I

116TH CONGRESS
2D SESSION

H. R. 14

To increase the Federal commitment to defeating the virus that causes COVID–19 and prepare for future pandemics, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 30, 2020

Mr. HUDSON (for himself, Mr. MCCARTHY, Mr. WALDEN, Mr. BRADY, and Ms. GRANGER) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Homeland Security, Transportation and Infrastructure, the Judiciary, Ways and Means, the Budget, and Science, Space, and Technology, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To increase the Federal commitment to defeating the virus that causes COVID–19 and prepare for future pandemics, 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 ''Commitment to Defeat the Virus and Keep America Healthy Act''.

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

TITLE I—PANDEMIC PREPAREDNESS AND RESPONSE

Subtitle A—Clarifying the Role of the Department of Health and Human Services During Public Health Emergencies

SEC. 1001. LEAD AGENCY FOR FEDERAL PUBLIC HEALTH AND MEDICAL RESPONSE TO PUBLIC HEALTH EMERGENCIES.

Section 2801 of the Public Health Service Act (42 U.S.C. 300hh) is amended—

(1) in subsection (a), by inserting after ''shall lead all Federal public health and medical response to public health emergencies and incidents'' the following: ''(including emergencies and disasters declared by the President pursuant to the National Emergencies Act or the Robert T. Stafford Disaster Relief and Emergency Assistance Act)''; and

(2) in subsection (b), by inserting after ''shall assume operational control of emergency public health and medical response assets, as necessary, in the event of a public health emergency'' the following: ''or in the event of an emergency or disaster declared by the President under the National Emer-

gencies Act or the Robert T. Stafford Disaster Relief and Emergency Assistance Act''.

SEC. 1002. DEPLOYMENT BY THE SECRETARY OF HEALTH AND HUMAN SERVICES OF NATIONAL STRATEGIC STOCKPILE.

Section 319F–2(a)(3)(F) of the Public Health Service Act (42 U.S.C. 247d–6b(a)(3)(F)) is amended by striking ''as required by'' and inserting ''in consultation with''.

SEC. 1003. AUTHORITY AND RESPONSIBILITIES OF THE FEDERAL EMERGENCY MANAGEMENT AGENCY REGARDING THE STRATEGIC NATIONAL STOCKPILE.

The Homeland Security Act of 2002 is amended—

(1) in subparagraph (A) of section 503(b)(2) (6 U.S.C. 313(b)(2)), by inserting '', in coordination with relevant Federal agencies,'' after ''lead''; and

(2) in subparagraph (D) of section 504(a)(3) (6 U.S.C. 314(a)(3)), by striking ''requiring'' and inserting '', at the direction of the Secretary of Health and Human Services, assisting in''.

Subtitle B—Reagan-Udall Foundation and Foundation for the National Institutes of Health

SEC. 1011. REAGAN-UDALL FOUNDATION AND FOUNDATION FOR THE NATIONAL INSTITUTES OF HEALTH.

(a) REAGAN-UDALL FOUNDATION FOR THE FOOD AND DRUG ADMINISTRATION.—Section 770(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(n)) is amended by striking ''$500,000 and not more than $1,250,000'' and inserting ''$1,250,000 and not more than $5,000,000''.

(b) FOUNDATION FOR THE NATIONAL INSTITUTES OF HEALTH.—Section 499(l) of the Public Health Service Act (42 U.S.C. 290b(l)) is amended by striking ''$500,000 and not more than $1,250,000'' and inserting ''$1,250,000 and not more than $5,000,000''.

Subtitle C—Protections for Good Samaritan Health Professionals

SEC. 1021. LIMITATION ON LIABILITY FOR VOLUNTEER HEALTH CARE PROFESSIONALS.

(a) IN GENERAL.—Title II of the Public Health Service Act (42 U.S.C. 202 et seq.) is amended by inserting after section 224 the following:

"SEC. 224A. LIMITATION ON LIABILITY FOR VOLUNTEER HEALTH CARE PROFESSIONALS.

"(a) LIMITATION ON LIABILITY.—Except as provided in subsection (b), a health care professional shall not be liable under Federal or State law for any harm caused by an act or omission of the professional in the provision of health care services if—

"(1) the professional is serving, for purposes of responding to a disaster, as a volunteer; and

"(2) the act or omission occurs—

"(A) during the period of the disaster, as determined under the laws listed in subsection (d)(1);

"(B) in the State or States for which the disaster is declared;

"(C) in the health care professional's capacity as a volunteer;

"(D) in the course of providing services that are within the scope of the license, registration, or certification of the volunteer, as defined by the State of licensure, registration, or certification; and

"(E) in a good faith belief that the individual being treated is in need of health care services.

''(b) EXCEPTIONS.—Subsection (a) does not apply if—

''(1) the harm was caused by an act or omission constituting willful or criminal misconduct, gross negligence, reckless misconduct, or a conscious flagrant indifference to the rights or safety of the individual harmed by the health care professional; or

''(2) the health care professional rendered the health care services under the influence (as determined pursuant to applicable State law) of alcohol or an intoxicating drug.

''(c) PREEMPTION.—

''(1) IN GENERAL.—This section preempts the laws of a State or any political subdivision of a State to the extent that such laws are inconsistent with this section, unless such laws provide greater protection from liability.

''(2) VOLUNTEER PROTECTION ACT.—Protections afforded by this section are in addition to those provided by the Volunteer Protection Act of 1997.

''(d) DEFINITIONS.—In this section:

''(1) The term 'disaster' means—

''(A) a national emergency declared by the President under the National Emergencies Act;

"(B) an emergency or major disaster declared by the President under the Robert T. Stafford Disaster Relief and Emergency Assistance Act; or

"(C) a public health emergency that is determined by the Secretary under section 319 of this Act with respect to one or more States specified in such determination—

"(i) during only the initial period covered by such determination; and

"(ii) excluding any period covered by a renewal of such determination.

"(2) The term 'harm' includes physical, nonphysical, economic, and noneconomic losses.

"(3) The term 'health care professional' means an individual who is licensed, registered, or certified under Federal or State law to provide health care services.

"(4) The term 'health care services' means any services provided by a health care professional, or by any individual working under the supervision of a health care professional, that relate to—

"(A) the diagnosis, prevention, or treatment of any human disease or impairment; or

"(B) the assessment or care of the health of a human being.

"(5) The term 'State' includes each of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, and any other territory or possession of the United States.

"(6)(A) The term 'volunteer' means a health care professional who, with respect to the health care services rendered, does not receive—

"(i) compensation; or

"(ii) any other thing of value in lieu of compensation, in excess of $500 per year.

"(B) For purposes of subparagraph (A), the term 'compensation'—

"(i) includes payment under any insurance policy or health plan, or under any Federal or State health benefits program; and

"(ii) excludes—

"(I) reasonable reimbursement or allowance for expenses actually incurred;

"(II) receipt of paid leave; and

"(III) receipt of items to be used exclusively for rendering the health services

in the health care professional's capacity as a volunteer described in subsection (a)(1).''.

(b) EFFECTIVE DATE.—

(1) IN GENERAL.—Section 224A of the Public Health Service Act, as added by subsection (a), shall take effect 90 days after the date of the enactment of this Act.

(2) APPLICATION.—Section 224A of the Public Health Service Act, as added by subsection (a), applies to a claim for harm only if the act or omission that caused such harm occurred on or after the effective date described in paragraph (1).

SEC. 1022. SENSE OF THE CONGRESS.

It is the sense of Congress that—

(1) health care professionals should be encouraged to register with the Emergency System for Advance Registration of Volunteer Health Professionals (ESAR–VHP), and States should employ online registration with the promptest processing possible of such registrations to foster the rapid deployment and utilization of volunteer health care professionals following a disaster;

(2) Federal and State agencies and licensing boards should cooperate to facilitate the timely

movement of properly licensed volunteer health care professionals to areas affected by a disaster; and

(3) the appropriate licensing entities should verify the licenses of volunteer health care professionals serving disaster victims as soon as is reasonably practical following a disaster.

Subtitle D—Medical Sheltering

SEC. 1031. REDUCING THE SPREAD OF COVID–19 THROUGH PAYMENTS TO STATES TO LEASE HOTELS TO TEMPORARILY HOUSE ELIGIBLE INDIVIDUALS.

(a) IN GENERAL.—The Secretary of Health and Human Services may make payments to States to lease hotels to temporarily house, on a voluntary basis, eligible individuals.

(b) FORMULA.—The Secretary shall allocate the amount appropriated to carry out this section pursuant to a formula developed by the Secretary that—

(1) distributes the amount among the States that—

(A) submit applications in accordance with subsection (c); and

(B) are determined by the Secretary to need such payments; and

(2) takes into consideration—

(A) the number of active cases of individuals infected with COVID–19 in the applying State relative to the overall population of the State; and

(B) the average income of individuals in the applying State relative to the average income of individuals in the United States.

(c) APPLICATIONS.—

(1) IN GENERAL.—To seek a payment under this section, a State shall submit an application to the Secretary at such time, in such manner, and containing such information and assurances as the Secretary may require.

(2) PROCESS.—The Secretary shall—

(A) not later than 15 days after the date of enactment of this Act, publish the process for States to apply for payments under this section; and

(B) not later than 15 days after the submission of an application in accordance with such process, approve or disapprove the application.

(3) CONTENTS.—The Secretary shall require the application of a State under this section to include—

(A) a plan for leasing hotels as described in subsection (a);

(B) health guidelines which the State will require to be implemented to protect the staff of the hotels;

(C) the rates to be paid to lease the hotels;

(D) a plan to ensure that the hotels each have—

(i) workplace safety standards for their staff;

(ii) proper personal protective equipment and sanitation supplies;

(iii) a cleaning protocol for rooms and facilities; and

(iv) at least one qualified health care professional onsite or on call to monitor the health of individuals being housed at the hotels;

(E) a plan to feed and provide other necessary materials to individuals described in subsection (a) at the hotels, including medications and hygiene products, without letting such individuals leave their rooms or accept visitors;

(F) a plan to assist the hotels in removing individuals who attempt to continue their stay after the allotted time;

(G) a plan for hospital networks, local health departments, and the hotels to coordinate on the exchange and protection of patient information in accordance with other applicable law;

(H) a plan to effectively communicate the State's program funded through this section to racial and ethnic minority groups and low-income communities; and

(I) each funding assurance listed in subsection (e).

(d) NO RESPONSIBILITY FOR DIET OR ADMINISTRATION OF MEDICINE.—Notwithstanding subsection (c)(3)(E), a contract between a State and a hotel pursuant to this section shall not make the hotel responsible for the diet of, or the administration of medications to, individuals described in subsection (a).

(e) FUNDING ASSURANCES.—As a condition on receipt of a payment of this section, a State shall give such assurances as the Secretary may require that—

(1) each contract between the State and a hotel pursuant to this section will be entered into on a vol-

untary basis, and no hotel will be required by the State to participate in the program under this section;

(2) individuals described in subsection (a) will not be charged for their lodging at a hotel pursuant to this section, except that such individuals may be required to reimburse the costs of receiving food and beverages;

(3) individuals described in subsection (a) will retain the option of self-isolating at home (including the option of checking out early and returning to their homes) rather than being required to stay at a hotel funded pursuant to this section;

(4) before an individual is allowed to stay at a hotel pursuant to this section, the individual will be required to present, in such form and manner as may be required by the local department of health, documentation from a physician that the individual meets the criteria described in subsection (a);

(5) any non-transient homeless population residing at a hotel will not be displaced for purposes of entering into or carrying out a contract between the State and the hotel under this section; and

(6) the State will pay (from funds provided to the State under this section or from other State funds)—

(A) at least 40 percent of the costs of the personal protective equipment and sanitation supplies needed by individuals staying at a hotel pursuant to this section and the staff of such hotel; and

(B) all of the costs of having one or more qualified health care professionals described in subsection (c)(3)(D)(iii) for the provision of monitoring described in such subsection (whether by being onsite or on call).

(f) REVIEW.—At the conclusion of the program under this section, the Inspector General of the Department of Health and Human Services shall—

(1) review the program and activities of each State funded pursuant to this section; and

(2) submit a report on the results of the review to—

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

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

(g) LIABILITY PROTECTION.—

(1) IN GENERAL.—Except as provided under paragraph (2), a hotel or member of the staff shall not be liable under Federal or State law for—

(A) any harm caused by an act or omission in the provision of hotel services pursuant to this section; or

(B) failing to keep an individual who is staying at a hotel pursuant to this section isolated from people other than the staff of the hotel and any qualified health care professional described in subsection (c)(3)(D)(iii).

(2) EXCEPTION.—Paragraph (1) does not apply in the case that the harm was caused by an act or omission constituting willful or criminal misconduct, gross negligence, reckless misconduct, or a conscious flagrant indifference to the rights or safety of the individual harmed.

(h) DEFINITIONS.—In this section:

(1) The term ''eligible individual'' means an individual who is unable to self-isolate at home, does

not require inpatient or outpatient health care treatment, and—

(A) has a laboratory-confirmed case of COVID–19;

(B) has a presumptive positive case of COVID–19; or

(C) is a person under investigation who is displaying symptoms of COVID–19.

(2) The terms ''Indian tribe'' and ''tribal organization'' have the meanings given to those terms in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304).

(3) The term ''Secretary'' means the Secretary of Health and Human Services.

(4) The term ''State'' includes each of 50 States, the District of Columbia, each Indian Tribe and tribal organization, Guam, American Samoa, the United States Virgin Islands, the Commonwealth of Puerto Rico, and the Commonwealth of the Northern Mariana Islands.

(i) FUNDING.—To carry out this section, there is authorized to be appropriated $1,000,000,000, to remain available through the earlier of—

(1) the end of calendar year 2021; or

(2) the end of the emergency period (as defined in section 1135(g)(1)(B) of the Social Security Act (42 U.S.C. 1320b–5(g)(1)(B))).

Subtitle E—CDC Campaign on COVID–19 Awareness

SEC. 1041. COVID–19 PUBLIC AWARENESS CAMPAIGN.

The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention and in coordination with other offices and agencies, as appropriate, shall award competitive grants or contracts to one or more public or private entities to carry out a national campaign that is multilingual and culturally competent and based on available scientific evidence to increase awareness and knowledge of COVID–19, including reducing stigma associated with COVID–19 and improving information on the availability of diagnostic testing and other related services at community health centers.

Subtitle F—Protecting Children From COVID–19

SEC. 1051. STUDY ON CHILDREN'S ROLE IN TRANSMITTING SARS–COV–2.

(a) STUDY.—

(1) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the

''Secretary''), in coordination with the heads of agencies of the Department of Health and Human Services and experts from outside of the Department, as appropriate, shall complete a study on children's role in transmitting SARS–CoV–2.

(2) ISSUES TO BE STUDIED.—The study under paragraph (1) shall address—

(A) the transmissibility of COVID–19 from child to child, child to adult, and adult to child;

(B) the vulnerability of children, especially those with underlying health conditions, to severe illness as such vulnerability relates to COVID–19;

(C) the vulnerability of adults, especially those with underlying health conditions, who send their children back to school; and

(D) the vulnerability of adults, especially those with underlying health conditions, who interact with children who may be asymptomatic but infectious.

(3) CONSIDERATIONS.—In carrying out the study under paragraph (1), the Secretary shall—

(A) take into consideration the best available science, including as provided by the National Academy of Sciences; and

(B) ensure that such study includes consideration of children who are members of racial or ethnic minority groups.

(b) REPORTING.—The Secretary shall submit a report to the Congress on children's role in transmitting SARS–CoV–2. The report shall include the results of the study under subsection (a).

(c) DISSEMINATION OF BEST PRACTICES.—The Secretary shall disseminate to stakeholders best practices for protecting children and adults in educational settings. The first best practices disseminated pursuant to the preceding sentence shall include any best practices for protecting children and adults in educational settings identified through the study under subsection (a).

(d) DEFINITION.—In this section, the term ''emergency period'' has the meaning given to such term in section 1135(g)(1)(B) of the Social Security Act (42 U.S.C. 1320b–5(g)(1)(B)).

Subtitle G—Ensuring Understanding of COVID–19

SEC. 1061. STUDY ON THE IMPACT OF COVID–19.

Part A of title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended by adding at the end the following:

"SEC. 404O. STUDY ON THE IMPACT OF COVID–19.

''(a) IN GENERAL.—The Secretary shall conduct a longitudinal study, over not less than 10 years, on the full impact of COVID–19 on infected individuals, including both short-term and long-term health impacts.

''(b) TIMING.—The Secretary shall begin enrolling patients in the study under this section not later than 6 months after the date of enactment of this section.

''(c) REQUIREMENTS.—The study under this section shall—

''(1) be nationwide;

''(2) include diversity of enrollees to account for gender, age, race, ethnicity, geography, comorbidities, and underrepresented populations, including pregnant and lactating women;

''(3) study individuals who were infected with COVID–19 who experienced mild symptoms, such individuals who experienced moderate symptoms, and such individuals who experienced severe symptoms;

''(4) monitor the health outcomes and symptoms of individuals who were infected with COVID–19, or had prenatal exposure to COVID–19, including lung capacity and function, and immune response, taking into account any pharmaceutical interventions such individuals may have received;

''(5) monitor the mental health outcomes of individuals infected with COVID–19, taking into account any interventions that affected mental health; and

''(6) monitor individuals enrolled in the study not less frequently that twice per year after the first year of the individual's infection with COVID–19.

''(d) PUBLIC-PRIVATE RESEARCH NETWORK.—For purposes of carrying out the study under this section, the Director of NIH may develop a network of public-private research partners, provided that all research, including the research carried out through any such partner, is available publicly.

''(e) SUMMARIES OF FINDINGS.—The Director of NIH shall make public a summary of findings under this section not less frequently than once every 3 months for the first 2 years of the study, and not less frequently than every 6 months thereafter. Such summaries may include information about how the findings of the study under this section compare with findings from research conducted abroad.

''(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this section.''.

Subtitle H—Safeguarding Therapeutics

SEC. 1071. AUTHORITY TO DESTROY COUNTERFEIT DEVICES.

(a) IN GENERAL.—Section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) is amended—

(1) in the fourth sentence, by inserting ''or counterfeit device'' after ''counterfeit drug''; and

(2) by striking ''The Secretary of the Treasury shall cause the destruction of'' and all that follows through ''liable for costs pursuant to subsection (c).'' and inserting the following: ''The Secretary of the Treasury shall cause the destruction of any such article refused admission unless such article is exported, under regulations prescribed by the Secretary of the Treasury, within 90 days of the date of notice of such refusal or within such additional time as may be permitted pursuant to such regulations, except that the Secretary of Health and Human Services may destroy, without the opportunity for export, any drug or device refused admission under this section, if such drug or device is valued at an amount that is $2,500 or less (or such higher amount as the Secretary of the Treasury may

set by regulation pursuant to section 498(a)(1) of the Tariff Act of 1930 (19 U.S.C. 1498(a)(1))) and was not brought into compliance as described under subsection (b). The Secretary of Health and Human Services shall issue regulations providing for notice and an opportunity to appear before the Secretary of Health and Human Services and introduce testimony, as described in the first sentence of this subsection, on destruction of a drug or device under the seventh sentence of this subsection. The regulations shall provide that prior to destruction, appropriate due process is available to the owner or consignee seeking to challenge the decision to destroy the drug or device. Where the Secretary of Health and Human Services provides notice and an opportunity to appear and introduce testimony on the destruction of a drug or device, the Secretary of Health and Human Services shall store and, as applicable, dispose of the drug or device after the issuance of the notice, except that the owner and consignee shall remain liable for costs pursuant to subsection (c).''.

