and any State supplemental rebates paid under a supplemental rebate agreement).

"(F) DEPARTMENT OF VETERANS AFFAIRS.—For purposes of subparagraph (A), the Secretary of Veterans Affairs shall report the total amount paid for each applicable antimicrobial drug procured by the Veterans Health Administration for individuals who receive health care from the Administration.

"(G) DEPARTMENT OF DEFENSE AND TRICARE PROGRAM.—For purposes of subparagraph (A), the Secretary of Defense shall report the sum of—

"(i) the total amount paid for each applicable antimicrobial drug procured by the Department of Defense for individuals

who receive health care from the Department; and

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

''(I) the per-unit ingredient cost, minus any per-unit rebate paid by the sponsor of the applicable antimicrobial drug; and

''(II) the number of units of such applicable antimicrobial drug dispensed under such program.

''(H) DEPARTMENT OF HOMELAND SECURITY.—For purposes of subparagraph (A), the Secretary of Homeland Security shall report the total amount paid for each applicable antimicrobial drug procured by the Department of Homeland Security for individuals who receive health care through a program carried out by the Department.

''(I) BUREAU OF PRISONS.—For purposes of subparagraph (A), the Director of the Bureau of Prisons shall report the total amount

paid for each applicable antimicrobial drug procured by the Bureau of Prisons for individuals who receive health care through the Bureau.

''(J) INDIAN HEALTH SERVICE.—For purposes of subparagraph (A), the Secretary, acting through the Indian Health Service, shall report the total amount paid for each applicable antimicrobial drug procured by the Service for individuals who receive health care through the Service.

''(2) REGULATIONS.—Not later than 1 year after the date of enactment of this part, the Secretary, in consultation with the heads of Federal agencies carrying out specified government programs, shall issue regulations to assist such heads (or their designees) in carrying out the requirements under this section.

''(3) SUBSCRIPTION CONTRACT ADJUSTMENT.—Pursuant to the contract entered into under this section with respect to an applicable antimicrobial drug, for each year of the term of such contract, the Secretary shall, not earlier than 6 months after the end of each calendar year, subtract from the payment installments determined for such contract under subsection (c)(1) for such year the revenue of the spon-

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

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

''(A) APPLICABLE ANTIMICROBIAL DRUG.—The term 'applicable antimicrobial drug' means an antimicrobial drug for which the sponsor of such drug receives a subscription contract under subsection (a).

''(B) SPECIFIED GOVERNMENT PROGRAM.—The term 'specified government program' means—

''(i) the Medicare part D program under part D of title XVIII of the Social Security Act;

''(ii) the Medicare Part B program under part B of such title XVIII;

''(iii) the Medicare Part A program under part A of such title XVIII;

''(iv) the Medicaid program established under title XIX of the Social Security Act and includes, with respect to a State, any waiver in effect with respect to such program;

"(v) any program under which prescription drugs are procured by the Department of Veterans Affairs;

"(vi) any program under which prescription drugs are procured by the Department of Defense;

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

"(viii) any program under which prescription drugs are procured by the Department of Homeland Security;

"(ix) any program under which prescription drugs are procured by the Bureau of Prisons; or

"(x) any program under which prescription drugs are procured by the Indian Health Service.

"(e) FAILURE TO ADHERE TO TERMS.—The Secretary shall cease any payment installments under a contract under this section if—

"(1) the sponsor—

"(A) permanently withdraws the antimicrobial drug from the market in the United States;

"(B) fails to meet criteria under subsection (b); or

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

"(2) the annual international and private insurance market revenues with respect to an antimicrobial drug (not counting any subscription revenues from any source pursuant to a contract under this section or other international or private entities) exceed 5 times the average annual amount of the subscription contract paid by the Secretary as certified by the sponsor annually; or

"(3) if the total revenue of the sponsor from specified government programs, as defined in subsection (d)(4), for a year exceeds the amount of the subscription contract paid by the Secretary for that year.

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

**"SEC. 399RR. ENCOURAGING APPROPRIATE USE OF ANTIBIOTICS AND COMBATING RESISTANCE.**

"(a) ESTABLISHMENT OF HOSPITAL GRANT PROGRAM.—

"(1) IN GENERAL.—Not later than 1 year after the date of enactment of this part, the Secretary and the Director of the Centers for Disease Control and Prevention shall coordinate with the Administrator of the Health Resources and Services Administration, the Administrator of the Centers for Medicare & Medicaid Services, the National Coordinator for Health Information Technology, and other relevant agencies, to establish a grant program under the Centers for Disease Control and Prevention to support hospital and other inpatient facility efforts—

"(A) to judiciously use antimicrobial drugs, such as by establishing or implementing appropriate use programs, including infectious disease telehealth programs, using appropriate diagnostic tools, partnering with academic hospitals, increasing health care-associated infection reporting, and monitoring antimicrobial resistance; and

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

tions Program Healthcare-Associated Infections Community Interface activity of the Centers for Disease Control and Prevention or a similar reporting program, as specified by the Secretary, relating to antimicrobial drugs.

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

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

''(b) SURVEILLANCE AND REPORTING OF ANTIBIOTIC USE AND RESISTANCE.—

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

"(A) appropriate conditions, outcomes, and measures causally related to antibacterial resistance, including types of infections, the causes for infections, and whether infections are acquired in a community or hospital setting, increased lengths of hospital stay, increased costs, and rates of mortality; and

"(B) changes in bacterial resistance to antimicrobial drugs in relation to patient outcomes, including changes in percent resistance, prevalence of antibiotic-resistant infections, and other such changes.

"(2) ANTIBIOTIC USE DATA.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall work with Federal agencies (including the Department of Veterans Affairs, the Department of Defense, the Department of Homeland Security, the Bureau of Prisons, the Indian Health Service, and the Centers for Medicare & Medicaid Services), private vendors, health care organizations, pharmacy benefit managers, and other entities as appropriate to obtain reliable and comparable human antibiotic drug consumption data (including, as available and appropriate, volume antibiotic distribution data and antibiotic use data, in-

cluding prescription data) by State or metropolitan areas.

''(3) ANTIBIOTIC RESISTANCE TREND DATA.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall intensify and expand efforts to collect antibiotic resistance data and encourage adoption of the Antibiotic Use and Resistance Module within the National Healthcare Safety Network among all health care facilities across the continuum of care, including, as appropriate, acute care hospitals, dialysis facilities, nursing homes, ambulatory surgical centers, and other ambulatory health care settings in which antimicrobial drugs are routinely prescribed. The Secretary shall seek to collect such data from electronic medication administration reports and laboratory systems to produce the reports described in paragraph (4).

''(4) PUBLIC AVAILABILITY OF DATA.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall, for the purposes of improving the monitoring of important trends in patient outcomes in relation to antibacterial resistance—

''(A) make the data derived from surveillance under this subsection publicly available through reports issued on a regular basis that is not less than annually; and

''(B) examine opportunities to make such data available in near real time.

**''SEC. 399SS. APPROPRIATIONS.**

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

''(b) EMERGENCY DESIGNATION.—

''(1) IN GENERAL.—The amounts provided by this section are designated as an emergency requirement pursuant to section 4(g) of the Statutory Pay-As-You-Go Act of 2010.

''(2) DESIGNATION IN SENATE.—In the Senate, this section is designated as an emergency requirement pursuant to section 4112(a) of H. Con. Res. 71 (115th Congress), the concurrent resolution on the budget for fiscal year 2018.

**''SEC. 399TT. STUDIES AND REPORTS.**

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

of the United States shall complete a study on the effectiveness of this part in developing priority antimicrobial drugs. Such study shall examine the indications for, usage of, development of resistance with respect to, and private and societal value of critical need antimicrobial drugs, and the impact of the programs under this part on patients and markets of critical need antimicrobial drugs. The Comptroller General shall report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on the findings of such study.

''(b) ANTIBIOTIC USE IN THE UNITED STATES; ANNUAL REPORTS.—The Director of the Centers for Disease Control and Prevention shall, each year, update the report entitled 'Antibiotic Use in the United States' to include updated information on progress and opportunities with respect to data, programs, and resources for prescribers to promote appropriate use of antimicrobial drugs.

''(c) REPORT ON ANTIMICROBIAL PROPHYLACTICS.—Not later than 3 years after the date of enactment of this part, the Director of the Centers for Disease Control and Prevention shall publish a report on antimicrobial prophylactics.

**''SEC. 399UU. DEFINITIONS.**

''In this part—

''(1) the term 'antimicrobial drug'—

''(A) means, subject to subparagraph (B), a product that is—

''(i) a drug that directly inhibits replication of or kills bacteria or fungi relevant to the proposed indication at concentrations likely to be attainable in humans to achieve the intended therapeutic effect; or

''(ii) a biological product that acts directly on bacteria or fungi or on the substances produced by such bacteria or fungi; and

''(B) does not include—

''(i) a drug that achieves the effect described by subparagraph (A)(i) only at a concentration that cannot reasonably be studied in humans because of its anticipated toxicity; or

''(ii) a vaccine; and

''(2) the term 'Committee' means the Committee on Critical Need Antimicrobials established under section 399OO.''.

# TITLE II—PATIENTS AND CAREGIVERS

## SEC. 201. EDUCATIONAL PROGRAMS AND TRAINING FOR CAREGIVERS.

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

### "SEC. 760A. EDUCATIONAL PROGRAMS AND TRAINING FOR CAREGIVERS.

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

''(1) to augment a care team; and

''(2) to complement, not compete with, a clinical visit.

''(b) TYPES OF PROGRAMS AND TRAINING.—Educational programs and training funded under subsection (a) may include—

''(1) specialized training in medication adherence and injections;

''(2) complementary strategies to ensure adherence to physical and occupational therapy regimens; and

''(3) nutritional compliance; and

''(4) other services provided in the home.

''(c) DEFINITION.—In this section, the term 'caregiver' means an individual who takes care of an aging, seriously ill, or disabled family member or friend.

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

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

Not later than one year after the date of the enactment of this Act, the Secretary of Health and Human Services, acting through the Administrator of the Centers for Medicare & Medicaid Services, shall issue a request for information to solicit recommendations on ways the Centers for Medicare & Medicaid Services can work with Federal health care program (as defined in section 1128B(f) of the Social Security Act (42 U.S.C. 1320a–7b)) stakeholders to promote increased patient health literacy, including recommendations for—

(1) identifying culturally competent, evidence-based interventions that have been proven to improve health literacy in populations served by such programs;

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

gram under title XVIII of the Social Security Act, Medicaid State plans under title XIX of such Act, or health care providers participating in such program or plans and that—

(A) have been proven to, or show promise to, reduce costs to individuals enrolled under such program or receiving medical assistance under such plans, respectively, and reduce expenditures under such respective title; or

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

(3) how the Centers for Medicare & Medicaid Services can encourage the use of evidence-based health literacy interventions through payment policies under the Medicare program under title XVIII of the Social Security Act or Medicaid program under title XIX of such Act; and

(4) improving patient health literacy with respect to health insurance, including an understanding of in-network providers, deductibles, co-insurance, co-payments, and differences between payors.

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

(a) UPDATED REPORTING ON INCLUSION OF DEMOGRAPHIC SUBGROUPS.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall—

(1) not later than 90 days after the date of enactment of this Act, submit to the Food and Drug Administration, and provide to the Congress, an updated version of the report under section 907(a) of the Food and Drug Administration Safety and Innovation Act (Public Law 115–52); and

(2) not later than 1 year after the publication of the updated report pursuant to paragraph (1), publish on the website of the Food and Drug Administration, and provide to the Congress, an updated version of the action plan under section 907(b) of such Act.

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

(1) complete a study—

(A) to review how the Department of Health and Human Services addresses barriers to participation by individuals from underrepresented populations in conducting or supporting clinical trials; and

(B) to formulate recommendations for addressing such barriers; and

(2) submit a report to the Congress on the results of such study.

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

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

(A) upcoming and ongoing clinical trials;

(B) how to enroll as subjects in such clinical trials; and

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

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

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

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

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

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

(A) the National Institutes of Health;

(B) the Food and Drug Administration;

(C) academic researchers; and

(D) patient organizations.

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

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

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

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

(2) by inserting after subsection (a) the following new subsection:

''(b) COLLECTION, SUBMISSION, AND USE OF DATA.—

''(1) IN GENERAL.—The Secretary shall—

''(A) for any drug for which an exemption is granted for investigational use under section

505(i) of this Act or section 351(a) of the Public Health Service Act, require the sponsor of the drug to collect standardized patient experience data as part of the clinical trials conducted pursuant to such exemption;

"(B) require any application for the approval or licensing of such drug under section 505(b) of this Act or section 351(a) of the Public Health Service Act to include—

"(i) the standardized patient experience data so collected; and

"(ii) such related information as the Secretary may require; and

"(C) consider patient experience data and related information that is submitted pursuant to subparagraph (B) in deciding whether to approve or license, as applicable, the drug involved.

"(2) APPLICABILITY.—Paragraph (1) applies only with respect to drugs for which a request for an exemption described in paragraph (1)(A) is submitted on or after the date of enactment of the Cures 2.0 Act, or an application under section 505(b) of this Act or section 351(a) of the Public Health Service Act is filed, as applicable, on or after

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

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

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

(a) REVISION TO DEFINITION OF APPROVED CLINICAL TRIAL IN INDIVIDUAL AND GROUP MARKET.—

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

''(D) The study or investigation is approved or funded (which may include funding through in-kind contributions) by the Patient Centered Outcomes Research Institute established under section 1181 of the Social Security Act.''.

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

(b) MEDICARE COVERAGE OF ROUTINE COSTS ASSOCIATED WITH CERTAIN CLINICAL TRIALS.—

(1) IN GENERAL.—Section 1862(m)(2) of the Social Security Act (42 U.S.C.1395y(m)(2)) is amended, in the matter preceding subparagraph (A), by inserting ''(including a trial funded by the Patient Centered Outcomes Research Institute established under section 1181)'' after ''means a trial''.

(2) EFFECTIVE DATE.—The amendment made by this paragraph shall apply with respect to items and services furnished on or after the date of the enactment of this Act.

# TITLE III—FOOD AND DRUG ADMINISTRATION

## SEC. 301. REPORT ON COLLABORATION AND ALIGNMENT IN REGULATING DIGITAL HEALTH TECHNOLOGIES.

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

the centers and offices of the Food and Drug Administration with respect to the regulation of digital health technologies.

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

(1) How the Commissioner of Food and Drugs and the heads of the centers and offices of the Food and Drug Administration collaborate in regulating digital health technologies, including recommendations with respect to—

(A) the use of digital endpoints for regulatory review, including the validation and qualification of digital endpoints and digital biomarkers;

(B) the acceptance of decentralized trials;

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

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

(2) How the Food and Drug Administration coordinates with foreign regulators to ensure harmonization on the regulation and use of digital health technologies.