(b) DEFINITION.—Section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)) is amended—

(1) by redesignating subparagraphs (1), (2), and (3) as clauses (A), (B), and (C), respectively; and

(2) after making such redesignations—

(A) by striking ''(h) The term'' and inserting ''(h)(1) The term''; and

(B) by adding at the end the following:

''(2) The term 'counterfeit device' means a device which, or the container, packaging, or labeling of which, without authorization, bears a trademark, trade name, or other identifying mark, imprint, or symbol, or any likeness thereof, or is manufactured using a design, of a device manufacturer, packer, or distributor other than the person or persons who in fact manufactured, packed, or distributed such device and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other device manufacturer, packer, or distributor.

''(3) For purposes of subparagraph (2)—

''(A) the term 'manufactured' refers to any of the following activities: manufacture, preparation, propagation, compounding, assembly, or processing; and

''(B) the term 'manufacturer' means a person who is engaged in any of the activities listed in clause (A).''.

SEC. 1072. DETERMINATION OF BUDGETARY EFFECTS.

The budgetary effects of this subtitle, for the purpose of complying with the Statutory Pay-As-You-Go Act of 2010, shall be determined by reference to the latest statement titled ''Budgetary Effects of PAYGO Legislation'' for this subtitle, submitted for printing in the Congressional Record by the Chairman of the House Budget Committee, provided that such statement has been submitted prior to the vote on passage.

Subtitle I—Advisory Committee on Immunization Practices

SEC. 1081. EXPEDITED MEETING OF ACIP FOR COVID–19 VACCINES.

(a) IN GENERAL.—Notwithstanding section 3091 of the 21st Century Cures Act (21 U.S.C. 360bbb–4 note), the Advisory Committee on Immunization Practices shall meet and issue a recommendation with respect to a vaccine that is intended to prevent or treat COVID–19 not later than 15 business days after the date on which such vaccine is licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) or authorized under section

564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3).

(b) DEFINITION.—In this section, the term ''Advisory Committee on Immunization Practices'' means the Advisory Committee on Immunization Practices established by the Secretary of Health and Human Services pursuant to section 222 of the Public Health Service Act (42 U.S.C. 217a), acting through the Director of the Centers for Disease Control and Prevention.

Subtitle J—Improvements to Transparency of the Pricing of Diagnostic Testing for COVID–19

SEC. 1091. IMPROVEMENTS TO TRANSPARENCY OF THE PRICING OF DIAGNOSTIC TESTING FOR COVID–19.

(a) IN GENERAL.—Section 3202 of the CARES Act (Public Law 116–136) is amended—

(1) in subsection (b)—

(A) in the heading, by inserting ''AND RELATED ITEMS AND SERVICES'' after ''DIAGNOSTIC TESTING FOR COVID–19'';

(B) in paragraph (1)—

(i) by striking ''a diagnostic test for COVID–19'' and inserting ''a test, item, or

service described in section 6001(a) of division F of the Families First Coronavirus Response Act (Public Law 116–127)''; and

(ii) by striking ''such test'' and inserting ''such test, item, or service''; and

(C) in paragraph (2), by striking ''a diagnostic test for COVID–19'' and inserting ''a test, item, or service described in section 6001(a) of division F of the Families First Coronavirus Response Act (Public Law 116–127)''; and

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

''(c) IMPROVEMENTS TO TRANSPARENCY POLICY.—

''(1) IN GENERAL.—Not later than 30 days after the date of the enactment of this subsection, the Secretary of Health and Human Services shall survey providers subject to the requirement under subsection (b) regarding the cash prices referred to in such subsection.

''(2) REPRESENTATIVE SAMPLE.—In carrying out paragraph (1), the Secretary shall survey a sample of providers that is representative of the diversity of sizes, geographic locations, and care settings (such as hospitals, laboratories, and independent

freestanding emergency departments) in which diagnostic testing for COVID–19 is performed.

''(3) CONSUMER COMPLAINTS.—The Secretary shall ensure that consumers have a method to submit complaints to the Department of Health and Human Services that identify providers that—

''(A) may be in violation of subsection (b); and

''(B) have not made public a cash price in accordance with such subsection.

''(d) PUBLIC REPORT.—Not later than 60 days after the date of the enactment of this subsection, the Secretary of Health and Human Services shall publish on the internet website of the Department of Health and Human Services a report on cash prices for items and services published under subsection (b)(1) during the period beginning on the date of the enactment of this Act and ending on the date of the enactment of this subsection, which shall include—

''(1) the percentage of providers that comply with the requirement under such subsection;

''(2) the average cash price for each such item and service published under such subsection; and

''(3) any providers identified pursuant to paragraph (2) or (3) of subsection (c) and found to be in violation of such requirement.''.

TITLE II—DOMESTIC MANUFACTURING AND SUPPLY CHAIN

Subtitle A—Sustained On-Shore Manufacturing Capacity for Public Health Emergencies

SEC. 2001. SUSTAINED ON-SHORE MANUFACTURING CAPACITY FOR PUBLIC HEALTH EMERGENCIES.

(a) IN GENERAL.—Section 319L of the Public Health Service Act (42 U.S.C. 247d–7e) is amended—

(1) in subsection (a)(6)(B)—

(A) by redesignating clauses (iv) and (v) as clauses (v) and (vi), respectively;

(B) by inserting after clause (iii), the following:

''(iv) activities to support domestic manufacturing surge capacity of products or platform technologies, including manufacturing capacity and capabilities to utilize platform technologies to provide for flexible manufacturing initiatives;''; and

(C) in clause (vi) (as so redesignated), by inserting ''manufacture,'' after ''improvement,'';

(2) in subsection (b)—

(A) in the first sentence of paragraph (1), by inserting ''support for domestic manufacturing surge capacity,'' after ''initiatives for innovation,''; and

(B) in paragraph (2)—

(i) in subparagraph (B), by striking ''and'' at the end;

(ii) by redesignating subparagraph (C) as subparagraph (D); and

(iii) by inserting after subparagraph (B), the following:

''(C) activities to support manufacturing surge capacities and capabilities to increase the availability of existing medical countermeasures and utilize existing novel platforms to manufacture new medical countermeasures to meet manufacturing demands to address threats that pose a significant level of risk to national security; and'';

(3) in subsection (c)—

(A) in paragraph (2)—

(i) in subparagraph (C), by striking ''and'' at the end;

(ii) in subparagraph (D), by striking the period and inserting ''; and''; and

(iii) by adding at the end the following:

''(E) promoting domestic manufacturing surge capacity and capabilities for countermeasure advanced research and development, including facilitating contracts to support flexible or surge manufacturing.'';

(B) in paragraph (4)—

(i) in subparagraph (B)—

(I) in clause (iii), by striking ''and'' at the end;

(II) in clause (iv), by striking the period and inserting ''; and''; and

(III) by adding at the end the following:

''(v) support and maintain domestic manufacturing surge capacity and capabilities, including through contracts to support flexible or surge manufacturing, to ensure that additional production of countermeasures is available in the event that the Secretary determines there is such a need for additional production.'';

(ii) in subparagraph (D)—

(I) in clause (ii), by striking ''and'' at the end;

(II) by redesignating clause (iii) as clause (iv); and

(III) by inserting after clause (ii) the following:

''(iii) research to advance manufacturing capacities and capabilities for medical countermeasures and platform technologies that may be utilized for medical countermeasures; and''; and

(iii) in subparagraph (E), by striking clause (ix); and

(C) in paragraph (7)(C)(i), by striking ''up to 100 highly qualified individuals, or up to 50 percent of the total number of employees, whichever is less,'' and inserting ''75 percent of the total number of employees'';

(4) in subsection (e)(1)—

(A) by redesignating subparagraphs (B) through (D) as subparagraphs (C) through (E), respectively; and

(B) by inserting after subparagraph (A), the following:

''(B) TEMPORARY FLEXIBILITY.—During a public health emergency under section 319, the Secretary shall be provided with an additional 60 business days to comply with information requests for the disclosure of information under section 552 of title 5, United States Code, related to the activities under this section (unless such activities are otherwise exempt under subparagraph (A)).''; and

(5) in subsection (f)—

(A) in paragraph (1), by striking ''Not later than 180 days after the date of enactment of this subsection'' and inserting ''Not later than 180 days after the date of enactment of the Commitment to Defeat the Virus and Keep America Healthy Act''; and

(B) in paragraph (2), by striking ''Not later than 1 year after the date of enactment of this subsection'' and inserting ''Not later than 1 year after the date of enactment of the Commitment to Defeat the Virus and Keep America Healthy Act''.

(b) MEDICAL COUNTERMEASURE INNOVATION PARTNER.—The restrictions under section 202 of division A of the Further Consolidated Appropriations Act, 2020 (Pub-

lic Law 116–94), or any other provision of law imposing a restriction on salaries of individuals related to a previous appropriation to the Department of Health and Human Services, shall not apply with respect to salaries paid pursuant to an agreement under the medical countermeasure innovation partner program under section 319L(c)(4)(E) of the Public Health Service Act (42 U.S.C. 247d–7e(c)(4)(E)).

Subtitle B—Manufacturing API, Drugs, and Excipients in America

SEC. 2011. REPORT TO CONGRESS ON BARRIERS TO DOMESTIC MANUFACTURING OF MEDICAL PRODUCTS AND SUPPLIES.

(a) REPORT.—Not later than January 1, 2021, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on barriers to domestic manufacturing of active pharmaceutical ingredients, drugs, and devices that are manufactured outside of the United States.

(b) CONTENTS.—Such report shall—

(1) identify factors that limit or otherwise discourage the domestic manufacturing of active phar-

maceutical ingredients, drugs, and devices that are currently manufactured outside of the United States, including any Federal, State, local, or Tribal laws and regulations that hinder domestic manufacturing opportunities; and

(2) recommend specific strategies to overcome the challenges identified under paragraph (1), including strategies—

(A) to develop effective incentives for domestic manufacturing; and

(B) to make changes to laws or regulations that hinder domestic manufacturing opportunities.

(c) CONSULTATION.—In carrying out the report under subsection (a), the Secretary shall consult with—

(1) the Food and Drug Administration, the Centers for Medicare & Medicaid Services, the Department of Defense, the Department of Commerce, the Department of State, the Department of Veterans Affairs, the Department of Justice, and any other Federal agencies as appropriate; and

(2) relevant stakeholders, including drug, device, and active pharmaceutical ingredient manufacturers, and other entities, as appropriate.

(d) DEFINITION.—In this section, the term ''active pharmaceutical ingredient'' has the meaning given to such term in section 207.1 of title 21, Code of Federal Regulations (and any successor regulations).

(e) PUBLICATION.—The Secretary shall make the report under subsection (a) available on the public website of the Department of Health and Human Services.

SEC. 2012. ENHANCING INTRA-AGENCY COORDINATION AND PUBLIC HEALTH ASSESSMENT WITH REGARD TO COMPLIANCE ACTIVITIES.

(a) BENEFIT/RISK FRAMEWORK.—

(1) IN GENERAL.—Paragraph (2) of section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(b)) is amended by adding at the end the following: ''The Secretary shall ensure timely and effective coordination among such offices regarding the reviews of such report and the alignment of any feedback regarding such report, and any corrective or preventive actions in response to such report, after consideration of the benefits and risks to the public health, patient safety, the drug supply and drug supply chain, and timely patient access to drugs.''.

(2) ANNUAL REPORTING.—Subsection (b) of section 704 of the Federal Food, Drug, and Cos-

metic Act (21 U.S.C. 374) is amended by adding at the end the following new paragraph:

''(3) On an annual basis, the Secretary shall prepare a report on the utilization of the framework described in paragraph (2) and post such report on the public website of the Food and Drug Administration.''.

(3) APPLICABILITY.—The amendments made by paragraphs (1) and (2) shall take effect on the effective date described in section 3112 of the CARES Act (Public Law 116–136), after executing the amendments made by such section 3112, and shall apply beginning on the date that is 1 year after the date of enactment of this Act.

(b) PUBLIC MEETING.—The Secretary of Health and Human Services shall publish in the Federal Register a notice of a public meeting to be held no later than six months after the date of enactment of this Act to discuss and obtain input and recommendations from public stakeholders, including patient advocates, consumers, regulated industry, and health care providers, regarding the contents of a benefit/risk framework described in section 704(b)(2) of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (a), that supports a safe, stable, redundant drug supply chain.

(c) GUIDANCE.—The Secretary of Health and Human Services shall—

(1) not later than one year after the date on which the public meeting described in subsection (b) is held, issue draft guidance regarding the goals and implementation of a benefit/risk framework described in subsection (b); and

(2) not later than two years after such date of enactment, issue final guidance with respect to the implementation of such a framework.

SEC. 2013. ENCOURAGING INTERNATIONAL HARMONIZATION.

(a) GAO STUDY.—Not later than one year after the date of enactment of this Act, the Comptroller General of the United States shall issue a report evaluating—

(1) the consistency with which the International Conference on Harmonisation (in this section referred to as ''ICH'') guidelines on good manufacturing practices, including ICH Guidelines Q8–11, are being implemented by drug regulatory authorities across countries and international regions;

(2) whether domestic active pharmaceutical ingredient manufacturers (including any such contract manufacturers) are provided sufficient opportunity

to participate with regulatory authorities in the development of guidelines prior to implementation;

(3) whether divergence from ICH guidelines or differing regulatory standards or requirements by drug regulatory authorities across countries and international regions creates—

(A) inefficiencies in drug manufacturing;

(B) incompatible requirements that can contribute to or exacerbate drug shortages; and

(C) the most common areas of divergence between ICH guidelines and regulatory standards and requirements by drug regulatory authorities across countries and international regions that, if rectified, may reduce the inefficiencies and incompatibilities identified pursuant to subparagraphs (A) and (B).

(b) INTERNATIONAL TRAINING PROGRAM.—Not later than two years after the date of enactment of this Act, informed by the needs identified in the report issued pursuant to subsection (a), the Secretary of Health and Human Services, in conjunction with drug regulatory authorities across countries and international regions and the ICH, shall develop and implement a training program for drug regulatory authorities across countries and international regions to promote consistent application of and

reduce divergence from ICH guidelines on good manufacturing practices.

SEC. 2014. MUTUAL RECOGNITION AGREEMENTS FOR INSPECTIONS AND REVIEW ACTIVITIES.

(a) MUTUAL RECOGNITION OF INSPECTIONS.—Pursuant to section 809 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384e), the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall establish or expand initiatives for mutual sharing of review and inspection findings between drug regulatory authorities across countries and international regions, such as through the Pharmaceutical Cooperation Inspection Scheme, the Mutual Recognition Agreement with the European Union, and the Australia-Canada-Singapore-Switzerland Consortium, to—

(1) reduce the potential for duplicative regulatory evaluation of medical products regulated by the Food and Drug Administration; and

(2) more constructively allocate appropriations to the Food and Drug Administration, including those attributable to user fees, to harmonized regulatory processes.

(b) ADDITIONAL COUNTRIES, REGIONS, AND EVALUATION.—In carrying out subsection (a), the Secretary may expand the initiatives to include—

(1) additional countries and geographic regions with established and competent regulatory frameworks; and

(2) additional types of regulatory evaluation, including with respect to—

(A) good manufacturing practice inspections; and

(B) approval of changes to the manufacturing of drugs for which an approval or licensure is in effect under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262).

(c) IMPLEMENTATION FRAMEWORK.—

(1) PUBLICATION.—Not later than one year after the date of enactment of this Act, the Secretary shall publish an implementation framework for the agreements to share review and inspection findings under subsection (a) on the public website of the Food and Drug Administration.

(2) CONTENTS.—The implementation framework under this subsection shall—

(A) include the timeline for establishing or expanding initiatives described in subsection (a);

(B) describe additional types of regulatory processes that will become subject to such initiatives;

(C) specify the countries and geographic regions where such initiatives will be established or expanded; and

(D) identify additional opportunities and challenges for expanding mutual recognition agreements in drug and biologic regulation.

(d) ANNUAL REPORTING.—

(1) IN GENERAL.—Not later than the end of calendar year 2020 and annually thereafter, the Secretary shall publish a report on the public website of the Food and Drug Administration on the utilization of agreements described in subsection (c)(1) in the previous fiscal year.

(2) CONTENTS.—The report under paragraph (1) shall include each of the following:

(A) The total number of establishments that are registered under section 510(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) and located outside of the United States, and of these establishments, the number in each region of interest.

(B) The total number of inspections conducted at establishments described in subparagraph (A).

(C) Of the inspections described in subparagraph (B), the total number of inspections in each of region of interest.

(D) Of the inspections in each region of interest reported pursuant to subparagraph (C), the number of inspections in each FDA inspection category.

(E) Of the number of inspections reported under each of subparagraphs (B), (C), and (D)—

(i) the number of inspections which have been conducted pursuant to an agreement described in subsection (c)(1); and

(ii) the number of inspections which have been conducted by employees or other agents of the Food and Drug Administration.

(3) DEFINITIONS.—In this subsection:

(A) The term ''region of interest'' refers to China, India, the European Union, and any other geographic region as determined appropriate by the Secretary.

(B) The term ''FDA inspection category'' means refers to the following inspection categories:

(i) Inspections to support an approval of a drug under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262).

(ii) Good manufacturing practice inspections.

(iii) For-cause inspections.

SEC. 2015. ENHANCING TRANSPARENCY OF DRUG FACILITY INSPECTION TIMELINES.

Section 902 of the FDA Reauthorization Act of 2017 (21 U.S.C. 355 note) is amended to read as follows:

''SEC. 902. ANNUAL REPORT ON INSPECTIONS.

''Not later than March 1 of each year, the Secretary of Health and Human Services shall post on the public website of the Food and Drug Administration information related to inspections of facilities necessary for approval of a drug under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), approval of a device under section 515 of such Act (21 U.S.C. 360e), or clearance of a device under section 510(k) of such Act (21 U.S.C. 360(k)) that were con-

ducted during the previous calendar year. Such information shall include the following:

"(1) The median time following a request from staff of the Food and Drug Administration reviewing an application or report to the beginning of the inspection, and the median time from the beginning of an inspection to the issuance of a report pursuant to section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(b)), including—

"(A) the median time for drugs described in 505(j)(11)(A)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(11)(A)(i));

"(B) the median time for drugs described in section 506C(a) of such Act (21 U.S.C. 356c(a)) only; and

"(C) the median time for drugs on the drug shortage list in effect under section 506E of such Act (21 U.S.C. 356f).

"(2) The median time from the issuance of a report pursuant to such section 704(b) to the sending of a warning letter, issuance of an import alert, or holding of a regulatory meeting for inspections for which the Secretary concluded that regulatory or enforcement action was indicated, including the me-

dian time for each category of drugs listed in subparagraphs (A) through (C) of paragraph (1).

''(3) The median time from the sending of a warning letter, issuance of an import alert, or holding of a regulatory meeting to resolution of the regulatory or enforcement action indicated for inspections for which the Secretary concluded that such action was indicated.