(c) DEFINITION.—In this section, the term ''digital health technologies'' includes those technologies in health

care or society that help deliver or provide access to health care products and services such as hardware (for example, wearable sensors, virtual reality headsets, and digitally-enabled drug delivery devices), advanced analytics (for example, artificial intelligence, machine learning, and sophisticated computation), cloud services (for example, storage, computing, and data processing), and software (for example, mobile medical applications, and software as a medical device).

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

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

(1) incorporating complex adaptive and other novel trial designs into clinical protocols and applications for drugs pursuant to an exemption for investigational use under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)); and

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

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

(c) DEFINITIONS.—In this section:

(1) The term ''digital health technologies'' has the meaning given to such term in section 301.

(2) The term ''patient experience data'' has the meaning given to such term by section 569C(d) of the Federal Food, Drug, and Cosmetic Act, as redesignated by section 204 of this Act.

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

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

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

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

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

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

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

(4) The current state of cell and gene therapies regulation by the Food and Drug Administration, including—

(A) the amount and nature of the submissions filed with the Food and Drug Administration;

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

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

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

(a) GUIDANCE.—

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

use of real world evidence in evaluating the safety and effectiveness of drugs subsequent to the approval or licensing of such drugs pursuant to subsection (a), (b), or (c) of section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) as a breakthrough therapy, a fast track product, or a product considered for accelerated approval.

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

(A) Special and underrepresented populations.

(B) Acceptable endpoints and outcomes measures.

(C) Data quality standards.

(D) Data transparency requirements.

(E) Study design considerations.

(b) HHS IDENTIFICATION AND IMPLEMENTATION OF APPROACHES.—

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

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

(i) in conducting and supporting research; and

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

(B) include in such approaches recommendations for any additional statutory authorities needed;

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

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

(2) IMPLEMENTATION.—Upon publication under paragraph (1) of the approaches identified pursuant to such paragraph, consistent with the authorities vested in the Department of Health and Human Services by other provisions of law, the Secretary take such actions as may be appropriate to implement the approaches identified pursuant to paragraph (1).

(c) REAL WORLD EVIDENCE TASK FORCE.—

(1) ESTABLISHMENT.—The Secretary shall establish a permanent task force, to be known as the Real World Evidence Task Force (in this subsection referred to as the ''Task Force'') to coordinate the programs and activities of the Department of Health and Human Services with regard to the collection and use of real world evidence.

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

(A) The Secretary (or the Secretary's designee), who shall serve as the Chair of the Task Force.

(B) The Administrator of the Centers for Medicare & Medicaid Services (or the Administrator's designee).

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

(D) The Director of the National Institutes of Health (or the Director's designee).

(E) Such additional Federal officials (or their designees) as the Secretary determines appropriate.

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

(3) RECOMMENDATIONS.—In carrying paragraph (1), the Task Force shall—

(A) develop and periodically update recommendations on ways to encourage patients to—

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

(ii) participate in postapproval clinical trials for the collection of real world evidence; and

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

**SEC. 305. IMPROVING FDA-CMS COMMUNICATION REGARDING TRANSFORMATIVE NEW THERAPIES.**

Upon the designation of a product as a breakthrough therapy, a fast track product, or a product eligible for accelerated approval under subsection (a), (b), or (c), respectively, of section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356), the Commissioner of Food and Drugs and the Administrator of the Centers for Medicare & Medicaid Services shall—

(1) maintain communication with each other regarding approval and coverage decisions with respect to such product; and

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

**SEC. 306. ESTABLISHMENT OF ADDITIONAL INTERCENTER INSTITUTES AT THE FOOD AND DRUG ADMINISTRATION.**

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

''(c) TIMING.—Not later than the date that is one year after the date of enactment of the Cures 2.0 Act or the end of the coronavirus disease 2019 (COVID–19) pandemic public health emergency under section 319 of the Public Health Service Act, whichever is later, the Secretary shall establish, in accordance with this section, at least two additional Institutes under subsection (a).''.

(b) CRITERIA.—In establishing the focus of the two Institutes referenced in the amendment made by subsection (a), the Secretary of Health and Human Services shall ensure the following:

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

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

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

(C) Represents a leading cause of mortality or disability in the United States.

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

(E) Contributes to increasing health care (personal, familial, private sector, and governmental) expenditures and impacts the United States economy as a whole.

(F) For which the SARS–CoV–2 virus exacerbates symptoms or causes serious complications.

(G) For which medical products are approved by the Food and Drug Administration at a much lower rate than products for other disease areas, including in abbreviated pathways.

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

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

(B) Over 90 percent of such diseases have no therapy approved by the Food and Drug Administration.

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

(D) Over 50 percent of patients are children.

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

**SEC. 307. IND APPLICATION NOT NEEDED TO INITIATE ACCELERATED APPROVAL.**

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

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

(b) REGENERATIVE ADVANCED THERAPIES.—Section 506(g)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(g)(3)) is amended by striking ''concurrently with, or at any time after, submission of an application for the investigation of the drug under section 505(i) of this Act or section 351(a)(3) of the Public Health Service Act'' and inserting ''at any point before or after submission of an application for approval of the drug under section 505(b) of this Act or licensure of the drug under section 351(a)(2) of the Public Health Service Act and shall include clinical evidence, including preliminary clinical evidence from clinical trials conducted outside of the United States''.

**SEC. 308. GUIDANCE REGARDING DEVELOPMENT AND SUBMISSION OF CHEMISTRY, MANUFACTURING, AND CONTROLS INFORMATION FOR EXPEDITED APPROVAL.**

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

(1) not later than 6 months after the date of enactment of this Act, issue draft revised guidance to provide clarity regarding the development and submission of chemistry, manufacturing, and controls information for purposes of subsections (a), (b), (c), and (g) of section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356; relating to breakthrough therapies, fast track products, accelerated approval, and regenerative advanced therapies); and

(2) not later than 90 days after the close of a period of public comment on such draft guidance, finalize the guidance.

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

(1) how the Food and Drug Administration will determine how, and by when, chemistry, manufacturing, and controls information is required to be submitted throughout development and during the

pre- and post-approval phases, taking into consideration—

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

(B) the phase and expedited nature of development; and

(C) the availability of relevant data and information from nonclinical and clinical studies, product applications, and post-approval oversight; and

(2) how the Food and Drug Administration will provide ongoing advice and opportunities for sponsors to interact with the Food and Drug Administration on, and how the Food and Drug Administration will facilitate, the submission of chemistry, manufacturing, and controls information throughout the life cycle of the product.

**SEC. 309. POST-APPROVAL STUDY REQUIREMENTS FOR ACCELERATED APPROVAL.**

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

dence, patient registries, or other sources of real world evidence,''.

# TITLE IV—CENTERS FOR MEDICARE & MEDICAID SERVICES

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

Not later than one year after the date of the enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on recommendations for administrative actions that may be taken by the Secretary of Health and Human Services (as well as recommendations for legislative changes needed) to—

(1) enhance coverage and reimbursement approaches under the Medicare program under title XVIII of the Social Security Act for innovative technologies that increase access to health care, improve health care quality, decrease expenditures under such program, or otherwise improve the Medicare program or health care for beneficiaries under such program; and

(2) better harmonize and integrate the operating structure of the Medicare program (and the Centers for Medicare & Medicaid Services) to improve interagency collaboration and communication.

**SEC. 402. STRATEGIES TO INCREASE ACCESS TO TELEHEALTH UNDER MEDICAID AND CHILDREN'S HEALTH INSURANCE PROGRAM.**

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

(1) existing strategies States can use to integrate telehealth and other virtual health care services into value-based health care models; and

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

(b) STUDIES.—

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

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

(A) evaluate cost, access, utilization, outcomes, and patient experience data from across the health care field, including States, Medicaid managed care organizations, provider organizations, and other organizations that provide or pay for telehealth under the Medicaid program and Children's Health Insurance Program;

(B) identify barriers and potential solutions to provider entry and participation in telehealth that States are experiencing, as well as barriers to providing telehealth across State lines, including during times of public health crisis or public health emergency;

(C) determine the frequency at which out-of-State telehealth is provided to patients enrolled in the Medicaid program and the potential impact on access to telehealth if State Medicaid policies were more aligned; and

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

(2) FEDERAL AGENCY TELEHEALTH COLLABORATION.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General of the United States shall conduct a study and submit to Congress a report evaluating collaboration between Federal agencies with respect to telehealth services furnished under the Medicaid or CHIP program to individuals under the age of 18, including such services furnished to such individuals in early care and education settings. Such report shall include recommendations on—

(A) opportunities for Federal agencies to improve collaboration with respect to such telehealth services; and

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

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

**SEC. 403. EXTENDING MEDICARE TELEHEALTH FLEXIBILITIES.**

(a) EXPANDING ACCESS TO TELEHEALTH SERVICES.—

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

"(iii) EXPANDING ACCESS TO TELEHEALTH SERVICES.—With respect to telehealth services furnished beginning on the first day after the end of the emergency period described in section 1135(g)(1)(B) of this clause, the term 'originating site' means any site at which the eligible telehealth individual is located at the time the service is furnished via a telecommunications system, including the home of an individual.".

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

(A) in paragraph (2)(B)—

(i) in clause (i), in the matter preceding subclause (I), by striking ''clause (ii)'' and inserting ''clauses (ii) and (iii)''; and

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

''(iii) NO FACILITY FEE FOR NEW SITES.—With respect to telehealth services furnished on or after the date of enactment of this clause, a facility fee shall only be paid under this subparagraph to an originating site that is described in paragraph (4)(C)(ii) (other than subclause (X) of such paragraph).'';

(B) in paragraph (4)(C)—

(i) in clause (i), in the matter preceding subclause (I), by inserting ''and clause (iii)'' after ''and (7)''; and

(ii) in clause (ii)(X), by inserting ''prior to the first day after the end of the emergency period described in section 1135(g)(1)(B)'' before the period;

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

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

(D) in paragraph (6)(A), by inserting ''and prior to the first day after the end of the emergency period described in section 1135(g)(1)(B),'' after ''January 1, 2019,''; and

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

''(C) SUNSET.—The provisions of this paragraph shall not apply with respect to services furnished on or after the first day after the end of the emergency period described in section 1135(g)(1)(B).''.

(b) EXPANDING PRACTITIONERS ELIGIBLE TO FURNISH TELEHEALTH SERVICES.—Section 1834(m) of the Social Security Act (42 U.S.C. 1395m(m)) is amended—

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

(2) in paragraph (4)(E)—

(A) by striking ''PRACTITIONER.—The term'' and inserting ''PRACTITIONER.—

''(A) IN GENERAL.—Subject to subparagraph (B), the term''; and

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

''(B) EXPANSION.—The Secretary, after consulting with stakeholders regarding services that are clinically appropriate, may expand the types of practitioners who may furnish telehealth services to include any health care professional that is eligible to bill the program under this title for their professional services.''.

(c) RETENTION OF ADDITIONAL SERVICES AND SUBREGULATORY PROCESS FOR MODIFICATIONS FOLLOWING EMERGENCY PERIOD.—Section 1834(m)(4)(F) of the Social Security Act (42 U.S.C. 1395m(m)(4)(F)) is amended—

(1) in clause (i), by inserting ''and clause (iii)'' after ''paragraph (8)'';

(2) in clause (ii), by striking ''The Secretary'' and inserting ''Subject to clause (iii), the Secretary''; and

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

''(iii) RETENTION OF ADDITIONAL SERVICES AND SUBREGULATORY PROCESS FOR MODIFICATIONS FOLLOWING EMERGENCY PERIOD.—With respect to tele-

health services furnished after the last day of the emergency period described in section 1135(g)(1)(B), the Secretary may—

''(I) retain as appropriate the expanded list of telehealth services specified in clause (i) pursuant to the waiver authority under section 1135(b)(8) during such emergency period; and

''(II) retain the subregulatory process used to modify the services included on the list of such telehealth services pursuant to clause (ii) during such emergency period.''.

(d) ENHANCING TELEHEALTH SERVICES FOR FEDERALLY QUALIFIED HEALTH CENTERS AND RURAL HEALTH CLINICS.—Section 1834(m)(8) of the Social Security Act (42 U.S.C. 1395m(m)(8)) is amended—

(1) in the paragraph heading by inserting ''AND AFTER'' after ''DURING'';

(2) in subparagraph (A), in the matter preceding clause (i), by inserting ''and after'' after ''During''; and

(3) in the first sentence of subparagraph (B)(i), by inserting ''and after'' after ''during''.

(e) USE OF TELEHEALTH, AS CLINICALLY APPROPRIATE, TO CONDUCT FACE-TO-FACE ENCOUNTER FOR HOSPICE CARE.—Section 1814(a)(7)(D)(i)(II) of the Social Security Act (42 U.S.C. 1395f(a)(7)(D)(i)(II)) is amended by inserting ''and after such emergency period as clinically appropriate'' after ''1135(g)(1)(B)''.

(f) USE OF TELEHEALTH, AS CLINICALLY APPROPRIATE, TO CONDUCT FACE-TO-FACE CLINICAL ASSESSMENTS FOR HOME DIALYSIS.—Clause (iii) of section 1881(b)(3)(B) of the Social Security Act (42 U.S.C. 1395rr(b)(3)(B)) is amended—

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

(2) by inserting ''and after such emergency period as clinically appropriate'' before the period.

(g) IMPLEMENTATION.—Notwithstanding any provision of law, the Secretary may implement the provisions of, and amendments made by, this section by interim final rule, program instruction, or otherwise.

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

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

**"SEC. 1899C. COVERAGE OF BREAKTHROUGH DEVICES.**

"(a) BREAKTHROUGH DEVICES.—For purposes of this section, the term 'breakthrough device' means a medical device that is a device (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act) and that is—

"(1) provided with review priority by the Secretary under subsection (d)(5) of section 515 of such Act; and

"(2) approved or cleared pursuant to section 510(k), 513(f), or 515 of such Act for use in treating an indication on or after March 15, 2021.

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

"(b) COVERAGE.—

"(1) TRANSITIONAL COVERAGE.—

"(A) IN GENERAL.—During the transitional coverage period (as defined in subparagraph (B)) a breakthrough device shall be—

"(i) deemed to be reasonable and necessary for purposes of section 1862(a)(1)(A);

"(ii) deemed to be approved for an additional payment under section

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

"(iii) deemed to be approved for pass-through payment under section 1833(t)(6) and section 1833(i) (other than with respect to the cost criterion under section 1833(t)(6)(A)(iv)); and

"(iv) insofar as such breakthrough device may be furnished in a setting for which payment is made under an applicable payment system described in subparagraphs (D) through (I) of subsection (c)(4), deemed eligible for an additional payment or payment adjustment, as the case may be, pursuant to subsection (d)(3) when furnished in a setting for which payment is made under such an applicable payment system during such transitional coverage period.