''(4) The number of times that a facility was issued a report pursuant to such section 704(b) and approval of an application was delayed due to the issuance of a withhold recommendation, including the number of such times for each category of drugs listed in subparagraphs (A) through (C) of paragraph (1).''.

SEC. 2016. ADVANCED MANUFACTURING TECHNOLOGIES PROGRAM.

Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

''SEC. 524B. ADVANCED MANUFACTURING TECHNOLOGIES PROGRAM.

''(a) IN GENERAL.—Not later than 1 year after the date of enactment of the Commitment to Defeat the Virus and Keep America Healthy Act, the Secretary shall con-

tinue in effect the program to evaluate new drug manufacturing technologies that are included in an application, or supplement to an application, for a drug under subsection (b) or (j) of section 505 of this Act or for a biological product submitted under subsection (a) or (k) of section 351 of the Public Health Service Act.

''(b) DESIGNATION.—The Secretary shall designate a method of manufacturing a drug as an advanced manufacturing technology under this section if the drug manufacturer demonstrates that such technology is likely to—

''(1) prevent or resolve a drug shortage;

''(2) maintain an adequate supply of critical medications for national emergencies; or

''(3) promote the adoption of innovative approaches to drug product design and manufacturing.

''(c) CONSULTATION.—If the Secretary designates a method of manufacturing as an advanced manufacturing technology under this section, the Secretary shall take actions to expedite the development and implementation of such method of manufacture for purposes of approval of the application under subsection (c) or (j) of section 505 of this Act or subsection (a) or (k) of section 351 of the Public Health Service Act, which may include, as appropriate—

''(1) holding meetings between the sponsor of the application and appropriate Food and Drug Administration staff throughout the development of the technology;

''(2) providing timely advice to, and interactive communication with, the sponsor regarding the development of the technology; and

''(3) involving senior managers and experienced staff of the Food and Drug Administration, as appropriate, in a collaborative, cross-disciplinary review of the method of manufacturing.

''(d) EVALUATION OF AN ADVANCED MANUFACTURING TECHNOLOGY.—

''(1) PACKAGE.—A sponsor who receives designation of an advanced manufacturing technology under this section shall provide the Secretary with a package of scientific evidence supporting the implementation of the advanced manufacturing technology in a particular context-of-use.

''(2) EVALUATION.—Within 90 days of receiving the package, the Secretary shall determine whether a designated advanced manufacturing technology is validated for the proposed context of use based on the scientific merit the supporting evidence provided by the sponsor.

''(3) EFFECT OF APPROVAL.—Upon approval, the same sponsor may rely upon the advanced manufacturing technology for use across multiple manufacturing product lines within the same context-of-use without having to re-submit data to the Secretary validating the underlying technology.

''(e) IMPLEMENTATION AND REPORTING.—

''(1) PUBLIC MEETING.—The Secretary shall publish in the Federal Register a notice of a public meeting to be held no later than 1 year after the date of enactment of the Commitment to Defeat the Virus and Keep America Healthy Act to discuss and obtain input and recommendations from stakeholders regarding the goals and scope of, and a suitable framework and procedures and requirements for, the program under this section.

''(2) PROGRAM GUIDANCE.—The Secretary shall—

''(A) not later than 1 year after the date of enactment of the Commitment to Defeat the Virus and Keep America Healthy Act, issue draft guidance regarding the goals and implementation of the program under this section; and

''(B) not later than 2 years after the date of enactment of the Commitment to Defeat the Virus and Keep America Healthy Act, issue final guidance with respect to the implementation of such program.

''(3) REPORT.—The Secretary shall make available on the public website of the Food and Drug Administration an annual report on the progress of the program under this section.''.

Subtitle C—Improving the American Drug Supply Chain

SEC. 2021. STUDY AND REPORTING ON DOMESTIC AND FOREIGN PRODUCTION.

(a) IN GENERAL.—The Secretary of Health and Human Services shall enter into an agreement with the National Academies of Sciences, Engineering, and Medicine (referred to in this section as the ''National Academies'') under which, not later than 24 months after the date of enactment of this Act, the National Academies will—

(1) study the current and historical production of drugs and key ingredients thereof (including active pharmaceutical ingredients) in the United States and in foreign countries;

(2) formulate recommendations for promoting increased production of drugs and key ingredients thereof (including active pharmaceutical ingredients) in the United States; and

(3) in a manner that does not compromise national security or disclose trade secrets or other confidential commercial information that is subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code, submit a report to the Congress on—

(A) the findings and conclusions of the study under paragraph (1); and

(B) the recommendations under paragraph (2).

(b) STUDY TOPICS.—The study pursuant to subsection (a)(1) shall include—

(1) evaluation of—

(A) the extent to which production of drugs for use in the United States and key ingredients thereof (including active pharmaceutical ingredients) takes place in the United States; and

(B) the extent to which such production takes place in foreign countries;

(2) identification of the foreign countries in which such production takes place;

(3) evaluation of historical changes in the countries in which such production takes place;

(4) determination of the reasons why such production takes place in foreign countries, including why such production takes place in particular foreign countries, including consideration of—

(A) the reasons for historical migration of such production to foreign countries, or from foreign countries to other foreign countries or the United States;

(B) economic factors, including economic impediments to domestic production and incentives for foreign production; and

(C) regulatory, intellectual property, international trade, and other legal and policy factors; and

(5) evaluation of the benefits of redundancies in the supply chain of drugs in the United States in the event of a public health emergency.

(c) RECOMMENDATIONS.—The agreement under subsection (a) shall—

(1) provide for inclusion in the recommendations under subsection (a)(2) of measures (which

may include statutory, regulatory, and other policy changes) that should be taken—

(A) to encourage the domestic production of drugs for use in the United States and key ingredients thereof (including active pharmaceutical ingredients); or

(B) to otherwise reduce the risks to the availability of drugs in the United States in the event of a public health emergency; and

(2) require consideration, in developing such recommendations, of—

(A) factors affecting the production of drugs, including—

(i) access to skilled labor;

(ii) the cost of raw materials, the cost of energy, and related costs;

(iii) taxes and other incentives; and

(iv) the effects of regulations; and

(B) the costs and consequences of implementing, or failing to implement, each such recommendation.

(d) INPUT.—The agreement under subsection (a) shall require—

(1) consideration of input from the Department of Health and Human Services, the Department of

Commerce, and, as appropriate, other Federal agencies; and

(2) consultation with relevant stakeholders, which—

(A) may include conducting public meetings and other forms of engagement, as appropriate;

(B) shall include consultation with experts in—

(i) the manufacturing of drugs;

(ii) pharmaceutical industry business and economics;

(iii) drug purchasing, pricing, and reimbursement;

(iv) regulatory and intellectual property issues affecting drug manufacturing;

(v) economics;

(vi) international trade policy; and

(vii) emergency planning; and

(C) may include consultation with other entities with experience in drug manufacturing and pricing, as appropriate.

(e) DEFINITIONS.—In this section, the term ''drug'' has the meaning given such term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

Subtitle D—Essential Medicines Strategic Stockpile

SEC. 2031. PILOT PROGRAM ON ENSURING MEDICATION SUPPLY STABILITY.

Part D of title III of the Public Health Service Act (42 U.S.C. 254b et seq.) is amended by adding at the end the following new subpart:

"Subpart XIII—Ensuring Medication Supply Stability

"SEC. 340J. ENSURING MEDICATION SUPPLY STABILITY.

''(a) AWARD OF CONTRACTS.—Beginning not later than January 1, 2021, the Secretary shall award contracts to eligible entities to each implement and test the effectiveness of acquiring, maintaining, managing, and distributing a stockpile that—

''(1) consists of generic drugs at risk of shortage; and

''(2) is of sufficient quantity to ensure that customers in the United States of the respective eligible entity have access to such drugs for at least 6 months (as specified by the Secretary based on the historic demand for those drugs).

''(b) SELECTION OF DRUGS.—

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

''(A) select not more than 50 types of drugs that may be included by eligible entities

in a stockpile pursuant to a contract under this section;

"(B) maintain an up-to-date list of such drugs; and

"(C) make such list publicly available.

"(2) CHOICE OF ELIGIBLE ENTITIES.—A contract awarded to an eligible entity under this section need not require the stockpile of the eligible entity to include all 50 types of drugs listed pursuant to paragraph (1).

"(c) SUFFICIENT QUANTITY.—For each generic drug in a stockpile maintained pursuant to subsection (a), the Secretary shall specify the quantity of such drug that is sufficient for purposes of such subsection to ensure that consumers in the United States of the respective eligible entity have access to such drug for at least 6 months.

"(d) DURATION; LIQUIDATION OF INVENTORY.—

"(1) DURATION.—A contract awarded under this section shall be for a term of no more than 3 years.

"(2) LIQUIDATION OF INVENTORY.—A drug held in a stockpile pursuant to a contract under this section may be liquidated by the eligible entity at the end of the period of the contract.

"(e) STOCKPILE REQUIREMENTS.—

''(1) ENSURING AVAILABILITY OF UNEXPIRED PRODUCTS.—Each eligible entity with a contract under this section for a stockpile of generic drugs at risk of shortage shall—

''(A) ensure that each drug maintained in the stockpile has an expiration date at least 1 year beyond the current date; and

''(B) to comply with subparagraph (A)—

''(i) sell drugs in the stockpile through normal commercial channels and replace those drugs; or

''(ii) if there is no commercial market for a drug in the stockpile, dispose of the drug, report such disposal to the Secretary, and replace the drug.

''(2) MANAGEMENT OF STOCKPILE.—

''(A) IN GENERAL.—Each eligible entity with a contract under this section for a stockpile of generic drugs at risk of shortage shall—

''(i) acquire not later than 6 months following the date the contract is awarded, and maintain thereafter, a 6-month supply of each type of drug the eligible entity has contracted to stockpile, which 6-month supply shall be in addition to the average

levels of inventory held by such eligible entity over the previous year for such drug; and

"(ii) if it is not possible to comply with clause (i), notify the Secretary, citing the reason why it is not possible and the expected time of acquisition of the drug.

"(B) INVENTORY MANAGEMENT.—Each eligible entity with a contract under this section for a stockpile of generic drugs at risk of shortage shall manage inventory to ensure that drugs in the stockpile are efficiently cycled to the commercial market and—

"(i) may stockpile inventory at the eligible entity's distribution center with specified inventory amounts virtually reserved for the Federal Government with constant cycling to reduce product expiration; or

"(ii) may store stockpiled inventory separately in a different location and replace drugs in the stockpile inventory with the same drug with newer dating.

"(C) INSUFFICIENT FUNDS.—If amounts available to an eligible entity through contracts under this section are not sufficient to acquire

or maintain a 6-month supply of any drug in the stockpile of the eligible entity funded under this section, the eligible entity—

"(i) may acquire and maintain less than a 6-month supply, but in no case less than a 3-month supply; and

"(ii) shall submit a report to the Secretary identifying—

"(I) each such drug; and

"(II) the reasons why such amounts are not sufficient to acquire or maintain a 6-month supply.

"(D) ANNUAL AUDITS.—Not more than annually, the Secretary may request a physical audit count of the inventories of all eligible entities with a contract under this section to validate that each such entity is maintaining the appropriate amount of stockpiled inventory.

"(3) PERIODIC PRODUCT REVIEW.—

"(A) USE OF PROCEEDS.—An eligible entity with a contract under this section for a stockpile of generic drugs at risk of shortage shall use the proceeds of the sale of any drugs in the stockpile to purchase drugs for the stockpile in accordance with this section.

"(B) MARKET INFLATION OR DEFLATION.—In the case of market inflation or deflation affecting the price of a drug in the stockpile of an eligible entity maintained pursuant to a contract under this section, the contract shall ensure that the Federal Government does not profit or suffer loss on items of such drug as a result of such inflation or deflation.

"(4) REPORTING.—Each eligible entity with a contract under this section shall submit reports at such time and in such manner as the Secretary may require regarding—

"(A) current inventory levels of stockpiled drugs at a drug level;

"(B) indicators of current inventory levels of stockpiled drugs relative to acceptable minimums; and

"(C) such other matters as the Secretary determines appropriate.

"(f) CONTRACT TERMS.—

"(1) PAYMENT OF MONTHLY FEES FOR MANAGEMENT.—Subject to paragraph (2), the Secretary shall pay to each eligible entity with a contract under this section for a stockpile of generic drugs at

risk of shortage appropriate monthly fees for the management of the stockpile.

''(2) PAYMENT CONDITIONED ON STOCKPILE ADEQUACY.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), each contract with an eligible entity under this section shall provide that no payment under the contract may be made until the entity demonstrates to the Secretary that the entity has stockpiled such portion of the total quantity of drugs to be stockpiled under the contract as the Secretary determines to be acceptable for payment.

''(B) EXCEPTIONS FOR ADVANCE PAYMENTS.—

''(i) IN GENERAL.—A contract under this section may provide that, if the Secretary determines (in the Secretary's discretion) that an advance payment, partial payment for significant milestones, or payment to increase capacity is necessary to ensure success of the terms of the contract, the Secretary shall pay, in advance of delivery, an amount not to exceed 10 percent of the total contract amount to be

paid to the eligible entity by the Secretary pursuant to the contract over the full period of the contract.

''(ii) COST OF CAPITAL.—A contract under this section may provide for payments to compensate the contracting eligible entity for additional capital requirements related to the additional inventory to be maintained.

''(iii) TIMING.—The Secretary shall, to the extent practicable, make any determination under clause (i) to make an advance payment at the same time as the issuance of a solicitation.

''(iv) REPAYMENT.—If the Secretary makes an advance payment pursuant to clause (i), the Secretary shall require the eligible entity receiving such advance payment to repay it if there is a failure to perform by the eligible entity.

''(3) TERMINATION.—

''(A) IN GENERAL.—Subject to subparagraph (B), nothing in this section shall be construed as affecting the rights of eligible entities under provisions of statute or regulation (in-

cluding the Federal Acquisition Regulation) relating to the termination of contracts for the convenience of the Government.

''(B) LIQUIDATION OF STOCKPILE.—If a contract under this section is terminated, the eligible entity with the contract shall liquidate the drugs comprising the stockpile funded through the contract and return to the Government any amounts owed in relation to such drugs, but shall collect the management fees associated with such liquidation.

''(g) CONGRESSIONAL OVERSIGHT.—

''(1) INDEPENDENT EVALUATION AND REPORT.—Not later than 1 year after the date of enactment of this section and annually thereafter, the Comptroller General of the United States shall conduct an independent evaluation, and submit to the appropriate congressional committees a report, concerning the program under this section.

''(2) CONTENTS OF REPORT.—The report under paragraph (1) shall review, assess, and provide recommendations, as appropriate, on the following:

''(A) Details on likely costs and resultant savings as compared to a stockpiling method

that does not incorporate perpetual inventory cycling.

''(B) Identification of drawdowns from the stockpile, as evidence of market shortage avoidance.

''(C) The allocation of drugs included in the stockpiles funded pursuant to this section to the customers of the eligible entities with contracts under this section.

''(D) The degree to which eligible entities with contracts under this section fulfilled their obligations under such contracts.

''(h) DEFINITIONS.—In this section:

''(1) The term 'eligible entity' means an entity that meets each of the following criteria:

''(A) The entity is licensed or registered in accordance with applicable Federal and State law and in good standing with respect to such licensure or registration.

''(B) The entity agrees—

''(i) to purchase all drugs to be maintained in its stockpile funded under this section directly from the manufacturers of the drugs or the exclusive distributors of such manufacturers; or

"(ii) in the case of an entity that is a co-op or chain pharmacy warehouse—

"(I) to purchase drugs to be maintained in its stockpile funded under this section from an authorized distributor; and

"(II) distribute those drugs only to its member pharmacies.

"(C) The entity holds a verified authorized wholesale distributor certification issued by the National Association of Boards of Pharmacy.

"(D) The entity sells more than 90 percent of its drugs to dispensers.

"(E) The entity agrees to distribute inventory from its stockpile funded under this section only to dispensers that are customers of the entity.

"(2) The term 'generic drug at risk of shortage' means a drug (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act) that—

"(A) is approved pursuant to section 505(j) of such Act;

"(B) is included in the World Health Organization's most recent Model List of Essential Medicines;

''(C) is included, at any point during the preceding 36 months, on the drug shortage list in effect under section 506E of the Federal Food, Drug, and Cosmetic Act; and

''(D) is manufactured by 3 or fewer persons that are registered under section 510 of the Federal Food, Drug, and Cosmetic Act for purposes of such manufacture.

''(i) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $120,000,000 for fiscal years 2021 through 2023, to remain available until expended.''.

Subtitle E—National Centers of Excellence in Continuous Pharmaceutical Manufacturing

SEC. 2041. NATIONAL CENTERS OF EXCELLENCE IN CONTINUOUS PHARMACEUTICAL MANUFACTURING.

(a) IN GENERAL.—Section 3016 of the 21st Century Cures Act (21 U.S.C. 399h) is amended to read as follows:

"SEC. 3016. NATIONAL CENTERS OF EXCELLENCE IN CONTINUOUS PHARMACEUTICAL MANUFACTURING.

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

"(1) shall solicit and, beginning not later than one year after the date of enactment of the Commitment to Defeat the Virus and Keep America Healthy Act, receive requests from institutions of higher education to be designated as a National Center of Excellence in Continuous Pharmaceutical Manufacturing (in this section referred to as a 'National Center of Excellence') to support the advancement and development of continuous manufacturing; and

"(2) shall so designate any institution of higher education that—

"(A) requests such designation; and

"(B) meets the criteria specified in subsection (c).

"(b) REQUEST FOR DESIGNATION.—A request for designation under subsection (a) shall be made to the Secretary at such time, in such manner, and containing such information as the Secretary may require. Any such request shall include a description of how the institution of

higher education meets or plans to meet each of the criteria specified in subsection (c).

''(c) CRITERIA FOR DESIGNATION DESCRIBED.—The criteria specified in this subsection with respect to an institution of higher education are that the institution has, as of the date of the submission of a request under subsection (a) by such institution—

''(1) physical and technical capacity for research and development of continuous manufacturing;

''(2) manufacturing knowledge-sharing networks with other institutions of higher education, large and small pharmaceutical manufacturers, generic and nonprescription manufacturers, contract manufacturers, and other entities;

''(3) proven capacity to design and demonstrate new, highly effective technology for use in continuous manufacturing;

''(4) a track record for creating and transferring knowledge with respect to continuous manufacturing;

''(5) the potential to train a future workforce for research on and implementation of advanced manufacturing and continuous manufacturing; and

''(6) experience in participating in and leading a continuous manufacturing technology partnership with other institutions of higher education, large and small pharmaceutical manufacturers, generic and nonprescription manufacturers, contract manufacturers, and other entities—

''(A) to support companies with continuous manufacturing in the United States;

''(B) to support Federal agencies with technical assistance, which may include regulatory and quality metric guidance as applicable, for advanced manufacturing and continuous manufacturing;

''(C) with respect to continuous manufacturing, to organize and conduct research and development activities needed to create new and more effective technology, capture and disseminate expertise, create intellectual property, and maintain technological leadership;

''(D) to develop best practices for designing continuous manufacturing; and

''(E) to assess and respond to the workforce needs for continuous manufacturing, including the development of training programs if needed.