"(B) TRANSITIONAL COVERAGE PERIOD DEFINED.—As used in this section, the term 'transitional coverage period' means, with respect to a breakthrough device, the period that—

"(i) begins on the date of the approval under section 515 of the Federal Food, Drug, and Cosmetic Act or of the clearance under section 510(k) of such Act, as applicable, of such device by the Secretary for the indication described in subsection (a)(1); and

"(ii) ends on the last day of the 4-year period that begins on the date that the Secretary, pursuant to subsection (c)(2), updates the relevant applicable payment system (as defined in subsection (c)(4)) to recognize the unique temporary or permanent code or codes assigned under subsection (c)(1) to such breakthrough device, except as provided in subsections (d)(1)(B) and (d)(2)(B).

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

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

''(2) PROCESS FOR REGULAR COVERAGE.—For purposes of the application of section 1862(a)(1)(A) to a breakthrough device furnished after the transitional coverage period (as defined in paragraph (1)(B)) for such device, the Secretary shall establish a process for the coverage of such breakthrough devices under this title after such period as follows:

''(A) IDENTIFICATION OF ADDITIONAL EVIDENCE.—

''(i) IN GENERAL.—With respect to a breakthrough device, not later than 1 year after the date of the approval of such device under section 515 of the Federal Food, Drug, and Cosmetic Act or of the clearance of such device under section 510(k) of such Act, as applicable, the Secretary shall identify whether any additional data or evidence is required with respect to any indications for such device for purposes of the application of such section 1862(a)(1)(A) to such device for such indications.

"(ii) NON-DUPLICATION OF DATA REQUESTS.—In carrying out clause (i) with respect to a breakthrough device, the Secretary shall ensure that data or evidence identified—

"(I) does not duplicate data required to be collected by the Food and Drug Administration with respect to such breakthrough device;

"(II) minimizes the administrative burdens of data collection and reporting on providers of services, suppliers, and manufacturers of breakthrough devices; and

"(III) is not otherwise unnecessary or redundant.

"(B) PROPOSAL FOR COVERAGE AFTER THE TRANSITIONAL COVERAGE PERIOD.—Not later than 2 years after the date of the approval or clearance of a breakthrough device by the Food and Drug Administration, the Secretary shall develop a proposal for coverage under this title of such breakthrough device for such indications as the Secretary determines to be appropriate, based on the data and evidence col-

lected under subparagraph (A), for such devices furnished after the transitional coverage period under paragraph (1) for such device. If the Secretary does not, on a date that is before the end of such two-year period, take action to modify the indications for which coverage of a breakthrough device may be provided under this title after such period, for purposes of section 1862(a)(1)(A) coverage under this title of such breakthrough device shall be made for all indications for which such device is approved under section 515 of the Federal Food, Drug, and Cosmetic Act or cleared under section 510(k) of such Act.

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

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

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

"(c) CODING.—

"(1) PROMPT ASSIGNMENT.—Not later than three months after the date of approval or clearance of a breakthrough device by the Food and Drug Administration, the Secretary shall assign a unique temporary or permanent code or codes for purposes of coverage and payment for such breakthrough device under the applicable payment systems (described in paragraph (4)).

"(2) UPDATES.—

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

"(B) OPPS.—The Secretary shall provide for quarterly updates under the applicable pay-

ment system described in paragraph (4)(B) (relating to the outpatient hospital prospective payment system) to recognize the code or codes assigned under paragraph (1).

''(C) OTHER PAYMENT SYSTEMS.—The Secretary shall provide for semiannual or quarterly updates, as the case may be, under the applicable payment systems described in subparagraphs (C) through (L) of paragraph (4) to recognize the code or codes assigned under paragraph (1).

''(3) TRANSPARENCY.—The process for the assignment of a code or codes under this subsection shall provide for public notice and a meaningful opportunity for public comment from affected parties.

''(4) APPLICABLE PAYMENT SYSTEMS DESCRIBED.—For purposes of this subsection, the term 'applicable payment systems' means—

''(A) with respect to inpatient hospital services, the prospective payment system for inpatient hospital services established under section 1886(d);

''(B) with respect to outpatient hospital services, the prospective payment system for

covered OPD services established under section 1833(t);

"(C) with respect to ambulatory surgical center services, the fee schedule for such services established under 1833(i);

"(D) with respect to physicians' services, the physician fee schedules established under section 1848;

"(E) with respect to covered items of durable medical equipment, the applicable fee schedules established under section 1834;

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

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

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

"(I) with respect to inpatient hospital services furnished by psychiatric hospitals and psy-

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

''(K) with respect to home health services, the prospective payment system under section 1895; and

''(L) with respect to items and services, or a provider of services or supplier, not described in subparagraphs (A) through (I), the payment system established under this title for such items and services when furnished by such provider of services or supplier.

''(d) PAYMENT.—

''(1) INPATIENT HOSPITAL PROSPECTIVE PAYMENT SYSTEM: DEEMED ELIGIBILITY FOR BREAKTHROUGH PAYMENT.—The Secretary shall deem each breakthrough device as approved for an additional payment under section 1886(d)(5)(K) for the 4-year period that begins—

''(A) except as provided in subparagraph (B), on the date that the Secretary, pursuant to subsection (c)(2)(A), updates the payment system under section 1886(d) to recognize the unique temporary or permanent code or codes assigned under subsection (c)(1) to such breakthrough device; or

''(B) in the case of a device that has not received approval or clearance as a breakthrough device by the Food and Drug Administration before such payment system is updated under subsection (c)(2)(A) to recognize the unique temporary or permanent code or codes assigned under subsection (c)(1) to such device, on the date of such approval or clearance.

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

''(2) OUTPATIENT PROSPECTIVE PAYMENT SYSTEM: DEEMED ELIGIBILITY FOR PASS-THROUGH PAYMENT.—The Secretary shall deem each breakthrough device as approved for pass-through payment under section 1833(t)(6) (including for purposes of section 1833(i)(2)(D)) during the 4-year period that begins—

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

tem under section 1833(t) to recognize the unique temporary or permanent code or codes assigned under subsection (c)(1) to such breakthrough device; or

''(B) in the case of a device that has not received approval or clearance as a breakthrough device by the Food and Drug Administration before such payment system is updated under subsection (c)(2)(B) to recognize the unique temporary or permanent code or codes assigned under subsection (c)(1) to such device, on the date of such approval or clearance.

Nothing in this paragraph shall be construed to affect the authority of the Secretary to use claims data to establish new ambulatory payment classification groups for breakthrough devices or to revise such groups to take into account breakthrough devices under annual rulemaking to carry out section 1833(t).

''(3) OTHER PAYMENT SYSTEMS.—

''(A) IN GENERAL.—In the case of breakthrough device that is furnished and for which payment may be made under the payment system established under section 1834, 1834A, 1848, 1886(j), 1886(m), 1886(s), or 1895 or

any other provision of this title (other than sections 1833(i), 1833(t), and 1886(d)), the Secretary shall provide for an additional payment for such breakthrough device under such applicable payment system or an adjustment to such applicable payment system, as the case may be. The payment basis for such additional payment or adjustment, as the case may be, shall equal an amount that the Secretary determines covers the costs of such breakthrough device.

''(B) COST INFORMATION.—In determining the costs of a breakthrough device for purposes of determining an additional payment or payment adjustment under subparagraph (A), the Secretary shall use the most recently available data and information on the costs of such breakthrough device, which may include list prices and invoice prices charged for such breakthrough device.