''(d) TERMINATION OF DESIGNATION.—The Secretary may terminate the designation of any National Center of Excellence designated under this section if the Secretary determines such National Center of Excellence no longer meets the criteria specified in subsection (c). Not later than 60 days before the effective date of such a termination, the Secretary shall provide written notice to the National Center of Excellence, including the rationale for such termination.

''(e) CONDITIONS FOR DESIGNATION.—As a condition of designation as a National Center of Excellence under this section, the Secretary shall require that an institution of higher education enter into an agreement with the Secretary under which the institution agrees—

''(1) to collaborate directly with the Food and Drug Administration to publish the reports required by subsection (g);

''(2) to share data with the Food and Drug Administration regarding best practices and research generated through the funding under subsection (f);

''(3) to develop, along with industry partners (which may include large and small biopharmaceutical manufacturers, generic and nonprescription manufacturers, and contract manufacturers) and another institution or institutions designated under

this section, if any, a roadmap for developing a continuous manufacturing workforce;

''(4) to develop, along with industry partners and other institutions designated under this section, a roadmap for strengthening existing, and developing new, relationships with other institutions; and

''(5) to provide an annual report to the Food and Drug Administration regarding the institution's activities under this section, including a description of how the institution continues to meet and make progress on the criteria listed in subsection (c).

''(f) FUNDING.—

''(1) IN GENERAL.—The Secretary shall award funding, through grants, contracts, or cooperative agreements, to the National Centers of Excellence designated under this section for the purpose of studying and recommending improvements to continuous manufacturing, including such improvements as may enable the Centers—

''(A) to continue to meet the conditions specified in subsection (e); and

''(B) to expand capacity for research on, and development of, continuing manufacturing.

''(2) CONSISTENCY WITH FDA MISSION.—As a condition on receipt of funding under this sub-

section, a National Center of Excellence shall agree to consider any input from the Secretary regarding the use of funding that would—

"(A) help to further the advancement of continuous manufacturing through the National Center of Excellence; and

"(B) be relevant to the mission of the Food and Drug Administration.

"(3) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection $80,000,000 for the period of fiscal years 2021 through 2025.

"(4) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as precluding a National Center for Excellence designated under this section from receiving funds under any other provision of this Act or any other Federal law.

"(g) ANNUAL REVIEW AND REPORTS.—

"(1) ANNUAL REPORT.—Beginning not later than one year after the date on which the first designation is made under subsection (a), and annually thereafter, the Secretary shall—

"(A) submit to Congress a report describing the activities, partnerships and collaborations, Federal policy recommendations, previous

and continuing funding, and findings of, and any other applicable information from, the National Centers of Excellence designated under this section; and

''(B) make such report available to the public in an easily accessible electronic format on the website of the Food and Drug Administration.

''(2) REVIEW OF NATIONAL CENTERS OF EXCELLENCE AND POTENTIAL DESIGNEES.—The Secretary shall periodically review the National Centers of Excellence designated under this section to ensure that such National Centers of Excellence continue to meet the criteria for designation under this section.

''(3) REPORT ON LONG-TERM VISION OF FDA ROLE.—Not later than 2 years after the date on which the first designation is made under subsection (a), the Secretary, in consultation with the National Centers of Excellence designated under this section, shall submit a report to the Congress on the long-term vision of the Department of Health and Human Services on the role of the Food and Drug Administration in supporting continuous manufacturing, including—

''(A) a national framework of principles related to the implementation and regulation of continuous manufacturing;

''(B) a plan for the development of Federal regulations and guidance for how advanced manufacturing and continuous manufacturing can be incorporated into the development of pharmaceuticals and regulatory responsibilities of the Food and Drug Administration; and

''(C) appropriate feedback solicited from the public, which may include other institutions, large and small biopharmaceutical manufacturers, generic and nonprescription manufacturers, and contract manufacturers.

''(h) DEFINITIONS.—In this section:

''(1) ADVANCED MANUFACTURING.—The term 'advanced manufacturing' means an approach for the manufacturing of pharmaceuticals that incorporates novel technology, or uses an established technique or technology in a new or innovative way (such as continuous manufacturing where the input materials are continuously transformed within the process by two or more unit operations) that enhances drug quality or improves the manufacturing process.

''(2) CONTINUOUS MANUFACTURING.—The term 'continuous manufacturing'—

''(A) means a process where the input materials are continuously fed into and transformed within the process, and the processed output materials are continuously removed from the system; and

''(B) consists of an integrated process that consists of a series of two or more unit operations.

''(3) INSTITUTION OF HIGHER EDUCATION.—The term 'institution of higher education' has the meaning given such term in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a)).

''(4) SECRETARY.—The term 'Secretary' means the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs.''.

(b) TRANSITION RULE.—Section 3016 of the 21st Century Cures Act (21 U.S.C. 399h), as in effect on the day before the date of the enactment of this section, shall apply with respect to grants awarded under such section before such date of enactment.

TITLE III—STRATEGIC NATIONAL STOCKPILE IMPROVEMENTS

Subtitle A—Stockpiling for America's Future Endeavors

SEC. 3001. STRATEGIC NATIONAL STOCKPILE.

Section 319F–2(a) of the Public Health Service Act (42 U.S.C. 247d–6b(a)) is amended by adding at the end the following:

''(6) ACCEPTANCE OF GIFTS.—

''(A) IN GENERAL.—The Secretary may, without further appropriation and without fiscal year limitation, accept, use, and dispose of gifts, bequests, or devises of money, services, or property, both real and personal, for the purpose of carrying out this subsection. Any such gift, bequest, or devise of money and proceeds from sales of other property received as a gift, bequest, or devise shall be deposited in the Treasury and shall be available for obligation and expenditure upon order of the Secretary.

''(B) LIMITATIONS.—

''(i) COMPROMISING INTEGRITY.—The Secretary may not accept a gift, bequest, or devise under this paragraph if the Sec-

retary determines that the use of the property or services would compromise the integrity or appearance of integrity of—

"(I) a program of the Department of Health and Human Services; or

"(II) an individual involved in a program of the Department.

"(ii) UNAPPROVED PRODUCTS.—The Secretary may accept a drug or device (as those terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act) as part of a gift, bequest, or devise under this paragraph only if such drug or device is—

"(I) a drug that is approved under section 505 of such Act, that meets the requirements for marketing under section 505G of such Act, or that is licensed under section 351 of this Act;

"(II) a device that is approved under section 515 of the Federal Food, Drug, and Cosmetic Act, that is classified under section 513(f)(2) of

such Act, that is licensed under section 351 of this Act, that is cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act, or for which a report is not required under such section 510(k);

''(III) authorized for emergency use in accordance with section 564 or 564A of the Federal Food, Drug, and Cosmetic Act or prepositioned for use in accordance with section 564B of such Act;

''(IV) authorized for investigational use under section 505, 512, or 520 of the Federal Food, Drug, and Cosmetic Act or section 351 of this Act;

''(V) determined by the Commissioner of Food and Drugs to be appropriate for use, without approval, licensure, authorization, or clearance, to respond to a shortage or potential shortage situation; or

''(VI) a respiratory protective device approved and determined to be a

priority, as described in section 319F–3(i)(1)(D) of this Act.

''(C) REPORT.—

''(i) IN GENERAL.—The Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate an annual report disclosing—

''(I) any gift, bequest, or devise that was accepted under this paragraph during the year covered by the report;

''(II) how the gifts, bequests, and devises contribute to the mission of the stockpile; and

''(III) the amount of Federal savings that were generated from the acceptance of the gifts, bequests, and devises.

''(ii) PUBLICATION.—Each report required under clause (i) shall be made publicly available.''.

Subtitle B—Stockpile Inventory Modernization

SEC. 3011. REIMBURSABLE TRANSFERS.

Section 319F–2(a) of the Public Health Service Act (42 U.S.C. 247d–6b(a)), as amended by section 3001, is further amended by adding at the end the following:

''(7) TRANSFERS AND REIMBURSEMENTS.—

''(A) IN GENERAL.—Without regard to chapter 5 of title 40, United States Code, the Secretary may transfer to any Federal department or agency, on a reimbursable basis, any drugs, vaccines and other biological products, medical devices, and other supplies in the stockpile if—

''(i) the transferred supplies are less than one year from expiry;

''(ii) the stockpile is able to replenish the supplies, as appropriate; and

''(iii) the Secretary decides the transfer is in the best interest of the United States Government.

''(B) USE OF REIMBURSEMENT.—Reimbursement derived from the transfer of supplies pursuant to subparagraph (A) may, to the extent and in the amounts made available in ad-

vance in appropriations Acts, be used by the Secretary to carry out this section. Funds made available pursuant to the preceding sentence are in addition to any other funds that may be made available for such purpose.

''(C) RULE OF CONSTRUCTION.—This paragraph shall not be construed to preclude transfers of products in the stockpile under other authorities.

''(D) REPORT.—Not later than September 30, 2022, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on each transfer made under this paragraph and the amount received by the Secretary in exchange for that transfer.

''(E) SUNSET.—The authority to make transfers under this paragraph shall cease to be effective on September 30, 2023.''.

Subtitle C—Equipment Maintenance

SEC. 3021. EQUIPMENT MAINTENANCE.

Section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b) is amended—

(1) in subsection (a)(3)—

(A) in subparagraph (I), by striking ''; and'' and inserting a semicolon;

(B) in subparagraph (J), by striking the period at the end and inserting a semicolon; and

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

''(K) ensure contents of the stockpile remain in good working order and, as appropriate, conduct maintenance services on contents of the stockpile; and''; and

(2) in subsection (c)(7)(B), by adding at the end the following new clause:

''(ix) EQUIPMENT MAINTENANCE SERVICE.—In carrying out this section, the Secretary may enter into contracts for the procurement of equipment maintenance services.''.

Subtitle D—Medical Supplies for Pandemics

SEC. 3031. SUPPLY CHAIN FLEXIBILITY MANUFACTURING PILOT.

(a) IN GENERAL.—Section 319F–2(a)(3) of the Public Health Service Act (42 U.S.C. 247d–6b(a)(3)), as

amended by section 3012, is further amended by adding at the end the following new subparagraph:

"(L) enhance medical supply chain elasticity and establish and maintain domestic reserves of critical medical supplies (including personal protective equipment, ancillary medical supplies, and other applicable supplies required for the administration of drugs, vaccines and other biological products, and other medical devices (including diagnostic tests)) by—

"(i) increasing emergency stock of critical medical supplies;

"(ii) geographically diversifying domestic production of such medical supplies, as appropriate;

"(iii) entering into cooperative agreements or partnerships with respect to manufacturing lines, facilities, and equipment for the domestic production of such medical supplies; and

"(iv) managing, either directly or through cooperative agreements with manufacturers and distributors, domestic reserves established under this subparagraph

by refreshing and replenishing stock of such medical supplies.''.

(b) REPORTING; SUNSET.—Section 319F–2(a) of the Public Health Service Act (42 U.S.C. 247d–6b(a)), as amended by section 3011, is further amended by adding at the end the following:

''(8) REPORTING.—Not later than September 30, 2022, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the details of each cooperative agreement or partnership entered into under paragraph (3)(L), including the amount expended by the Secretary on each such cooperative agreement or partnership.

''(9) SUNSET.—The authority to enter into cooperative agreements or partnerships pursuant to paragraph (3)(L) shall cease to be effective on September 30, 2023.''.

(c) FUNDING.—Section 319F–2(f) of the Public Health Service Act (42 U.S.C. 247d–6b(f)) is amended by adding at the end the following:

''(3) SUPPLY CHAIN ELASTICITY.—

''(A) IN GENERAL.—For the purpose of carrying out subsection (a)(3)(L), there is au-

thorized to be appropriated $500,000,000 for each of fiscal years 2021 through 2023, to remain available until expended.

''(B) RELATION TO OTHER AMOUNTS.—The amount authorized to be appropriated by subparagraph (A) for the purpose of carrying out subsection (a)(3)(L) is in addition to any other amounts available for such purpose.''.

Subtitle E—State Stockpile Readiness

SEC. 3041. GRANTS FOR STATE STRATEGIC STOCKPILES.

Title III of the Public Health Service Act is amended by inserting after section 319F–4 of such Act (42 U.S.C. 247d–6e) the following new section:

''SEC. 319F–5. GRANTS FOR STATE STRATEGIC STOCKPILES.

''(a) IN GENERAL.—The Secretary may establish a pilot program consisting of awarding grants to States to expand or maintain a strategic stockpile of commercially available drugs, devices, personal protective equipment, and other products deemed by the State to be essential in the event of a public health emergency.

''(b) ALLOWABLE USE OF FUNDS.—

''(1) USES.—A State receiving a grant under this section may use the grant funds to—

"(A) acquire commercially available products listed pursuant to paragraph (2) for inclusion in the State's strategic stockpile;

"(B) store, maintain, and distribute products in such stockpile; and

"(C) conduct planning in connection with such activities.

"(2) LIST.—The Secretary shall develop and publish a list of the products that are eligible, as described in subsection (a), for inclusion in a State's strategic stockpile using funds received under this section.

"(3) CONSULTATION.—In developing the list under paragraph (2) and otherwise determining the allowable uses of grant funds under this section, the Secretary shall consult with States and relevant stakeholders, including public health organizations.

"(c) FUNDING REQUIREMENT.—The Secretary may not obligate or expend any funds to award grants or fund any previously awarded grants under this section for a fiscal year unless the total amount made available to carry out section 319F–2 for such fiscal year is equal to or greater than the total amount of funds made available to carry out section 319F–2 for fiscal year 2020.

"(d) MATCHING FUNDS.—

''(1) IN GENERAL.—With respect to the costs of expanding and maintaining a strategic stockpile through a grant under this section, as a condition on receipt of the grant, a State shall make available (directly) non-Federal contributions in cash toward such costs in an amount that is equal to not less than the amount of Federal funds provided through the grant.

''(2) WAIVER.—The Secretary may waive the requirement of paragraph (1) with respect to a State for the first two years of the State receiving a grant under this section if the Secretary determines that such waiver is needed for the State to establish a strategic stockpile described in subsection (a).

''(e) TECHNICAL ASSISTANCE.—The Secretary shall provide technical assistance to States in establishing, expanding, and maintaining a stockpile described in subsection (a).

''(f) DEFINITION.—In this section, the term 'drug' has the meaning given to that term in section 201 of the Federal Food, Drug, and Cosmetic Act.

''(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $3,500,000,000 for each of fiscal years 2021 through 2023, to remain available until expended.

''(h) SUNSET.—The authority vested by this section terminates at the end of fiscal year 2023.''.

Subtitle F—Process Improvements and Reports

SEC. 3051. GAO STUDY ON THE FEASIBILITY AND BENEFITS OF USER FEE AGREEMENTS.

(a) IN GENERAL.—The Comptroller General of the United States shall conduct a study to investigate the feasibility of establishing user fees to offset certain Federal costs attributable to the procurement of single-source materials for the Strategic National Stockpile under section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b) and distributions of such materials from the Stockpile. In conducting this study, the Comptroller General shall consider, to the extent information is available—

(1) whether entities receiving such distributions generate profits from those distributions;

(2) any Federal costs attributable to such distributions;

(3) whether such user fees would provide the Secretary with funding to potentially offset procurement costs of such materials for the Strategic National Stockpile; and

(4) any other issues the Comptroller General identifies as relevant.

(b) REPORT.—Not later than February 1, 2023, the Comptroller General of the United States shall submit to the Congress a report on the findings and conclusions of the study under subsection (a).

SEC. 3052. ACTION REPORTING.

(a) IN GENERAL.—The Secretary of Health and Human Services or the Assistant Secretary for Preparedness and Response, in consultation with the Administrator of the Federal Emergency Management Agency, shall—

(1) not later than 30 days after the date of enactment of this Act, issue 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 regarding all State, local, Tribal, and territorial requests for supplies from the Strategic National Stockpile related to COVID–19; and

(2) not less than every 30 days thereafter through the end of the emergency period (as such term is defined in section 1135(g)(1)(B) of the Social Security Act (42 U.S.C. 1320b–5(g)(1)(B))), submit to such committees an updated version of such report.

(b) REPORTING PERIOD.—

(1) INITIAL REPORT.—The initial report under subsection (a) shall address all requests described in such subsection made during the period—

(A) beginning on January 31, 2020; and

(B) ending on the date that is 30 days before the date of submission of the report.

(2) UPDATES.—Each update to the report under subsection (a) shall address all requests described in such subsection made during the period—

(A) beginning at the end of the previous reporting period under this section; and

(B) ending on the date that is 30 days before the date of submission of the updated report.

(c) CONTENTS OF REPORT.—The report under subsection (a) (and updates thereto) shall include—

(1) the details of each request described in such subsection, including—

(A) the specific medical countermeasures, devices, personal protective equipment, and other materials requested; and

(B) the amount of such materials requested; and

(2) the outcomes of each request described in subsection (a), including—

(A) whether the request was wholly fulfilled, partially fulfilled, or denied;

(B) if the request was wholly or partially fulfilled, the fulfillment amount; and

(C) if the request was partially fulfilled or denied, a rationale for such outcome.

SEC. 3053. IMPROVED, TRANSPARENT PROCESSES.

(a) IN GENERAL.—Not later than January 1, 2021, the Secretary of Health and Human Services shall develop and implement improved, transparent processes for the use and distribution of drugs, vaccines and other biological products, medical devices, and other supplies (including personal protective equipment, ancillary medical supplies, and other applicable supplies required for the administration of drugs, vaccines and other biological products, medical devices, and diagnostic tests) in the Strategic National Stockpile under section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b) (in this section referred to as the ''Stockpile'').

(b) PROCESSES.—The processes developed under subsection (a) shall include—

(1) the form and manner in which States, localities, Tribes, and territories are required to submit requests for supplies from the Stockpile;

(2) the criteria used by the Secretary of Health and Human Services in responding to such requests, including the reasons for fulfilling or denying such requests;

(3) what circumstances result in prioritization of distribution of supplies from the Stockpile to States, localities, Tribes, or territories;

(4) clear plans for future, urgent communication between the Secretary and States, localities, Tribes, and territories regarding the outcome of such requests; and

(5) any differences in the processes developed under subsection (a) for geographically related emergencies, such as weather events, and national emergencies, such as pandemics.

(c) CLASSIFICATION.—The processes developed under subsection (a) shall be unclassified to the greatest extent possible consistent with national security. The Secretary of Health and Human Services may classify portions of such processes as necessary to protect national security.

(d) REPORT TO CONGRESS.—Not later than January 1, 2021, the Secretary of Health and Human Services shall—

(1) 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 regarding the improved, transparent processes developed under this section;

(2) include in such report recommendations for opportunities for communication (by telebriefing, phone calls, or in-person meetings) between the Secretary and States, localities, Tribes, and territories regarding such improved, transparent processes; and

(3) submit such report in unclassified form to the greatest extent possible, except that the Secretary may include a classified appendix if necessary to protect national security.

Subtitle G—Strategic National Stockpile Funding

SEC. 3061. AUTHORIZATION OF APPROPRIATIONS.

Section 319F–2(f)(1) of the Public Health Service Act (42 U.S.C. 247d–6b(f)(1)) is amended by striking ''$610,000,000 for each of fiscal years 2019 through 2023'' and inserting ''$705,000,000 for each of fiscal years 2021 through 2023''.

TITLE IV—PUBLIC HEALTH INFRASTRUCTURE IMPROVEMENTS

Subtitle A—Public Health Infrastructure Modernization

SEC. 4001. PUBLIC HEALTH DATA SYSTEM TRANSFORMATION.

Subtitle C of title XXVIII of the Public Health Service Act (42 U.S.C. 300hh–31 et seq.) is amended by adding at the end the following:

"SEC. 2822. PUBLIC HEALTH DATA SYSTEM TRANSFORMATION.

''(a) EXPANDING CDC AND PUBLIC HEALTH DEPARTMENT CAPABILITIES.—

''(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall—

''(A) conduct activities to expand, enhance, and improve public health data systems used by the Centers for Disease Control and Prevention, related to the interoperability and improvement of such systems (including with respect to preparedness for, prevention and detection of, and response to public health emergencies); and

"(B) award grants or cooperative agreements to State, local, Tribal, or territorial public health departments for the expansion and modernization of public health data systems, to assist public health departments in—

"(i) assessing current data infrastructure capabilities and gaps to improve consistency in data collection, storage, and analysis, and as appropriate to improve dissemination of public health-related information;

"(ii) improving secure public health data collection, transmission, exchange, maintenance, and analysis;

"(iii) improving the secure exchange of data between the Centers for Disease Control and Prevention, State, local, Tribal, and territorial public health departments, public health organizations, and health care providers, including—

"(I) between public health officials in multiple jurisdictions within a State; and

"(II) by simplifying and supporting reporting by health care pro-

viders pursuant to State law, including through the use of health information technology;

''(iv) enhancing the interoperability of public health data systems (including systems created or accessed by public health departments) with health information technology, including with health information technology certified under section 3001(c)(5);

''(v) supporting and training public health data systems, data science, and informatics personnel;

''(vi) supporting earlier disease and health condition detection, such as through near real-time data monitoring, to support rapid public health responses;

''(vii) supporting activities within the applicable jurisdiction related to the expansion and modernization of electronic case reporting; and

''(viii) developing and disseminating information related to the use and importance of public health data.

''(2) DATA STANDARDS.—In carrying out paragraph (1), the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall, as appropriate and in coordination with the Office of the National Coordinator for Health Information Technology, designate data and technology standards (including standards for interoperability) for public health data systems, with deference given to standards published by consensus-based standards development organizations with public input and voluntary consensus-based standards bodies.

''(3) PUBLIC-PRIVATE PARTNERSHIPS.—The Secretary may develop and utilize public-private partnerships for technical assistance, training, and related implementation support for State, local, Tribal, and territorial public health departments, and the Centers for Disease Control and Prevention, on the expansion and modernization of electronic case reporting and public health data systems, as applicable.

''(b) REQUIREMENTS.—

''(1) HEALTH INFORMATION TECHNOLOGY STANDARDS.—The Secretary may not award a grant or cooperative agreement under subsection (a)(1)(B)

unless the applicant uses or agrees to use standards endorsed by the National Coordinator for Health Information Technology pursuant to section 3001(c)(1) or adopted by the Secretary under section 3004.

''(2) WAIVER.—The Secretary may waive the requirement under paragraph (1) with respect to an applicant if the Secretary determines that the activities under subsection (a)(1)(B) cannot otherwise be carried out within the applicable jurisdiction.

''(3) APPLICATION.—A State, local, Tribal, or territorial health department applying for a grant or cooperative agreement under this section shall submit an application to the Secretary at such time and in such manner as the Secretary may require. Such application shall include information describing—

''(A) the activities that will be supported by the grant or cooperative agreement; and

''(B) how the modernization of the public health data systems involved will support or impact the public health infrastructure of the health department, including a description of remaining gaps, if any, and the actions needed to address such gaps.

''(c) STRATEGY AND IMPLEMENTATION PLAN.—Not later than 180 days after the date of enactment of this section, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a coordinated strategy and an accompanying implementation plan that identifies and describes the measures the Secretary will utilize to—

''(1) update and improve public health data systems used by the Centers for Disease Control and Prevention; and

''(2) carry out the activities described in this section to support the improvement of State, local, Tribal, and territorial public health data systems.

''(d) CONSULTATION.—In carrying out this section, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall consult with State, local, Tribal, and territorial public health departments, professional medical and public health associations, associations representing hospitals or other health care entities, health information technology experts, and other appropriate public or private entities.

''(e) REPORT TO CONGRESS.—Not later than 1 year after the date of enactment of this section, the Secretary shall submit a 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 that includes—

''(1) a description of any barriers to—

''(A) public health authorities implementing interoperable public health data systems and electronic case reporting;

''(B) the exchange of information pursuant to electronic case reporting; or

''(C) reporting by health care providers using such public health data systems, as appropriate, and pursuant to State law;

''(2) an assessment of the potential public health impact of implementing electronic case reporting and interoperable public health data systems; and

''(3) a description of the activities carried out pursuant to this section.

''(f) ELECTRONIC CASE REPORTING.—In this section, the term 'electronic case reporting' means the automated identification, generation, and bilateral exchange of reports of health events among electronic health record or

health information technology systems and public health authorities.

''(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $100,000,000 for each of fiscal years 2021 through 2025.''.

Subtitle B—Modernizing Infectious Disease Data Collection

SEC. 4011. MODERNIZING INFECTIOUS DISEASE DATA COLLECTION.

(a) IMPROVING INFECTIOUS DISEASE DATA COLLECTION.—Section 319D of the Public Health Service Act (42 U.S.C. 247d–4) is amended—

(1) in subsection (c)—

(A) in paragraph (3)(A)(iv), by inserting ''(such as commercial, academic, and other hospital laboratories)'' after ''clinical laboratories'';

(B) in paragraph (5)—

(i) in subparagraph (A)—

(I) in the matter preceding clause (i), by striking ''and operating'' and inserting '', operating, and updating'';

(II) in clause (iv), by striking ''and'' at the end;

(III) in clause (v), by striking the period and inserting ''; and''; and

(IV) by adding at the end the following:

''(vi) integrate and update applicable existing Centers for Disease Control and Prevention data systems and networks in collaboration with State, local, tribal, and territorial public health officials, including public health surveillance and disease detection systems.''; and

(ii) in subparagraph (B)—

(I) in clause (i), by inserting ''and 60 days after the date of enactment of the Commitment to Defeat the Virus and Keep America Healthy Act'' after ''Innovation Act of 2019'';

(II) in clause (ii), by inserting ''epidemiologists, clinical microbiologists, pathologists and laboratory experts, experts in health information technology, privacy, and data security'' after ''forecasting);''; and

(III) in clause (iii)—

(aa) in subclause (V), by striking ''and'' at the end;

(bb) in subclause (VI), by striking the period; and

(cc) by adding at the end the following:

''(VII) strategies to integrate laboratory and epidemiology systems and capabilities to conduct rapid and accurate laboratory tests;

''(VIII) strategies to improve the collection and reporting of appropriate, aggregated, deidentified demographic data to inform responses to public health emergencies, including identification of at-risk populations and to address health disparities; and

''(IX) strategies to improve the electronic exchange of health information between State and local health departments and health care providers and facilities to improve public health surveillance.''; and

(C) in paragraph (6)—

(i) in subparagraph (A)—

(I) in clause (iii)—

(aa) in subclause (III), by striking ''and'' at the end;

(bb) in subclause (IV), by inserting '', including the ability to conduct and report on rapid and accurate laboratory testing during a public health emergency'' before the semicolon; and

(cc) by adding at the end the following:

''(V) improve coordination and collaboration, as appropriate, with other Federal departments; and

''(VI) implement applicable lessons learned from recent public health emergencies to address gaps in situational awareness and biosurveillance capabilities, including an evaluation of ways to improve the collection and reporting of aggregated, deidentified demographic data to inform public health preparedness and response'';

(II) in clause (iv), by striking ''and'' at the end;

(III) in clause (v), by striking the period and inserting ''including a description of how such steps will further the goal of improving awareness of and timely responses to emerging infectious disease threats; and''; and

(IV) by adding at the end the following:

''(vi) identifies and demonstrates measurable steps the Secretary will take to further develop and integrate infectious disease detection, including expanding capabilities to conduct rapid and accurate diagnostic laboratory testing during a public health emergency, and improve coordination and collaboration with State, local, Tribal, and territorial public health officials, clinical laboratories (including commercial, hospital and academic laboratories), and other entities with expertise in public health surveillance.''; and

(ii) by redesignating subparagraph (B) as subparagraph (C); and

(iii) by inserting after subparagraph (A), the following:

"(B) REPORTS.—

"(i) IN GENERAL.—Not later than 1 month after date of enactment of the Commitment to Defeat the Virus and Keep America Healthy Act, and as provided for in clause (ii), the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report on the status of the Department of Health and Human Services' biosurveillance modernization and assessment progress with respect to emerging infectious disease threats.

"(ii) ADDITIONAL REPORTS.—During the 2-year period beginning on the date of enactment of the Commitment to Defeat the Virus and Keep America Healthy Act, the Secretary shall provide additional reports under clause (i) every 90 days after the submission of the initial report under such clause. The Secretary shall provide such reports annually thereafter. The Secretary may provide such additional reports

less frequently, but not less frequently than every 180 days, during an ongoing public health emergency or another significant infectious disease outbreak.'';

(2) in subsection (d)—

(A) in paragraph (2)(C), by inserting '', including any public-private partnerships entered into to improve such capacity'' before the semicolon; and

(B) in paragraph (3)—

(i) in subparagraph (B), by striking ''and'' at the end;

(ii) in subparagraph (C), by striking the period and inserting ''; and''; and

(iii) by adding at the end the following:

''(D) may establish, enhance, or maintain a system or network for the collection of data to provide for early detection of infectious disease outbreaks, near real-time access to relevant electronic data and integration of electronic data and information from public health and other appropriate sources, such as laboratories, hospitals, and epidemiology systems, to enhance the capability to conduct rapid and ac-

curate diagnostic laboratory tests to provide for disease detection.'';

(3) in subsection (f)(1)(A), by inserting ''pathologists, clinical microbiologists, laboratory professionals, epidemiologists,'' after ''forecasting),''; and

(4) in subsection (h), by adding at the end the following: ''Such evaluation shall include identification of any gaps in biosurveillance and situational awareness capabilities identified related to recent public health emergencies, any immediate steps taken to address such gaps, and any long-term plans to address such gaps, including steps related to activities authorized under this section.''.

(b) NATIONAL HEALTH SECURITY STRATEGY.—Section 2802(b)(2) of the Public Health Service Act (42 U.S.C. 300hh–1(b)(2)) is amended—

(1) in subparagraph (A), by inserting ''such as by integrating laboratory and epidemiology systems and capability to conduct rapid and accurate laboratory tests,'' after ''detection, identification,''; and

(2) in subparagraph (B), by inserting ''laboratory testing,'' after ''services and supplies,''.

(c) EPIDEMIOLOGY-LABORATORY CAPACITY GRANTS.—Section 2821(a) of the Public Health Service Act (42 U.S.C. 300hh–31(a)) is amended—

(1) in paragraph (3), by striking ''and'';

(2) in paragraph (4), by striking the period and inserting ''; and''; and

(3) by adding at the end the following:

''(5) supporting activities of State and local public health departments related to biosurveillance and disease detection, which may include activities related to section 319D, as appropriate.''.

Subtitle C—Diagnostic Testing for Public Health Labs

SEC. 4021. GRANTS FOR PUBLIC HEALTH LABORATORIES TO ACQUIRE HIGH-THROUGHPUT DIAGNOSTIC EQUIPMENT.

Section 2821 of the Public Health Service Act (42 U.S.C. 300hh–31) is amended—

(1) by redesignating subsection (b) as subsection (c);

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

''(b) GRANTS FOR PUBLIC HEALTH LABORATORIES TO ACQUIRE HIGH-THROUGHPUT DIAGNOSTIC EQUIPMENT.—

''(1) GRANTS.—The Secretary shall award grants to eligible entities to assist such entities in purchasing high-throughput diagnostic equipment

and related supplies and in hiring and training staff to use such equipment.

''(2) ELIGIBILITY.—To be eligible for a grant under paragraph (1), an entity shall—

''(A) be—

''(i) a State, local, or Tribal public health laboratory;

''(ii) a laboratory within a public health laboratory network coordinated or managed by the Centers for Disease Control and Prevention;

''(iii) a laboratory not described in clause (i) or (ii) that the Secretary determines (at the Secretary's discretion) provides population-based testing for the prevention and control of infectious, communicable, genetic, or chronic diseases; or

''(iv) a consortium of 2 or more entities described in any of clauses (i) through (iii); and

''(B) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may reasonably require.

''(3) USE OF FUNDS.—Amounts received through a grant under this subsection shall be used—

''(A) to purchase high-throughput diagnostic equipment and such materials as are necessary to administer, store, and process applicable tests, including diagnostic and serological tests; and

''(B) to hire and train staff to use such equipment.

''(4) AMOUNT OF GRANT.—The amount of a grant under paragraph (1) may not exceed $2,000,000, except in the case of eligible entity described in paragraph (2)(A)(iv).

''(5) HIGH-THROUGHPUT DIAGNOSTIC EQUIPMENT DEFINED.—In this subsection, the term 'high-throughput diagnostic equipment' means legally marketed equipment and supplies capable of performing multichannel analysis for use in clinical laboratory diagnostic testing.''; and

(3) in subsection (c), as so redesignated—

(A) by redesignating paragraphs (1), (2), and (3) as subparagraphs (A), (B), and (C), respectively, and moving the margin of each such redesignated subparagraph 2 ems to the right;

(B) by striking ''There are authorized to be appropriated to carry out this section'' and inserting the following:

''(1) IN GENERAL.—There are authorized to be appropriated to carry out subsection (a)''; and

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

''(2) AUTHORIZATION OF APPROPRIATIONS.—

''(A) IN GENERAL.—For the purpose of carrying out subsection (b), there is authorized to be appropriated $250,000,000 for fiscal year 2021, to remain available until expended.

''(B) ADMINISTRATIVE EXPENSES.—Of the amount made available to carry out subsection (b) for any fiscal year, the Secretary may not use more than 5 percent of such amount for the expenses of administering subsection (b).''.

Subtitle D—Rapid Testing for Communities

SEC. 4031. GRANTS FOR SAME-DAY POINT-OF-CARE CLINICAL LABORATORY DIAGNOSTIC TESTING IN COMMUNITIES.

Section 2821 of the Public Health Service Act (42 U.S.C. 300hh–31) is amended—

(1) by redesignating subsection (c), as redesignated by section 4021, as subsection (d);

(2) by inserting after subsection (b), as added by section 4021, the following new subsection:

''(c) GRANTS FOR SAME-DAY POINT-OF-CARE CLINICAL LABORATORY DIAGNOSTIC TESTING IN COMMUNITIES.—

''(1) GRANTS.—The Secretary shall award grants to eligible entities to assist such entities in acquiring legally marketed equipment and supplies capable of performing same-day clinical laboratory diagnostic testing in a point-of-care setting.

''(2) ELIGIBILITY.—To be eligible for a grant under paragraph (1), an entity shall—

''(A) be—

''(i) a hospital;

''(ii) a primary care facility;

''(iii) a clinic;

''(iv) a physician; or

''(v) another type of health care provider as the Secretary may define; and

''(B) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may reasonably require.

''(3) USE OF FUNDS.—Amounts received through a grant under this subsection shall be used to purchase legally marketed rapid diagnostic equipment and such materials as are necessary to administer, store, and process same-day clinical laboratory diagnostic testing in a point-of-care setting, including diagnostic and serological tests.

''(4) AMOUNT OF GRANT.—The amount of a grant under paragraph (1) may not exceed $20,000.

''(5) PRIORITY IN MAKING AWARDS.—In awarding grants under paragraph (1), the Secretary shall give priority to eligible entities providing services to—

''(A) medically underserved populations (as defined in section 330(b)(3)) in rural areas; and

''(B) all other areas.''; and

(3) by adding at the end of subsection (d), as redesignated, the following new paragraph:

''(3) AUTHORIZATION OF APPROPRIATIONS.—

''(A) IN GENERAL.—For the purpose of carrying out subsection (c), there is authorized to be appropriated $500,000,000 for fiscal year 2021, to remain available until expended.

''(B) ADMINISTRATIVE EXPENSES.—Of the amount made available to carry out subsection

(c) for any fiscal year, the Secretary may not use more than 5 percent of such amount for the expenses of administering this section.''.

Subtitle E—Public Health Workforce Loan Repayment

SEC. 4041. PUBLIC HEALTH WORKFORCE LOAN REPAYMENT PROGRAM.

Part D of title III of the Public Health Service Act (42 U.S.C. 254b et seq.), as amended by section 2031, is further amended by adding at the end the following new subpart:

''Subpart XIV—Public Health Workforce

''SEC. 340K. LOAN REPAYMENT PROGRAM.

''(a) ESTABLISHMENT.—The Secretary of Health and Human Services shall establish a program to be known as the Public Health Workforce Loan Repayment Program (referred to in this section as the 'Program') to assure an adequate supply of and encourage recruitment of public health professionals to eliminate critical public health workforce shortages in local, State, and Tribal public health agencies.

''(b) ELIGIBILITY.—To be eligible to participate in the Program, an individual shall—

''(1)(A) be accepted for enrollment, or be enrolled, as a student in an accredited academic edu-

cational institution in a State or territory in the final year of a course of study or program leading to a public health or health professions degree or certificate and have accepted employment with a local, State, or Tribal public health agency, or a related training fellowship, as recognized by the Secretary, to commence upon graduation; or

''(B)(i) have graduated, during the preceding 10-year period, from an accredited educational institution in a State or territory and received a public health or health professions degree or certificate; and

''(ii) be employed by, or have accepted employment with, a local, State, or Tribal public health agency or a related training fellowship, as recognized by the Secretary;

''(2) be a United States citizen;

''(3)(A) submit an application to the Secretary to participate in the Program; and

''(B) execute a written contract as required in subsection (c); and

''(4) not have received, for the same service, a reduction of loan obligations under section 428J, 428K, 428L, 455(m), or 460 of the Higher Edu-

cation Act of 1965 (20 U.S.C. 1078–10, 1078–11, 1078–12, 1087e(m), and 1087j).

''(c) CONTRACT.—The written contract referred to in subsection (b)(3)(B) between the Secretary and an individual shall contain—

''(1) an agreement on the part of the Secretary that the Secretary will repay, on behalf of the individual, loans incurred by the individual in the pursuit of the relevant degree or certificate in accordance with the terms of the contract;

''(2) an agreement on the part of the individual that the individual will serve in the full-time employment of a local, State, or Tribal public health agency or a related fellowship program in a position related to the course of study or program for which the contract was awarded for a period of time equal to the greater of—

''(A) 3 years; or

''(B) such longer period of time as determined appropriate by the Secretary and the individual;

''(3) an agreement, as appropriate, on the part of the individual to relocate to a priority service area (as determined by the Secretary) in exchange for an

additional loan repayment incentive amount to be determined by the Secretary;

''(4) a provision that any financial obligation of the United States arising out of a contract entered into under this section and any obligation of the individual that is conditioned thereon, is contingent on funds being appropriated for loan repayments under this section;

''(5) a statement of the damages to which the United States is entitled, under this section for the individual's breach of the contract; and

''(6) such other statements of the rights and liabilities of the Secretary and of the individual as the Secretary determines appropriate, not inconsistent with this section.