''(C) RULE OF CONSTRUCTION.—Nothing in this paragraph shall be construed to affect the authority of the Secretary to use claims data to establish new or modify existing ambulatory payment classification groups, diagnosis-related groups, level II HCPCS codes or such

other groups or codes as the Secretary may establish under the annual rulemaking authority under the provisions referred to in subparagraph (A).

''(D) CLINICAL DIAGNOSTIC LABORATORY TESTS.—An additional payment or payment adjustment under subparagraph (A) for a breakthrough device under the applicable payment system established in section 1834A may be in the form of an increase to the amount determined for the breakthrough device using crosswalking under section 1834A(c)(1)(A), an extension of the initial period of payment applicable to advance diagnostic laboratory tests under section 1834A(d)(1)(A), and in such other form or manner as the Secretary determines reflects the costs for such breakthrough device under the relevant provisions of section 1834A.

''(4) PAYMENT FOR BREAKTHROUGH DEVICES AFTER THE TRANSITIONAL COVERAGE PERIOD.—Payment for a breakthrough device that is furnished after the conclusion of the transitional coverage period under subsection (b)(1) for such device shall be made pursuant to the applicable payment system in-

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

''(e) SPECIAL RULES FOR CERTAIN BREAKTHROUGH DEVICES.—

''(1) COVERAGE OF SPECIFIED BREAKTHROUGH DEVICES.—

''(A) IN GENERAL.—Subject to the succeeding provisions of this subsection and notwithstanding any other provision of law, the Secretary shall provide for coverage and payment pursuant to this section of a specified breakthrough device (as defined in subparagraph (B)).

''(B) SPECIFIED BREAKTHROUGH DEVICE DEFINED.—In this section, the term 'specified breakthrough device' means a breakthrough device with respect to which no Medicare benefit category exists.

''(2) PERIOD OF TRANSITIONAL COVERAGE.—

''(A) IN GENERAL.—Subject to subparagraph (C), the provisions of subsection (b)(1) (relating to the transitional coverage period and payment for breakthrough devices, including the use of the most recently available data and information on costs) shall apply to a specified

breakthrough device in the same manner as such provisions apply to a breakthrough device. The Secretary may use methodologies under existing payment systems established under this title, may provide for appropriate adjustments to such methodologies, or may establish a new payment methodology under this title, to provide for payment for a specified breakthrough device to ensure the payment basis for such payment covers costs of the specified breakthrough device are covered by such payment.

''(B) REPORT.—

''(i) IN GENERAL.—With respect to each specified breakthrough device, the Secretary shall submit to Congress a report on the coverage of and payment for such specified breakthrough device under this section that includes the following information:

''(I) The manner in which coverage is provided and payment is made for the specified breakthrough device, including how such device was classified (such as an item of durable medical equipment or otherwise) and

the payment methodology the Secretary applied with respect to such device.

''(II) The impact of the availability of the specified breakthrough device to Medicare beneficiaries, including impacts on the quality of patient care, patient outcomes, and patient experience.

''(III) The impact of the availability of the specified breakthrough device to Medicare beneficiaries on program expenditures under this title.

''(IV) Such other information as the Secretary determines to be appropriate.

''(ii) DEADLINE.—

''(I) IN GENERAL.—Except as provided in subclause (II), the Secretary shall submit a report required under this subparagraph no later than the end of the transitional period of coverage and payment applicable to such specified breakthrough device.

"(II) EXTENSION TO GENERATE ADDITIONAL DATA.—If the Secretary determines that additional data or evidence is required to complete a report required under this subparagraph with respect to a specified breakthrough device, the deadline under this clause may be extended for an additional two years.

"(C) ADDITIONAL PERIOD OF TRANSITIONAL COVERAGE TO DEVELOP ADDITIONAL DATA.—Insofar as the Secretary determines that additional data or evidence is required to complete a report required under subparagraph (B) with respect to a specified breakthrough device, the transitional coverage period of coverage and payment for such device shall be extended by the lesser of—

"(i) two years; or

"(ii) the amount of additional time required for the submission of the report with respect to such device.

"(3) COVERAGE AND PAYMENT AFTER THE TRANSITIONAL PERIOD.—The Secretary may continue to provide for coverage of and payment for a

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

''(A) improves the quality of care and patient outcomes;

''(B) improves the delivery of care; or

''(C) reduces spending under this title without reducing the quality of care.''.

(b) CONFORMING AMENDMENTS.—

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

''(x) Effective for discharges occurring on or after October 1, 2019, in the case of a new medical service or technology that is a breakthrough device (as defined in section 1899C(a)), the additional payment established for such breakthrough device under this subparagraph shall be made for the 4-year period applicable to such breakthrough device under section 1899C(d)(1). In determining the amount of the additional payment for a break-

through device under this subparagraph during such 4-year period, the Secretary shall apply section 412.88(b) of title 42, Code of Federal Regulations, as in effect on the date of the enactment of this clause, except as if the reference in such section to '65 percent' were a reference to '65 percent (or such greater percent specified by the Secretary)'.''.

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

''(iii) SPECIAL RULE FOR BREAKTHROUGH DEVICES.—Notwithstanding clause (i) or (ii), or any other provision of this paragraph to the contrary, in the case of a breakthrough device (as defined in section 1899C(a)) that is furnished on or after January 1, 2020, payment under this paragraph for such breakthrough device shall be made for the 4-year period applicable to such breakthrough device under section 1899C(d)(2). The provisions of this clause shall also apply for purposes of

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

(c) EFFECTIVE DATE.—This section, and the amendments made by this section, shall take effect on the date of the enactment of this Act and, unless otherwise specified in this section (or in an amendment made by this section), shall apply to breakthrough devices (as defined in section 1899C(a) of the Social Security Act, as added by subsection (a)), approved or cleared on or after July 1, 2019, or, in the case of a specified breakthrough device (as defined in such section as so added), approved or cleared on or after December 1, 2018.

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

Not later than [one year after the date of the enactment of this Act,] the Secretary of Health and Human Services, in collaboration with the Administrator of the Centers for Medicare & Medicaid Services, and following a request for information, shall submit to Congress a report containing a proposal that—

(1) specifies, for purposes of payment and coverage under title XVIII of the Social Security Act, a definition for digital alternatives to treatment and

therapies, including wearables and digital applications and platforms;

(2) establishes a standardized process for determining which technologies satisfy the definition pursuant to paragraph (1);

(3) establishes a standardized process for determining coverage under such title of digital alternatives as defined pursuant to paragraph (1) that are prescribed by a physician; and

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

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

Not later than one year after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to Congress a report on the following:

(1) The current state of computer systems of the Centers for Medicare & Medicaid Services, including an analysis of the capabilities and deficiencies of such systems in helping to managing the operations of the programs administered by the Centers for Medicare & Medicaid Services.