''(d) PAYMENTS.—

''(1) IN GENERAL.—A loan repayment provided for an individual under a written contract referred to in subsection (b)(3)(B) shall consist of payment, in accordance with paragraph (2), on behalf of the individual of the principal, interest, and related expenses on government and commercial loans received by the individual regarding the undergraduate or graduate education of the individual (or both), which

loans were made for tuition expenses incurred by the individual.

''(2) PAYMENTS FOR YEARS SERVED.—For each year of service that an individual contracts to serve pursuant to subsection (c)(2), the Secretary may pay not more than $35,000 on behalf of the individual for loans described in paragraph (1). With respect to participants under the Program whose total eligible loans are less than $105,000, the Secretary shall pay an amount that does not exceed ⅓ of the eligible loan balance for each year of such service of such individual.

''(3) TAX LIABILITY.—For the purpose of providing reimbursements for tax liability resulting from payments under paragraph (2) on behalf of an individual, the Secretary shall, in addition to such payments, make payments to the individual in an amount not to exceed 39 percent of the total amount of loan repayments made for the taxable year involved.

''(e) POSTPONING OBLIGATED SERVICE.—With respect to an individual receiving a degree or certificate from a health professions or other related school, the date of the initiation of the period of obligated service may be postponed as approved by the Secretary.

''(f) BREACH OF CONTRACT.—An individual who fails to comply with the contract entered into under subsection (c) shall be subject to the same financial penalties as provided for under section 338E of the Public Health Service Act (42 U.S.C. 254o) for breaches of loan repayment contracts under section 338B of such Act (42 U.S.C. section 254l–1).

''(g) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section—

''(1) $100,000,000 for fiscal year 2021; and

''(2) $75,000,000 for each of fiscal years 2022 through 2026.''.

Subtitle F—Vaccine Awareness and Disease Prevention

SEC. 4051. IMPROVING AWARENESS OF DISEASE PREVENTION.

(a) IN GENERAL.—The Public Health Service Act is amended by striking section 313 of such Act (42 U.S.C. 245) and inserting the following:

''SEC. 313. PUBLIC AWARENESS CAMPAIGN ON THE IMPORTANCE OF VACCINATIONS.

''(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in coordination with other offices and agencies, as appropriate, shall award competitive grants or

contracts to one or more public or private entities to carry out a national, evidence-based campaign to increase awareness and knowledge of the safety and effectiveness of vaccines for the prevention and control of diseases, combat misinformation about vaccines, and disseminate scientific and evidence-based vaccine-related information, with the goal of increasing rates of vaccination across all ages, as applicable, particularly in communities with low rates of vaccination, to reduce and eliminate vaccine-preventable diseases.

''(b) CONSULTATION.—In carrying out the campaign under this section, the Secretary shall consult with appropriate public health and medical experts, including the National Academy of Medicine and medical and public health associations and nonprofit organizations, in the development, implementation, and evaluation of the evidence-based public awareness campaign.

''(c) REQUIREMENTS.—The campaign under this section shall—

''(1) be a nationwide, evidence-based media and public engagement initiative;

''(2) include the development of resources for communities with low rates of vaccination, including culturally and linguistically appropriate resources, as applicable;

''(3) include the dissemination of vaccine information and communication resources to public health departments, health care providers, and health care facilities, including such providers and facilities that provide prenatal and pediatric care;

''(4) be complementary to, and coordinated with, any other Federal, State, local, or Tribal efforts, as appropriate; and

''(5) assess the effectiveness of communication strategies to increase rates of vaccination.

''(d) ADDITIONAL ACTIVITIES.—The campaign under this section may—

''(1) include the use of television, radio, the internet, and other media and telecommunications technologies;

''(2) include the use of in-person activities;

''(3) be focused to address specific needs of communities and populations with low rates of vaccination; and

''(4) include the dissemination of scientific and evidence-based vaccine-related information, such as—

''(A) advancements in evidence-based research related to diseases that may be prevented by vaccines and vaccine development;

"(B) information on vaccinations for individuals and communities, including individuals for whom vaccines are not recommended by the Advisory Committee for Immunization Practices, and the effects of low vaccination rates within a community on such individuals;

"(C) information on diseases that may be prevented by vaccines; and

"(D) information on vaccine safety and the systems in place to monitor vaccine safety.

"(e) EVALUATION.—The Secretary shall—

"(1) establish benchmarks and metrics to quantitatively measure and evaluate the awareness campaign under this section;

"(2) conduct qualitative assessments regarding the awareness campaign under this section; and

"(3) prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and Committee on Energy and Commerce of the House of Representatives an evaluation of the awareness campaign under this section.

"(f) SUPPLEMENT NOT SUPPLANT.—Funds appropriated under this section shall be used to supplement and not supplant other Federal, State, and local public funds provided for activities described in this section.

"(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section and subsections (k) and (n) of section 317 $10,000,000 for each of fiscal years 2021 through 2025.".

(b) GRANTS TO ADDRESS VACCINE-PREVENTABLE DISEASES.—Section 317 of the Public Health Service Act (42 U.S.C. 247b) is amended—

(1) in subsection (k)(1)—

(A) in subparagraph (C), by striking "; and" and inserting a semicolon;

(B) in subparagraph (D), by striking the period and inserting a semicolon; and

(C) by adding at the end the following:

"(E) planning, implementation, and evaluation of activities to address vaccine-preventable diseases, including activities to—

"(i) identify communities at high risk of outbreaks related to vaccine-preventable diseases, including through improved data collection and analysis;

"(ii) pilot innovative approaches to improve vaccination rates in communities and among populations with low rates of vaccination;

''(iii) reduce barriers to accessing vaccines and evidence-based information about the health effects of vaccines;

''(iv) partner with community organizations and health care providers to develop and deliver evidence-based interventions, including culturally and linguistically appropriate interventions, to increase vaccination rates;

''(v) improve delivery of evidence-based, vaccine-related information to parents and others; and

''(vi) improve the ability of State, local, Tribal, and territorial public health departments to engage communities at high risk for outbreaks related to vaccine-preventable diseases, in coordination, as appropriate, with local educational agencies, as defined in section 8101 of the Elementary and Secondary Education Act of 1965; and

''(F) research related to strategies for improving awareness of scientific and evidence-based, vaccine-related information, including for communities with low rates of vaccination, in

order to understand barriers to vaccination, improve vaccination rates, and assess the public health outcomes of such strategies.''; and

(2) by adding at the end the following:

''(n) VACCINATION DATA.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall expand and enhance, and, as appropriate, establish and improve, programs and conduct activities to collect, monitor, and analyze vaccination coverage data to assess levels of protection from vaccine-preventable diseases, including by assessing factors contributing to underutilization of vaccines and variations of such factors, and identifying communities at high risk of outbreaks associated with vaccine-preventable diseases.''.

(c) SUPPLEMENTAL GRANT FUNDS.—Section 330(d)(1) of the Public Health Service Act (42 U.S.C. 254b) is amended—

(1) in subparagraph (F), by striking ''and'' at the end;

(2) in subparagraph (G), by striking the period and inserting ''; and''; and

(3) by adding at the end the following:

''(H) improving access to recommended immunizations.''.

(d) UPDATE OF 2015 NVAC REPORT.—The National Vaccine Advisory Committee established under section 2105 of the Public Health Service Act (42 U.S.C. 300aa–5) shall, as appropriate, update the report entitled, ''Assessing the State of Vaccine Confidence in the United States: Recommendations from the National Vaccine Advisory Committee'', approved by the National Vaccine Advisory Committee on June 10, 2015, with respect to factors affecting childhood vaccination.

Subtitle G—Protecting the Health of America's Older Adults During COVID–19 & Beyond

SEC. 4061. NATIONAL COVID–19 RESOURCE CENTER FOR OLDER ADULTS.

(a) IN GENERAL.—The Secretary of Health and Human Services (in this subtitle referred to as the ''Secretary'') shall establish within the Office of the Assistant Secretary for Health a National COVID–19 Resource Center for Older Adults (in this section referred to as the ''Center'') to identify, curate, and disseminate, promising and proven practices and tools for the care of older adults in their homes, community-based care settings, hospitals, and nursing and acute care facilities.

(b) INVOLVEMENT BY FEDERAL DEPARTMENTS AND ALL LEVELS OF GOVERNMENT.—The Center shall—

(1) be advised by a team of senior officials from—

(A) agencies across the Department of Health and Human Services, including the Administration for Community Living (including the Administration on Aging), the Centers for Disease Control and Prevention, the Centers for Medicare & Medicaid Services, the Health Resources and Services Administration, the Indian Health Service, and the Office of Minority Health in the Office of the Secretary; and

(B) other Federal departments, including the Department of Housing and Urban Development and the Department of Veterans Affairs; and

(2) collaborate with State and local governments, Indian tribes and Tribal organizations, and nonprofit organizations.

(c) ACTIVITIES.—The Center shall perform the following activities:

(1) Develop a set of best practices for older adult health and well-being during and beyond the period of the COVID–19 pandemic, including such best practices with respect to the following focus areas:

(A) Providing specialized services to overcome the risks associated with social isolation, such as additional resources for home-delivered meals and other nutrition programs to provide not only food but also face-to-face interactions.

(B) Streamlining and improving access to screening, testing, and health care services and resources, and prioritizing venues older adults can reach.

(C) Expanding the use of telemedicine, including the provision of technology to execute televisits that safely and comprehensively address older adults' health care needs.

(D) Supporting family caregivers, including those with additional responsibilities for homebound individuals.

(E) Reducing disparities among underserved populations.

(F) Developing cross-sector collaborative efforts.

(2) Create and disseminate tools, technical assistance, training, and funding to State, local, Tribal, and territorial governments to adopt best practices developed under subparagraphs (E) and (F) of paragraph (1).

(3) Establish mechanisms for providing training and technical assistance to State, local, Tribal, and territorial governments to ensure that complementary cross-sector activities are replicated at the State, local, Tribal, and territorial levels.

(4) Facilitate the development of learning networks of practitioners at the hospital, nursing facility, and community levels to disseminate the best practices developed under paragraph (1) and ensure implementation of such best practices to reduce morbidity and mortality of older adults affected by COVID–19.

(5) Identify and disseminate approaches that strengthen public health and health care system capacity to serve older Americans with regard to health issues during and beyond the COVID–19 pandemic.

SEC. 4062. HEALTHY AGING PROGRAM.

(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish a Healthy Aging Program for the purpose of promoting the health and well-being of older adults by—

(1) improving the coordination of public health interventions that promote the health and well-being of older adults;

(2) disseminating and implementing evidence-based best practices and programs with respect to promoting the health and well-being of older adults; and

(3) coordinating multisectoral efforts to promote the health and well-being of older adults across governmental and nongovernmental health and related agencies.

(b) ACTIVITIES.—For the purpose described in subsection (a), the Secretary shall design the Healthy Aging Program to carry out the following activities:

(1) Regularly assess the health-related needs of older adults and promote policies addressing those needs through evidence-based public health interventions to promote overall health and well-being among older adults and reduce health care costs.

(2) Identify disparities in health among vulnerable populations of older adults.

(3) Identify gaps in existing public health programs and policies that focus on older adults.

(4) Promote public health partnerships with aging and other sector stakeholders to ensure non-

duplication of efforts and increase efficiency by working collaboratively across sectors.

(5) Work with multisectoral agencies to improve emergency preparedness plans and activities for vulnerable older adult populations.

(6) Coordinate efforts to promote the health of older adults with the Administration for Community Living, other Federal departments and agencies, and nonprofit organizations.

(7) Identify resources and evidence-based programs available to local and State health departments, including resources and programs that could be coordinated across sectors, to address the health and well-being of older adults.

(c) GRANTS TO HEALTH DEPARTMENTS.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall award grants or cooperative agreements to eligible health departments to carry out any of the following activities:

(1) Improving availability of data on the older adult population, including through data-sharing with elder affairs agencies.

(2) Linking the health care sector with the community services sector (including aging services

and supports) to coordinate and promote community-based prevention services.

(3) Ensuring that State and local emergency preparedness plans and activities address the special needs of older adults, particularly the most vulnerable populations.

(4) Training State and local public health personnel to implement or adapt evidence-based and innovative health promotion and disease prevention programs and policies.

(5) Improving community conditions and addressing social determinants to promote health and well-being and foster independence among older adults, such as efforts to advance age-friendly communities and dementia-friendly communities.

(d) TECHNICAL ASSISTANCE.—The Secretary shall (directly or through grants, cooperative agreements, or contracts) provide technical assistance to eligible health departments in carrying out activities described in subsection (c).

(e) EVALUATIONS.—The Secretary shall (directly or through grants, cooperative agreements, or contracts) provide for the evaluation of activities carried out under subsections (a), (b), and (c) in order to determine the extent to which such activities have been effective in carrying out

the purpose described in subsection (a), including the effects of such activities on addressing health disparities.

(f) DEFINITION.—In this section, the term ''eligible health department'' means a health department of a State, the District of Columbia, the Commonwealth of Puerto Rico, the United States Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, a Tribe (as defined in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304)), or a large city (as defined by the Director of the Centers for Disease Control and Prevention for purposes of this section).

SEC. 4063. AUTHORIZATION OF APPROPRIATIONS.

There is authorized to be appropriated—

(1) $10,000,000 for the period of fiscal years 2021 through 2025 to carry out section 4061, to remain available until September 30, 2025; and

(2) $20,000,000 for each of fiscal years 2021 through 2025 to carry out section 4062, including for grants under section 4062(c), to remain available until September 30, 2025.

Subtitle H—Expanding Capacity for Health Outcomes

SEC. 4071. EXPANDING CAPACITY FOR HEALTH OUTCOMES.

Title III of the Public Health Service Act is amended by inserting after section 330M (42 U.S.C. 254c–19) the following:

"SEC. 330N. EXPANDING CAPACITY FOR HEALTH OUTCOMES.

''(a) DEFINITIONS.—In this section:

''(1) ELIGIBLE ENTITY.—The term 'eligible entity'—

''(A) means an entity that provides, or supports the provision of, health care services—

''(i) in rural areas, frontier areas, health professional shortage areas, or medically underserved areas; or

''(ii) to medically underserved populations or Native Americans, including Indian Tribes, Tribal organizations, or urban Indian organizations; and

''(B) may include entities leading, or capable of leading, a technology-enabled collaborative learning and capacity building model or engaging in technology-enabled collaborative training of participants in such model.

''(2) HEALTH PROFESSIONAL SHORTAGE AREA.—The term 'health professional shortage area' means a health professional shortage area designated under section 332.

''(3) INDIAN TRIBE.—The terms 'Indian Tribe' and 'Tribal organization' have the meanings given the terms 'Indian tribe' and 'tribal organization' in section 4 of the Indian Self-Determination and Education Assistance Act.

''(4) MEDICALLY UNDERSERVED POPULATION.—The term 'medically underserved population' has the meaning given the term in section 330(b)(3).

''(5) NATIVE AMERICANS.—The term 'Native Americans' has the meaning given such term in section 736 and includes Indian Tribes and Tribal organizations.

''(6) TECHNOLOGY-ENABLED COLLABORATIVE LEARNING AND CAPACITY BUILDING MODEL.—The term 'technology-enabled collaborative learning and capacity building model' means a distance health education model that connects health care professionals, and particularly specialists, with multiple other health care professionals through simultaneous interactive videoconferencing for the purpose of fa-

cilitating case-based learning, disseminating best practices, and evaluating outcomes.

''(7) URBAN INDIAN ORGANIZATION.—The 'urban Indian organization' has the meaning given the term 'Urban Indian organization' in section 4 of the Indian Health Care Improvement Act.

''(b) PROGRAM ESTABLISHED.—The Secretary shall, as appropriate, award grants to evaluate, develop, and, as appropriate, expand the use of technology-enabled collaborative learning and capacity building models, to improve retention of health care providers and increase access to health care services, such as those to address chronic diseases and conditions, infectious diseases, mental health, substance use disorders, prenatal and maternal health, pediatric care, pain management, palliative care, and other specialty care in rural areas, frontier areas, health professional shortage areas, or medically underserved areas and for medically underserved populations or Native Americans, including Indian Tribes and Tribal organizations.

''(c) USE OF FUNDS.—

''(1) IN GENERAL.—Grants awarded under subsection (b) shall be used for—

''(A) the development and acquisition of instructional programming, and the training of health care providers and other professionals

that provide or assist in the provision of services through models described in subsection (b), such as training on best practices for data collection and leading or participating in such technology-enabled activities consistent with technology-enabled collaborative learning and capacity building models;

''(B) information collection and evaluation activities to study the impact of such models on patient outcomes and health care providers, and to identify best practices for the expansion and use of such models; or

''(C) other activities consistent with achieving the objectives of the grants awarded under this section, as determined by the Secretary.

''(2) OTHER USES.—In addition to any of the uses under paragraph (1), grants awarded under subsection (b) may be used for—

''(A) equipment to support the use and expansion of technology-enabled collaborative learning and capacity building models, including for hardware and software that enables distance learning, health care provider support, and the secure exchange of electronic health information; or

"(B) support for health care providers and other professionals that provide or assist in the provision of services through such models.

"(d) LENGTH OF GRANTS.—Grants awarded under subsection (b) shall be for a period of up to 5 years.

"(e) GRANT REQUIREMENTS.—The Secretary may require entities awarded a grant under this section to collect information on the effect of the use of technology-enabled collaborative learning and capacity building models, such as on health outcomes, access to health care services, quality of care, and provider retention in areas and populations described in subsection (b). The Secretary may award a grant or contract to assist in the coordination of such models, including to assess outcomes associated with the use of such models in grants awarded under subsection (b), including for the purpose described in subsection (c)(1)(B).

"(f) APPLICATION.—An eligible entity that seeks to receive a grant under subsection (b) shall submit to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require. Such application shall include plans to assess the effect of technology-enabled collaborative learning and capacity building models on patient outcomes and health care providers.

''(g) ACCESS TO BROADBAND.—In administering grants under this section, the Secretary may coordinate with other agencies to ensure that funding opportunities are available to support access to reliable, high-speed internet for grantees.

''(h) TECHNICAL ASSISTANCE.—The Secretary shall provide (either directly through the Department of Health and Human Services or by contract) technical assistance to eligible entities, including recipients of grants under subsection (b), on the development, use, and evaluation of technology-enabled collaborative learning and capacity building models in order to expand access to health care services provided by such entities, including for medically underserved areas and to medically underserved populations or Native Americans, including Indian Tribes and Tribal organizations.

''(i) RESEARCH AND EVALUATION.—The Secretary, in consultation with stakeholders with appropriate expertise in such models, shall develop a strategic plan to research and evaluate the evidence for such models. The Secretary shall use such plan to inform the activities carried out under this section.

''(j) REPORT BY SECRETARY.—Not later than 4 years after the date of enactment of this section, the Secretary shall prepare and submit to the Committee on

Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, and post on the internet website of the Department of Health and Human Services, a report including, at minimum—

''(1) a description of any new and continuing grants awarded to entities under subsection (b) and the specific purpose and amounts of such grants;

''(2) an overview of—

''(A) the evaluations conducted under subsection (b);

''(B) technical assistance provided under subsection (h); and

''(C) activities conducted by entities awarded grants under subsection (b); and

''(3) a description of any significant findings or developments related to patient outcomes or health care providers and best practices for eligible entities expanding, using, or evaluating technology-enabled collaborative learning and capacity building models, including through the activities described in subsection (h).

''(k) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $20,000,000 for each of fiscal years 2021 through 2025.''.

Subtitle I—Community Readiness

SEC. 4081. GRANTS FOR RESEARCH ON, OR ESTABLISHING, WASTEWATER SURVEILLANCE AND OTHER EARLY WARNING SYSTEMS.

Subtitle C of title XXVIII of the Public Health Service Act (42 U.S.C. 300hh–31 et seq.) is amended by adding at the end the following:

"SEC. 2823. GRANTS FOR RESEARCH ON, OR ESTABLISHING, WASTEWATER SURVEILLANCE AND OTHER EARLY WARNING SYSTEMS.

''(a) IN GENERAL.—The Secretary, in consultation with the Administrator of the Environmental Protection Agency, may award grants to eligible entities to conduct research on, or to establish, a wastewater surveillance or other early warning system through—

''(1) wastewater testing;

''(2) temperature tracking to monitor axillary body temperature; and

''(3) other methods deemed permissible by the Secretary and Administrator.

''(b) PERMISSIBLE USES OF FUNDS.—A grant recipient under this section may use grant funds to support the activities described in subsection (a), including by—

''(1) paying for data-centric services that can detect infectious diseases before positive cases or hospitalizations;

''(2) entering into contracts with private companies to implement early warning detection methods; or

''(3) funding research to study early warning detection methods.

''(c) PRIORITY.—In selecting grant recipients under this section, the Secretary shall give priority to eligible entities proposing to conduct research on, or to establish, wastewater surveillance or other early warning system in one or more areas that—

''(1) are (or include one or more areas that are) a hot spot; or

''(2) a higher percentage of vulnerable populations than the national average.

''(d) FEDERAL PRIVACY REQUIREMENTS.—Nothing in this section shall be construed to supersede any Federal privacy or confidentiality requirement, including the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 and section 543 of this Act.

''(e) DEFINITIONS.—In this section:

''(1) The term 'Administrator' means the Administrator of the Environmental Protection Agency.

''(2) The term 'eligible entity' means—

''(A) a State government;

''(B) a local government;

''(C) a Tribal government;

''(D) an entity that conducts health research; and

''(E) an academic institution.

''(3) The term 'emergency period' has the meaning given to that term in section 1135(g)(1)(B) of the Social Security Act.

''(4) The term 'hot spot' means a geographic area where the rate of infection with a particular pathogen exceeds the national average.

''(5) The term 'local government' means a county, municipality, town, township, village, parish, borough, or other unit of general local government.

''(6) The term 'Secretary' means the Secretary of Health and Human Services.

''(7) The term 'State' means each of the several States, the District of Columbia, the Commonwealth of Puerto Rico, American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, the

Virgin Islands, and the Trust Territory of the Pacific Islands.

''(8) The term 'vulnerable population' means people at increased risk of severe illness.

''(f) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $18,000,000 for each of fiscal years 2021 through 2025.''.

TITLE V—ADDRESSING COVID–19 HEALTH DISPARITIES

Subtitle A—Tribal Health Data Improvement

SEC. 5001. COLLECTION AND AVAILABILITY OF HEALTH DATA WITH RESPECT TO INDIAN TRIBES.

(a) DATA COLLECTION.—Section 3101(a)(1) of the Public Health Service Act (42 U.S.C. 300kk(a)(1)) is amended—

(1) by striking '', by not later than 2 years after the date of enactment of this title,''; and

(2) in subparagraph (B), by inserting ''Tribal,'' after ''State,''.

(b) DATA REPORTING AND DISSEMINATION.—Section 3101(c) of the Public Health Service Act (42 U.S.C. 300kk(c)) is amended—

(1) by amending subparagraph (F) of paragraph (1) to read as follows:

"(F) the Indian Health Service, Indian Tribes, Tribal organizations, and epidemiology centers authorized under the Indian Health Care Improvement Act;"; and

(2) in paragraph (3), by inserting "Indian Tribes, Tribal organizations, and epidemiology centers," after "Federal agencies,".

(c) PROTECTION AND SHARING OF DATA.—Section 3101(e) of the Public Health Service Act (42 U.S.C. 300kk(e)) is amended by adding at the end the following new paragraphs:

"(3) DATA SHARING STRATEGY.—With respect to data access for Tribal epidemiology centers and Tribes, the Secretary shall create a data sharing strategy that takes into consideration recommendations by the Secretary's Tribal Advisory Committee for—

"(A) ensuring that Tribal epidemiology centers and Indian Tribes have access to the data sources necessary to accomplish their public health responsibilities; and

"(B) protecting the privacy and security of such data.

"(4) TRIBAL PUBLIC HEALTH AUTHORITY.—

"(A) AVAILABILITY.—Beginning not later than 180 days after the date of the enactment of the Commitment to Defeat the Virus and Keep America Healthy Act, the Secretary shall make available to the entities listed in subparagraph (B) all data that is collected pursuant to this title with respect to health care and public health surveillance programs and activities, including such programs and activities that are federally supported or conducted, so long as—

"(i) such entities request the data pursuant to statute; and

"(ii) the data is requested for use—

"(I) consistent with Federal law and obligations; and

"(II) to satisfy a particular purpose or carry out a specific function consistent with the purpose for which the data was collected.

"(B) ENTITIES.—The entities listed in this subparagraph are—

"(i) the Indian Health Service;

"(ii) Indian Tribes and Tribal organizations; and

''(iii) epidemiology centers.''.

(d) TECHNICAL UPDATES.—Section 3101 of the Public Health Service Act (42 U.S.C. 300kk) is amended—

(1) by striking subsections (g) and (h); and

(2) by redesignating subsection (i) as subsection (h).

(e) DEFINITIONS.—After executing the amendments made by subsection (d), section 3101 of the Public Health Service Act (42 U.S.C. 300kk) is amended by inserting after subsection (f) the following new subsection:

''(g) DEFINITIONS.—In this section:

''(1) The term 'epidemiology center' means an epidemiology center established under section 214 of the Indian Health Care Improvement Act, including such Tribal epidemiology centers serving Indian Tribes regionally and any Tribal epidemiology center serving Urban Indian organizations nationally.

''(2) The term 'Indian Tribe' has the meaning given to the term 'Indian tribe' in section 4 of the Indian Self-Determination and Education Assistance Act.

''(3) The term 'Tribal organization' has the meaning given to the term 'tribal organization' in

section 4 of the of the Indian Self-Determination and Education Assistance Act.

''(4) The term 'Urban Indian organization' has the meaning given to that term in section 4 of the Indian Health Care Improvement Act.''.

(f) TECHNICAL CORRECTION.—Section 3101(b) of the Public Health Service Act (42 U.S.C. 300kk(b)) is amended by striking ''DATA ANALYSIS.—'' and all that follows through ''For each federally'' and inserting ''DATA ANALYSIS.—For each federally''.

SEC. 5002. IMPROVING HEALTH STATISTICS REPORTING WITH RESPECT TO INDIAN TRIBES.

(a) TECHNICAL AID TO STATES AND LOCALITIES.—Section 306(d) of the Public Health Service Act (42 U.S.C. 242k(d)) is amended by inserting '', Indian Tribes, Tribal organizations, and epidemiology centers'' after ''jurisdictions''.

(b) COOPERATIVE HEALTH STATISTICS SYSTEM.—Section 306(e)(3) of the Public Health Service Act (42 U.S.C. 242k(e)(3)) is amended by inserting '', Indian Tribes, Tribal organizations, and epidemiology centers'' after ''health agencies''.

(c) FEDERAL-STATE-TRIBAL COOPERATION.—Section 306(f) of the Public Health Service Act (42 U.S.C. 242k(f)) is amended—

(1) by inserting ''the Indian Health Service,'' before ''the Departments of Commerce'';

(2) by inserting a comma after ''the Departments of Commerce and Labor'';

(3) by inserting '', Indian Tribes, Tribal organizations, and epidemiology centers'' after ''State and local health departments and agencies''; and

(4) by striking ''he shall'' and inserting ''the Secretary shall''.

(d) REGISTRATION AREA RECORDS.—Section 306(h)(1) of the Public Health Service Act (42 U.S.C. 242k(h)(1)) is amended—

(1) by striking ''in his discretion'' and inserting ''in the discretion of the Secretary''; and

(2) by striking ''Hispanics, Asian Americans, and Pacific Islanders'' and inserting ''American Indians and Alaska Natives, Hispanics, Asian Americans, and Native Hawaiian and other Pacific Islanders''.

(e) NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS.—Section 306(k) of the Public Health Service Act (42 U.S.C. 242k(k)) is amended—

(1) in paragraph (3), by striking '', not later than 60 days after the date of the enactment of the

Health Insurance Portability and Accountability Act of 1996,'' each place it appears; and

(2) in paragraph (7), by striking ''Not later than 1 year after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996, and annually thereafter, the Committee shall'' and inserting ''The Committee shall, on an biennial basis,''.

(f) GRANTS FOR ASSEMBLY AND ANALYSIS OF DATA ON ETHNIC AND RACIAL POPULATIONS.—Section 306(m)(4) of the Public Health Service Act (42 U.S.C. 242k(m)(4)) is amended—

(1) in subparagraph (A)—

(A) by striking ''Subject to subparagraph (B), the'' and inserting ''The''; and

(B) by striking ''and major Hispanic subpopulation groups and American Indians'' and inserting '', major Hispanic subgroups, and American Indians and Alaska Natives''; and

(2) by amending subparagraph (B) to read as follows:

''(B) In carrying out subparagraph (A), with respect to American Indians and Alaska Natives, the Secretary shall—

''(i) consult with Indian Tribes, Tribal organizations, the Tribal Technical Advisory Group of the Centers for Medicare & Medicaid Services maintained under section 5006(e) of the American Recovery and Reinvestment Act of 2009, and the Tribal Advisory Committee established by the Centers for Disease Control and Prevention, in coordination with epidemiology centers, to develop guidelines for State and local health agencies to improve the quality and accuracy of data with respect to the birth and death records of American Indians and Alaska Natives;

''(ii) confer with Urban Indian organizations to develop guidelines for State and local health agencies to improve the quality and accuracy of data with respect to the birth and death records of American Indians and Alaska Natives;

''(iii) enter into cooperative agreements with Indian Tribes, Tribal organizations, Urban Indian organizations, and epidemiology centers to address misclassification and undersampling of American Indians and Alaska Natives with respect to—

''(I) birth and death records; and

''(II) health care and public health surveillance systems, including, but not limited to, data with respect to chronic and infectious dis-

eases, unintentional injuries, environmental health, child and adolescent health, maternal health and mortality, foodborne and waterborne illness, reproductive health, and any other notifiable disease or condition;

''(iv) encourage States to enter into data sharing agreements with Indian Tribes, Tribal organizations, and epidemiology centers to improve the quality and accuracy of public health data; and

''(v) not later than 180 days after the date of enactment of the Commitment to Defeat the Virus and Keep America Healthy Act, and biennially thereafter, issue a report on the following:

''(I) Which States have data sharing agreements with Indian Tribes, Tribal organizations, Urban Indian organizations, and Tribal epidemiology centers to improve the quality and accuracy of health data.

''(II) What the Centers for Disease Control and Prevention is doing to encourage States to enter into data sharing agreements with Indian Tribes, Tribal organizations, Urban Indian organizations, and Tribal epidemiology centers to improve the quality and accuracy of health data.

''(III) Best practices and guidance for States, Indian Tribes, Tribal organizations, Urban Indian organizations, and Tribal epidemiology centers that wish to enter into data sharing agreements.

''(IV) Best practices and guidance for local, State, Tribal, and Federal uniform standards for the collection of data on race and ethnicity.''.

(g) DEFINITIONS.—Section 306 of the Public Health Service Act (42 U.S.C. 242k) is amended—

(1) by redesignating subsection (n) as subsection (o); and

(2) by inserting after subsection (m) the following:

''(n) In this section:

''(1) The term 'epidemiology center' means an epidemiology center established under section 214 of the Indian Health Care Improvement Act, including such Tribal epidemiology centers serving Indian Tribes regionally and any Tribal epidemiology center serving Urban Indian organizations nationally.

''(2) The term 'Indian Tribe' has the meaning given to the term 'Indian tribe' in section 4 of the

Indian Self-Determination and Education Assistance Act.

''(3) The term 'Tribal organization' has the meaning given to the term 'tribal organization' in section 4 of the Indian Self-Determination and Education Assistance Act.

''(4) The term 'Urban Indian organization' has the meaning given to that term in section 4 of the Indian Health Care Improvement Act.''.

(h) AUTHORIZATION OF APPROPRIATIONS.—Section 306(o) of the Public Health Service Act, as redesignated by subsection (g), is amended to read as follows:

''(o)(1) To carry out this section, there is authorized to be appropriated $185,000,000 for each of the fiscal years 2021 through 2025.

''(2) Of the amount authorized to be appropriated to carry out this section for a fiscal year, the Secretary shall not use more than 10 percent for the combined costs of—

''(A) administration of this section; and

''(B) carrying out subsection (m)(2).''.

Subtitle B—Tribal Medical Supplies Stockpile Access

SEC. 5011. PROVISION OF ITEMS TO INDIAN PROGRAMS AND FACILITIES.

(a) STRATEGIC NATIONAL STOCKPILE.—Section 319F–2(a)(3)(G) of the Public Health Service Act (42 U.S.C. 247d–6b(a)(3)(G)) is amended by inserting ", and, in the case that the Secretary deploys the stockpile under this subparagraph, ensure that appropriate drugs, vaccines and other biological products, medical devices, and other supplies are deployed by the Secretary directly to health programs or facilities operated by the Indian Health Service, an Indian tribe, a tribal organization (as those terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304)), or an inter-tribal consortium (as defined in section 501 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5381)) or through an urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act), while avoiding duplicative distributions to such programs or facilities" before the semicolon.

(b) DISTRIBUTION OF QUALIFIED PANDEMIC OR EPIDEMIC PRODUCTS TO IHS FACILITIES.—Title III of the Public Health Service Act (42 U.S.C. 241 et seq.), as

amended by section 3015, is further amended by inserting after section 319F–5 the following:

"SEC. 319F–6. DISTRIBUTION OF QUALIFIED PANDEMIC OR EPIDEMIC PRODUCTS TO INDIAN PROGRAMS AND FACILITIES.

"In the case that the Secretary distributes qualified pandemic or epidemic products (as defined in section 319F–3(i)(7)) to States or other entities, the Secretary shall ensure that, as appropriate, such products are distributed directly to health programs or facilities operated by the Indian Health Service, an Indian tribe, a tribal organization (as those terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304)), or an inter-tribal consortium (as defined in section 501 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5381)) or through an urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act), while avoiding duplicative distributions to such programs or facilities.".

Subtitle C—Native American Suicide Prevention

SEC. 5021. NATIVE AMERICAN SUICIDE PREVENTION.

Section 520E(b) of the Public Health Service Act (42 U.S.C. 290bb–36(b)) is amended by inserting after paragraph (3) the following:

''(4) CONSULTATION.—A State applying for a grant or cooperative agreement under this section shall, in the development and implementation of a statewide early intervention strategy, consult or confer with entities described in paragraph (1)(C) in such State.''.

Subtitle D—Pursuing Equity in Mental Health

PART 1—HEALTH EQUITY AND ACCOUNTABILITY

SEC. 5031. INTEGRATED HEALTH CARE DEMONSTRATION PROGRAM.

Part D of title V of the Public Health Service Act (42 U.S.C. 290dd et seq.) is amended by adding at the end the following:

''SEC. 554. INTERPROFESSIONAL HEALTH CARE TEAMS FOR PROVISION OF BEHAVIORAL HEALTH CARE IN PRIMARY CARE SETTINGS.

''(a) GRANTS.—The Secretary shall award grants to eligible entities for the purpose of establishing interprofessional health care teams that provide behavioral health care.

''(b) ELIGIBLE ENTITIES.—To be eligible to receive a grant under this section, an entity shall be a federally qualified health center (as defined in section 1861(aa) of the Social Security Act), rural health clinic, or behavioral

health program, serving a high proportion of individuals from racial and ethnic minority groups (as defined in section 1707(g)).

''(c) SCIENTIFICALLY BASED.—Integrated health care funded through this section shall be scientifically based, taking into consideration the results of the most recent peer-reviewed research available.

''(d) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $20,000,000 for each of the first 5 fiscal years following the date of enactment of the Commitment to Defeat the Virus and Keep America Healthy Act.''.

SEC. 5032. ADDRESSING RACIAL AND ETHNIC MINORITY MENTAL HEALTH DISPARITIES RESEARCH GAPS.

Not later than 6 months after the date of the enactment of this Act, the Director of the National Institutes of Health shall enter into an arrangement with the National Academies of Sciences, Engineering, and Medicine (or, if the National Academies of Sciences, Engineering, and Medicine decline to enter into such an arrangement, the Patient-Centered Outcomes Research Institute, the Agency for Healthcare Research and Quality, or another appropriate entity)—

(1) to conduct a study with respect to mental health disparities in racial and ethnic minority groups (as defined in section 1707(g) of the Public Health Service Act (42 U.S.C. 300u–6(g))); and

(2) to submit to the Congress a report on the results of such study, including—

(A) a compilation of information on the dynamics of mental disorders in such racial and ethnic minority groups; and

(B) a compilation of information on the impact of exposure to community violence, adverse childhood experiences, structural racism, and other psychological traumas on mental disorders in such racial and minority groups.

SEC. 5033. HEALTH PROFESSIONS COMPETENCIES TO ADDRESS RACIAL AND ETHNIC MINORITY MENTAL HEALTH DISPARITIES.

(a) IN GENERAL.—The Secretary of Health and Human Services shall award grants to qualified national organizations for the purposes of—

(1) developing, and disseminating to health professional educational programs best practices or core competencies addressing mental health disparities among racial and ethnic minority groups for use in the training of students in the professions of social

work, psychology, psychiatry, marriage and family therapy, mental health counseling, and substance misuse counseling; and

(2) certifying community health workers and peer wellness specialists with respect to such best practices and core competencies and integrating and expanding the use of such workers and specialists into health care to address mental health disparities among racial and ethnic minority groups.

(b) BEST PRACTICES; CORE COMPETENCIES.—Organizations receiving funds under subsection (a) may use the funds to engage in the following activities related to the development and dissemination of best practices or core competencies described in subsection (a)(1):

(1) Formation of committees or working groups comprised of experts from accredited health professions schools to identify best practices and core competencies relating to mental health disparities among racial and ethnic minority groups.

(2) Planning of workshops in national fora to allow for public input into the educational needs associated with mental health disparities among racial and ethnic minority groups.

(3) Dissemination and promotion of the use of best practices or core competencies in undergraduate

and graduate health professions training programs nationwide.