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

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

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

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

[(a) DEMONSTRATION PROGRAM TO PROVIDE DNA SEQUENCING CLINICAL SERVICES FOR CERTAIN CHILDREN [ALTERNATIVE OPTION AS A PILOT PROGRAM].—]

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

plans) to eligible individuals for purposes of providing such individuals with DNA sequencing clinical services.**]**

**[**(2) DEMONSTRATION PROJECT PAYMENT REQUIREMENTS.—Under each demonstration project under this section conducted by a State, the following shall apply:**]**

**[**(A) The State shall provide a health care provider (as defined by the State) with payments for the provision of DNA sequencing clinical services to any eligible individual. Payments made to a health care provider for such services shall be treated as medical assistance for purposes of section 1903(a) of the Social Security Act (42 U.S.C. 1396b(a)), except that the Federal medical assistance percentage applicable to such payments shall be equal to 100 percent.**]**

**[**(B) The State shall specify the methodology the State will use for determining payment for the provision of DNA sequencing clinical services. Such methodology for determining payment shall be established consistent with section 1902(a)(30)(A) of such Act (42 U.S.C. 1396a(a)(30)(A)).**]**

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

[(A) An explanation of how and the extent to which DNA sequencing clinical services under the demonstration project of the State will provide information and data on how such services improve the diagnosing of rare diseases.]

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

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

State) to provide DNA sequencing clinical services.]

[(D) An explanation of how genetic and genomic testing may improve health outcomes for all populations in the State, including—]

[(i) individuals with a rare disease, including a metabolic disease, a hereditary cancer syndrome, and a neurologic disease with known treatments; and]

[(ii) special populations, including infants and children, critically ill (non-infectious and non-trauma) patients, transplant patients, individuals with cardiac disease, and [(v)] [*should this be a new clause?*] individuals with, or who have a family history of, a birth defect or developmental disability.]

[(4) PREFERENCES IN CONSIDERING APPLICATIONS.—In considering applications submitted under paragraph (3), the Secretary of Health and Human Services shall give preference to States that do not, as of the date of the enactment of this section, cover DNA sequencing clinical services under (or do not cover the majority of DNA sequencing clinical serv-

ices under) the State plan under title XIX of the Social Security Act (or waiver of such plan).]

[(5) TECHNICAL ASSISTANCE.—The Secretary of Health and Human Services shall provide technical assistance to assist States in planning and designing the demonstration project for purposes of applying for conducting such project under this subsection.]

[(6) REPORTS BY STATES.—Not later than four years after the date on which a State enters into an agreement under paragraph (1) with the Secretary for conducting a demonstration project, the State shall submit a report to the Administrator of the Centers for Medicare & Medicaid Services and the Administrator of the Health Resources and Services Administration on the extent to which DNA sequencing clinical services reduce health disparities.]

[(7) REPORTS BY HEALTH CARE PROVIDERS.—As a condition for receiving payment for DNA sequencing clinical services provided to an eligible individual under a demonstration project conducted by a State under this section, a health care provider shall report to the State, in accordance with such requirements as the Secretary shall specify, on all ap-

plicable measures for determining the quality and efficacy of such services.]

[(8) DEFINITIONS.—In this subsection:]

[(A) ELIGIBLE INDIVIDUAL.—The term ''eligible individual'' means, with respect to a State, an individual who—]

[(i) is eligible for medical assistance under the State plan under title XIX of the Social Security Act (or a waiver of such plan);]

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

[(iii) has been referred or admitted to an intensive care unit, or has been seen by at least one medical specialist, for a suspected genetic or undiagnosed disease; or]

[(iv) is suspected by at least one medical specialist to have a neonatal-onset or pediatric-onset genetic disease.]

**[**(B) **[**DNA SEQUENCING CLINICAL SERVICES**]****[***change to ''genetic and genomic testing services''?***]**.—The term ''DNA sequencing clinical services'', with respect to an eligible individual—**]**

**[**(i) means the determination of an **[***Is this necessary?:* exact**]** sequence of deoxyribonucleic acid bases in the genome of such individual, and, if for the sole benefit of the individual, a biological parent of such individual for the purpose of determining whether one or more potentially disease-causing genetic variants are present in the genome of such individual or such biological parent; and**]**

**[**(ii) includes—**]**

**[**(I) sequencing of the entire genome, of the exome, **[**of a panel of genes, or other regions of the genome**]**; and**]**

**[**(II) any analysis, interpretation, and data report derived from such sequencing.**]**

(b) NATIONAL ACADEMY OF MEDICINE STUDY.—

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

(A) how genetic and genomic testing may improve preventative care and precision medicine;

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

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

(D) how the Federal Government may help to reduce barriers to genetic and genomic testing, including—

(i) encouraging the expansion of health insurance coverage of genetic and genomic testing, including diagnostic, predictive, and presymptomatic testing, and DNA sequencing clinical services (as defined in subsection (a)(8)(B));

(ii) supporting the collection of evidence for the clinical utility and appro-

priate use of genetic and genomic tests; and

(iii) improving access to genetic counselors, pathologists, and other relevant professions, including strengthening related workforce education and training efforts;

(E)(i) the extent to which coverage provisions in the Medicare and Medicaid programs under titles XVIII and XIX of the Social Security Act (42 U.S.C. 1395 et seq., 1396 et seq.) may restrain the use of genetic and genomic testing that may improve clinical outcomes for beneficiaries;

(ii) the extent to which coverage provided pursuant to subsection (a) increased the use of genetic and genomic testing and improved clinical outcomes for beneficiaries; and

(iii) how the Centers for Medicare & Medicaid Services may make coverage determinations that better suit a precision medicine approach to treatment; and

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

(i) individuals with a rare disease, including—

(I) a metabolic disease;

(II) a hereditary cancer syndrome; and

(III) a neurologic disease with known treatments; and

(ii) special populations, including—

(I) infants and children;

(II) critically ill (non-infectious and non-trauma) patients;

(III) transplant patients;

(IV) individuals with cardiac disease; and

(V) individuals with, or who have a family history of, a birth defect or developmental disability.

(2) REPORT.—

(A) IN GENERAL.—The arrangement under paragraph (1) shall provide for the National Academy of Medicine to submit, not later than 6 years after the date of enactment of this section, a report on the results of the study under paragraph (1) to—

(i) the Secretary of Health and Human Services;

(ii) the Committee on Ways and Means and the Committee on Energy and Commerce of the House of Representatives; and

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

(B) CONSULTATION.—The arrangement under paragraph (1) shall provide for the National Academy of Medicine, in developing the report required by subparagraph (A), to consult with physicians, other health professionals, health educators, health professional organizations, relevant companies, patients, patient organizations, the Health Resources and Services Administration, the National Cancer Institute, the National Institutes of Health, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services.

(C) USE OF INFORMATION.—The National Academy of Medicine shall, to the extent possible, in conducting the study under paragraph (1), utilize information included in the reports

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

(c) CENTERS FOR MEDICARE & MEDICAID SERVICES REPORT ON MEDICAID COVERAGE FOR DNA SEQUENCING CLINICAL SERVICES.—Not later than two years after the date of the enactment of this section, the Centers for Medicare & Medicaid Services shall submit to the Secretary of Health and Human Services, the Committees on Ways and Means and on Energy and Commerce of the House of Representatives, and the Committees on Finance and Health, Education, Labor, and Pensions of the Senate a report on the extent to which each of the 50 States provide coverage under the State plan under title XIX of the Social Security Act (or waiver of such plan) of DNA sequencing clinical services (as defined in subsection (a)(8)(B)), including which types of DNA clinical sequencing options (if any) are so covered and under what circumstances (if any), the impact of coverage on patient outcomes, and the impact of coverage on subsequent health care costs.

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

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

(1) in subsection (s)(2)—

(A) by striking ''and'' at the end of subparagraph (GG);

(B) by striking the period at the end of subparagraph (HH) and inserting ''; and''; and

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

''(II) genomic precision medicine consultations provided by a qualified clinical pharmacist (as such terms are defined in subsection (lll)).''; and

(2) by adding at the end the following new subsection:

''(lll) GENOMIC PRECISION MEDICINE CONSULTATION.—

''(1) GENOMIC PRECISION MEDICINE CONSULTATION DEFINED.—The term 'genomic precision medicine consultation' means, with respect to a genetic or genomic test (including next generation sequencing) furnished to an individual, an interpretation of such test (or a consultation with respect to such test) provided to the physician treating such individual to provide such physician [based on such test] with advice and recommendations regarding

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

''(2) QUALIFIED CLINICAL PHARMACIST.—The term 'qualified clinical pharmacist' means an individual—

''(A) with a doctoral degree in pharmacy;

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

''(C) has appropriate pharmacy specialty certifications or appropriate training, as determined by the Secretary; and

''(D) meets other qualifications as specified by the Secretary.''.

(b) PAYMENT FOR GENOMIC PRECISION MEDICINE CONSULTATION.—Section 1832(a)(2) of the Social Security Act (42 U.S.C. 1395k(a)(2)) is amended—

(1) by striking ''and'' at the end of subparagraph (I);

(2) by striking the period at the end of subparagraph (J) and inserting ''; and''; and

(3) by adding at the end the following new subparagraph:

''(K) genomic precision medicine consultations (as defined in subsection (lll)).''.

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

**SEC. 409. PROHIBITING THE USE OF GEOGRAPHIC TRACKING FEATURES AND BIOMETRICS WITHIN MEDICAID ELECTRONIC VISIT VERIFICATION SYSTEMS.**

(a) IN GENERAL.—Section 1903(l)(5)(A) of the Social Security Act (42 U.S.C. 1396b(l)(5)(A)) is amended by inserting ''(without the use of geographic tracking or biometrics)'' after ''electronically verified''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply with respect to calendar quarters beginning on or after **[**_____**]**.

# TITLE I—RESEARCH

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

The mission of the Advanced Research Projects Agency for Health (ARPA–H) will be to speed transformational innovation in health research and speed application and implementation of health breakthroughs by funding projects that could—**]**

[(1) tackle bold challenges requiring large scale, sustained coordination;]

[(2) create new capabilities (e.g., technologies, data resources, disease models);]

[(3) support high-risk exploration that could establish entirely new paradigms; or]

[(4) overcome market failures through critical solutions, including financial incentives; or]

[(5) complement NIH's existing research portfolio and mission and the private sector's research initiatives.]

**SEC. 502. RESEARCH INVESTMENT TO SPARK THE ECONOMY.**

(a) AUTHORITY.—

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

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

(A) The Secretary of Commerce, acting through the Administrator of the National Oceanic and Atmospheric Administration and the Director of the National Institute of Standards and Technology.

(B) The Secretary of Agriculture.

(C) The Secretary of Defense.

(D) The Secretary of Education.

(E) The Secretary of Energy, acting for the Department of Energy (with respect to Energy Efficiency and Renewable Energy, Nuclear Energy, and Fossil Research and Development) and through the Office of Science, the Advanced Research Projects Agency–Energy (ARPA–E), and the Office of Electricity.

(F) The Secretary of the Interior, acting through the Director of the United States Geological Survey.

(G) The Secretary of Health and Human Services, acting through the Director of the National Institutes of Health.

(H) The Secretary of Transportation.

(I) The Administrator of the National Aeronautics and Space Administration.

(J) The Administrator of the Environmental Protection Agency.

(K) The Director of the National Science Foundation.

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

(A) provide supplemental funding to extend the duration of an award disrupted because of the COVID–19 public health emergency to a research institution, Research Laboratory, or individual that was awarded before the date of the enactment of this Act, or to expand the purposes of such an award, in order to—

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

(ii) enable research scientists, technical staff, research associates, and principal investigators to complete work;

(iii) extend the training of a postsecondary student, or the employment of a post-doctoral researcher, on an ongoing research project for up to 2 years because of the disruption of the job market;

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

(v) replace, refurbish, or otherwise make usable laboratory animals, reagents, equipment, or other items required for research;

(vi) facilitate other research (including field work), training, and ongoing construction activities, including at institutions that are disproportionately affected by the COVID–19 public health emergency (such as minority-serving institutions and 2-year institutions of higher education);

(vii) enable experimental field campaigns and maintenance of field infrastructure, including through replacement of disrupted experimental data to enable completion of impacted research; and

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

(B) issue awards to research institutions, Research Laboratories, or other individuals to conduct research on the effects of the COVID–19 and future potential pandemics, on the effects and effectiveness of responses to such diseases, and on improving the prediction of the possible courses of such pandemics; and

(C) provide flexibility on an award for funds made available to an agency, by any prior or subsequent Act, by modifying the terms and conditions of the award with a research institution, Research Laboratory, or individual due to facility closures or other limitations during the COVID–19 public health emergency.

(4) MODIFICATIONS.—The modifications authorized by paragraph (3)(C) include—

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

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

(b) PROCEDURES.—The officers specified in subsection (a)(2) shall each establish procedures to carry out subsection (a).

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

(d) AUTHORIZATIONS OF APPROPRIATIONS.—

(1) DEPARTMENT OF COMMERCE.—There is authorized to be appropriated for fiscal year 2021 for the Department of Commerce, $450,000,000 to carry out subsection (a), of which—

(A) $300,000,000 shall be for use by the National Oceanic and Atmospheric Administration; and

(B) $150,000,000 shall be for use by the National Institute of Standards and Technology.

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

(3) DEPARTMENT OF DEFENSE.—There is authorized to be appropriated for fiscal year 2021 for the Department of Defense, $3,000,000,000 to carry out subsection (a).

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

(5) DEPARTMENT OF ENERGY.—There is authorized to be appropriated for fiscal year 2021 for the Department of Energy, $5,000,000,000 to carry out subsection (a), of which—

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

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

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

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

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

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

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

(7) DEPARTMENT OF HEALTH AND HUMAN SERVICES.—There is authorized to be appropriated for fiscal year 2021 for the Department of Health and Human Services, $10,000,000,000 to carry out subsection (a), which shall be for use by the National Institutes of Health.

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

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

(9) NATIONAL AERONAUTICS AND SPACE ADMINISTRATION.—There is authorized to be appropriated for fiscal year 2021 for the National Aeronautics and Space Administration, $2,000,000,000 to carry out subsection (a).

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

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

(12) AVAILABILITY OF FUNDS FOR ADMINISTRATION.—

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

(B) LIMITATION.—Not more than 5 percent of each of the amounts appropriated pursuant to this subsection may be used for administration of awards under subsection (a).

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

(e) DEFINITIONS.—In this section:

(1) AWARD.—The term ''award'' includes a grant, cooperative agreement, or other financial assistance.

(2) COVID–19 PUBLIC HEALTH EMERGENCY.—The term ''COVID–19 public health emergency'' means the public health emergency declared by the Secretary of Health and Human Services under section 319 of the Public Health Service Act (42 U.S.C. 247d) on January 31, 2020, with respect to coronavirus disease 2019 (COVID–19).

(3) RESEARCH INSTITUTION.—The term ''research institution'' means the following:

(A) An institution of higher education (as defined in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a))).

(B) A Tribal College or University (as defined in section 316 of the Higher Education Act of 1965 (20 U.S.C. 1059c)).

(C) A nonprofit entity that conducts federally funded research.

(4) RESEARCH LABORATORY.—The term ''Research Laboratory'' means the following:

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

(B) A Federally Funded Research and Development Center for purposes of section 3.5.017 of title 48, Code of Federal Regulations.