(4) Establishing external stakeholder advisory boards to provide meaningful input into policy and program development and best practices to reduce mental health disparities among racial and ethnic minority groups.

(c) DEFINITIONS.—In this section:

(1) QUALIFIED NATIONAL ORGANIZATION.—The term ''qualified national organization'' means a national organization that focuses on the education of students in one or more of the professions of social work, psychology, psychiatry, marriage and family therapy, mental health counseling, and substance misuse counseling.

(2) RACIAL AND ETHNIC MINORITY GROUP.—The term ''racial and ethnic minority group'' has the meaning given to such term in section 1707(g) of the Public Health Service Act (42 U.S.C. 300u–6(g)).

SEC. 5034. RACIAL AND ETHNIC MINORITY BEHAVIORAL AND MENTAL HEALTH OUTREACH AND EDUCATION STRATEGY.

Part D of title V of the Public Health Service Act (42 U.S.C. 290dd et seq.), as amended by section 5031,

is further amended by adding at the end the following new section:

"SEC. 555. BEHAVIORAL AND MENTAL HEALTH OUTREACH AND EDUCATION STRATEGY.

''(a) IN GENERAL.—The Secretary shall, in consultation with advocacy and behavioral and mental health organizations serving racial and ethnic minority groups, develop and implement an outreach and education strategy to promote behavioral and mental health and reduce stigma associated with mental health conditions and substance abuse among racial and ethnic minority groups. Such strategy shall—

''(1) be designed to—

''(A) meet the diverse cultural and language needs of the various racial and ethnic minority groups; and

''(B) be developmentally and age-appropriate;

''(2) increase awareness of symptoms of mental illnesses common among such groups, taking into account differences within at-risk subgroups;

''(3) provide information on evidence-based, culturally and linguistically appropriate and adapted interventions and treatments;

''(4) ensure full participation of, and engage, both consumers and community members in the development and implementation of materials; and

''(5) seek to broaden the perspective among both individuals in these groups and stakeholders serving these groups to use a comprehensive public health approach to promoting behavioral health that addresses a holistic view of health by focusing on the intersection between behavioral and physical health.

''(b) REPORTS.—Beginning not later than 1 year after the date of the enactment of this section and annually thereafter, the Secretary shall submit to Congress, and make publicly available, a report on the extent to which the strategy developed and implemented under subsection (a) increased behavioral and mental health outcomes associated with mental health conditions and substance abuse among racial and ethnic minority groups.

''(c) DEFINITION.—In this section, the term 'racial and ethnic minority group' has the meaning given to that term in section 1707(g).

''(d) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $10,000,000 for each of fiscal years 2021 through 2025.''.

SEC. 5035. ADDITIONAL FUNDS FOR NATIONAL INSTITUTES OF HEALTH.

(a) IN GENERAL.—In addition to amounts otherwise authorized to be appropriated to the National Institutes of Health, there is authorized to be appropriated to such Institutes $100,000,000 for each of fiscal years 2021 through 2025 to build relations with communities and conduct or support clinical research, including clinical research on racial or ethnic disparities in physical and mental health.

(b) DEFINITION.—In this section, the term ''clinical research'' has the meaning given to such term in section 409 of the Public Health Service Act (42 U.S.C. 284d).

SEC. 5036. ADDITIONAL FUNDS FOR NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES.

In addition to amounts otherwise authorized to be appropriated to the National Institute on Minority Health and Health Disparities, there is authorized to be appropriated to such Institute $650,000,000 for each of fiscal years 2021 through 2025.

PART 2—OTHER PROVISIONS

SEC. 5037. REAUTHORIZATION OF MINORITY FELLOWSHIP PROGRAM.

Section 597(c) of the Public Health Service Act (42 U.S.C. 297ll(c)) is amended by striking ''$12,669,000 for

each of fiscal years 2018 through 2022'' and inserting ''$25,000,000 for each of fiscal years 2021 through 2025''.

SEC. 5038. STUDY ON THE EFFECTS OF SMARTPHONE AND SOCIAL MEDIA USE ON ADOLESCENTS.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall conduct or support research on—

(1) smartphone and social media use by adolescents; and

(2) the effects of such use on—

(A) emotional, behavioral, and physical health and development; and

(B) disparities in minority and underserved populations.

(b) REPORT.—Not later than 5 years after the date of the enactment of this Act, the Secretary shall submit to the Congress, and make publicly available, a report on the findings of research described in this section.

SEC. 5039. TECHNICAL CORRECTION.

Title V of the Public Health Service Act (42 U.S.C. 290aa et seq.) is amended—

(1) by redesignating the second section 550 of such Act (42 U.S.C. 290ee–10) (relating to Sobriety

Treatment And Recovery Teams) as section 553; and

(2) by moving such section 553, as so redesignated, so as to appear after section 552 of such Act (42 U.S.C. 290ee–7).

Subtitle E—Maternal Health Quality Improvement

SEC. 5041. INNOVATION FOR MATERNAL HEALTH.

Part D of title III of the Public Health Service Act (42 U.S.C. 254b et seq.), as amended by section 4071, is further amended—

(1) in the section designation of section 330M of such Act (42 U.S.C. 254c–19) by inserting a period after ''330M''; and

(2) by inserting after section 330N of such Act, as inserted by section 4071, the following:

''SEC. 330O. INNOVATION FOR MATERNAL HEALTH.

''(a) IN GENERAL.—The Secretary, in consultation with experts representing a variety of clinical specialties, State, Tribal, or local public health officials, researchers, epidemiologists, statisticians, and community organizations, shall establish or continue a program to award competitive grants to eligible entities for the purposes of—

''(1) identifying, developing, or disseminating best practices to improve maternal health care qual-

ity and outcomes, eliminate preventable maternal mortality and severe maternal morbidity, and improve infant health outcomes, which may include—

"(A) information on evidence-based practices to improve the quality and safety of maternal health care in hospitals and other health care settings of a State or health care system, including by addressing topics commonly associated with health complications or risks related to prenatal care, labor care, birthing, and postpartum care;

"(B) best practices for improving maternal health care based on data findings and reviews conducted by a State maternal mortality review committee that address topics of relevance to common complications or health risks related to prenatal care, labor care, birthing, and postpartum care; and

"(C) information on addressing determinants of health that impact maternal health outcomes for women before, during, and after pregnancy;

"(2) collaborating with State maternal mortality review committees to identify issues for the development and implementation of evidence-based

practices to improve maternal health outcomes and reduce preventable maternal mortality and severe maternal morbidity;

''(3) providing technical assistance and supporting the implementation of best practices identified pursuant to paragraph (1) to entities providing health care services to pregnant and postpartum women; and

''(4) identifying, developing, and evaluating new models of care that improve maternal and infant health outcomes, which may include the integration of community-based services and clinical care.

''(b) ELIGIBLE ENTITIES.—To be eligible for a grant under subsection (a), an entity shall—

''(1) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require; and

''(2) demonstrate in such application that the entity is capable of carrying out data-driven maternal safety and quality improvement initiatives in the areas of obstetrics and gynecology or maternal health.

''(c) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appro-

priated $5,000,000 for each of fiscal years 2021 through 2025.''.

SEC. 5042. TRAINING FOR HEALTH CARE PROVIDERS.

Title VII of the Public Health Service Act is amended by striking section 763 (42 U.S.C. 294p) and inserting the following:

''SEC. 763. TRAINING FOR HEALTH CARE PROVIDERS.

''(a) GRANT PROGRAM.—The Secretary shall establish a program to award grants to accredited schools of allopathic medicine, osteopathic medicine, and nursing, and other health professional training programs for the training of health care professionals to reduce and prevent discrimination (including training related to implicit and explicit biases) in the provision of health care services related to prenatal care, labor care, birthing, and postpartum care.

''(b) ELIGIBILITY.—To be eligible for a grant under subsection (a), an entity described in such subsection shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

''(c) REPORTING REQUIREMENT.—Each entity awarded a grant under this section shall periodically submit to the Secretary a report on the status of activities

conducted using the grant, including a description of the impact of such training on patient outcomes, as applicable.

''(d) BEST PRACTICES.—The Secretary may identify and disseminate best practices for the training of health care professionals to reduce and prevent discrimination (including training related to implicit and explicit biases) in the provision of health care services related to prenatal care, labor care, birthing, and postpartum care.

''(e) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $5,000,000 for each of fiscal years 2021 through 2025.''.

SEC. 5043. STUDY ON TRAINING TO REDUCE AND PREVENT DISCRIMINATION.

Not later than 2 years after date of enactment of this Act, the Secretary of Health and Human Services shall, through a contract with an independent research organization, conduct a study and make recommendations for accredited schools of allopathic medicine, osteopathic medicine, and nursing, and other health professional training programs, on best practices related to training to reduce and prevent discrimination, including training related to implicit and explicit biases, in the provision of health care services related to prenatal care, labor care, birthing, and postpartum care.

SEC. 5044. PERINATAL QUALITY COLLABORATIVES.

Section 317K(a)(2) of the Public Health Service Act (42 U.S.C. 247b–12(a)(2)) is amended by adding at the end the following:

''(E)(i) The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in coordination with other offices and agencies, as appropriate, shall establish or continue a competitive grant program for the establishment or support of perinatal quality collaboratives to improve perinatal care and perinatal health outcomes for pregnant and postpartum women and their infants. A State, Indian Tribe, or Tribal organization may use funds received through such grant to—

''(I) support the use of evidence-based or evidence-informed practices to improve outcomes for maternal and infant health;

''(II) work with clinical teams; experts; State, local, and, as appropriate, Tribal public health officials; and stakeholders, including patients and families, to identify, develop, or disseminate best practices to improve perinatal care and outcomes; and

"(III) employ strategies that provide opportunities for health care professionals and clinical teams to collaborate across health care settings and disciplines, including primary care and mental health, as appropriate, to improve maternal and infant health outcomes, which may include the use of data to provide timely feedback across hospital and clinical teams to inform responses, and to provide support and training to hospital and clinical teams for quality improvement, as appropriate.

"(ii) To be eligible for a grant under clause (i), an entity shall submit to the Secretary an application in such form and manner and containing such information as the Secretary may require.".

SEC. 5045. INTEGRATED SERVICES FOR PREGNANT AND POSTPARTUM WOMEN.

(a) GRANTS.—Title III of the Public Health Service Act is amended by inserting after section 330O of such Act, as added by section 5041, the following:

"SEC. 330P. INTEGRATED SERVICES FOR PREGNANT AND POSTPARTUM WOMEN.

''(a) IN GENERAL.—The Secretary may award grants to States, Indian Tribes, and Tribal organizations for the purpose of establishing or operating evidence-based or innovative, evidence-informed programs to deliver integrated health care services to pregnant and postpartum women to optimize the health of women and their infants, including to reduce adverse maternal health outcomes, pregnancy-related deaths, and related health disparities (including such disparities associated with racial and ethnic minority populations), and, as appropriate, by addressing issues researched under subsection (b)(2) of section 317K.

''(b) INTEGRATED SERVICES FOR PREGNANT AND POSTPARTUM WOMEN.—

''(1) ELIGIBILITY.—To be eligible to receive a grant under subsection (a), a State, Indian Tribe, or Tribal organization shall work with relevant stakeholders that coordinate care (including coordinating resources and referrals for health care and social services) to develop and carry out the program, including—

''(A) State, Tribal, and local agencies responsible for Medicaid, public health, social services, mental health, and substance use disorder treatment and services;

''(B) health care providers who serve pregnant and postpartum women; and

''(C) community-based health organizations and health workers, including providers of home visiting services and individuals representing communities with disproportionately high rates of maternal mortality and severe maternal morbidity, and including individuals representing racial and ethnic minority populations.

''(2) TERMS.—

''(A) PERIOD.—A grant awarded under subsection (a) shall be made for a period of 5 years. Any supplemental award made to a grantee under subsection (a) may be made for a period of less than 5 years.

''(B) PREFERENCE.—In awarding grants under subsection (a), the Secretary shall—

''(i) give preference to States, Indian Tribes, and Tribal organizations that have the highest rates of maternal mortality and severe maternal morbidity relative to other such States, Indian Tribes, or Tribal organizations, respectively; and

''(ii) shall consider health disparities related to maternal mortality and severe maternal morbidity, including such disparities associated with racial and ethnic minority populations.

''(C) PRIORITY.—In awarding grants under subsection (a), the Secretary shall give priority to applications from up to 15 entities described in subparagraph (B)(i).

''(D) EVALUATION.—The Secretary shall require grantees to evaluate the outcomes of the programs supported under the grant.

''(c) DEFINITIONS.—In this section, the terms 'Indian Tribe' and 'Tribal organization' have the meanings given the terms 'Indian tribe' and 'tribal organization', respectively, in section 4 of the Indian Self-Determination and Education Assistance Act.

''(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $10,000,000 for each of fiscal years 2021 through 2025.''.

(b) REPORT ON GRANT OUTCOMES AND DISSEMINATION OF BEST PRACTICES.—

(1) REPORT.—Not later than February 1, 2026, the Secretary of Health and Human Services shall submit to the Committee on Health, Edu-

cation, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that describes—

(A) the outcomes of the activities supported by the grants awarded under the amendment made by this section on maternal and child health;

(B) best practices and models of care used by recipients of grants under such amendment; and

(C) obstacles identified by recipients of grants under such amendment, and strategies used by such recipients to deliver care, improve maternal and child health, and reduce health disparities.

(2) DISSEMINATION OF BEST PRACTICES.—Not later than August 1, 2026, the Secretary of Health and Human Services shall disseminate information on best practices and models of care used by recipients of grants under the amendment made by this section (including best practices and models of care relating to the reduction of health disparities, including such disparities associated with racial and ethnic minority populations, in rates of maternal mortality and severe maternal morbidity) to relevant stake-

holders, which may include health providers, medical schools, nursing schools, relevant State, Tribal, and local agencies, and the general public.

SEC. 5046. IMPROVING RURAL MATERNAL AND OBSTETRIC CARE DATA.

(a) MATERNAL MORTALITY AND MORBIDITY ACTIVITIES.—Section 301(e) of the Public Health Service Act (42 U.S.C. 241(e)) is amended by inserting ", preventable maternal mortality and severe maternal morbidity," after "delivery".

(b) OFFICE OF WOMEN'S HEALTH.—Section 310A(b)(1) of the Public Health Service Act (42 U.S.C. 242s(b)(1)) is amended by striking "and sociocultural contexts," and inserting "sociocultural (including among American Indians, Native Hawaiians, and Alaska Natives), and geographical contexts".

(c) SAFE MOTHERHOOD.—Section 317K of the Public Health Service Act (42 U.S.C. 247b–12) is amended—

(1) in subsection (a)(2)(A), by inserting ", including improving collection of data on race, ethnicity, and other demographic information" before the period; and

(2) in subsection (b)(2)—

(A) in subparagraph (L), by striking "and" at the end;

(B) by redesignating subparagraph (M) as subparagraph (N); and

(C) by inserting after subparagraph (L) the following:

''(M) an examination of the relationship between maternal health and obstetric services in rural areas and outcomes in delivery and postpartum care; and''.

(d) OFFICE OF RESEARCH ON WOMEN'S HEALTH.—Section 486 of the Public Health Service Act (42 U.S.C. 287d) is amended—

(1) in subsection (b), by amending paragraph (3) to read as follows:

''(3) carry out paragraphs (1) and (2) with respect to—

''(A) the aging process in women, with priority given to menopause; and

''(B) pregnancy, with priority given to deaths related to preventable maternal mortality and severe maternal morbidity;''; and

(2) in subsection (d)(4)(A)(iv), by inserting '', including preventable maternal morbidity and severe maternal morbidity'' before the semicolon.

SEC. 5047. RURAL OBSTETRIC NETWORK GRANTS.

The Public Health Service Act is amended by inserting after section 330A–1 (42 U.S.C. 254c–1a) the following:

"SEC. 330A–2. RURAL OBSTETRIC NETWORK GRANTS.

"(a) PROGRAM ESTABLISHED.—The Secretary shall award grants or cooperative agreements to eligible entities to establish collaborative improvement and innovation networks (referred to in this section as 'rural obstetric networks') to improve maternal and infant health outcomes and reduce preventable maternal mortality and severe maternal morbidity by improving maternity care and access to care in rural areas, frontier areas, maternity care health professional target areas, or jurisdictions of Indian Tribes and Tribal organizations.

"(b) USE OF FUNDS.—Grants or cooperative agreements awarded pursuant to this section shall be used for the establishment or continuation of collaborative improvement and innovation networks to improve maternal health in rural areas by improving infant health and maternal outcomes and reducing preventable maternal mortality and severe maternal morbidity. Rural obstetric networks established in accordance with this section may—

"(1) develop a network to improve coordination and increase access to maternal health care and assist pregnant women in the areas described in sub-

section (a) with accessing and utilizing maternal and obstetric care, including health care services related to prenatal care, labor care, birthing, and postpartum care to improve outcomes in birth and maternal mortality and morbidity;

''(2) identify and implement evidence-based and sustainable delivery models for maternal and obstetric care (including health care services related to prenatal care, labor care, birthing, and postpartum care for women in the areas described in subsection (a)), including home visiting programs and culturally appropriate care models that reduce health disparities;

''(3) develop a model for maternal health care collaboration between health care settings to improve access to care in areas described in subsection (a), which may include the use of telehealth;

''(4) provide training for professionals in health care settings that do not have specialty maternity care;

''(5) collaborate with academic institutions that can provide regional expertise and help identify barriers to providing maternal health care, including strategies for addressing such barriers; and

''(6) assess and address disparities in infant and maternal health outcomes, including among racial and ethnic minority populations and underserved populations in areas described in subsection (a).

''(c) DEFINITIONS.—In this section:

''(1) ELIGIBLE ENTITIES.—The term 'eligible entities' means entities providing maternal health care services in rural areas, frontier areas, or medically underserved areas, or to medically underserved populations or Indian Tribes or Tribal organizations.

''(2) FRONTIER AREA.—The term 'frontier area' means a frontier county, as defined in section 1886(d)(3)(E)(iii)(III) of the Social Security Act.

''(3) INDIAN TRIBES; TRIBAL ORGANIZATION.—The terms 'Indian Tribe' and 'Tribal organization' have the meanings given the terms 'Indian tribe' and 'tribal organization', respectively, in section 4 of the Indian Self-Determination and Education Assistance Act.

''(4) MATERNITY CARE HEALTH PROFESSIONAL TARGET AREA.—The term 'maternity care health professional target area' has the meaning described in section 332(k)(2).

''(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $3,000,000 for each of fiscal years 2021 through 2025.''.

SEC. 5048. TELEHEALTH NETWORK AND TELEHEALTH RESOURCE CENTERS GRANT PROGRAMS.

Section 330I of the Public Health Service Act (42 U.S.C. 254c–14) is amended—

(1) in subsection (f)(3), by adding at the end the following:

''(M) Providers of maternal care, including prenatal, labor care, birthing, and postpartum care services and entities operating obstetric care units.''; and

(2) in subsection (h)(1)(B), by inserting ''labor care, birthing care, postpartum care,'' before ''or prenatal''.

SEC. 5049. RURAL MATERNAL AND OBSTETRIC CARE TRAINING DEMONSTRATION.

Subpart 1 of part E of title VII of the Public Health Service Act (42 U.S.C. 294n et seq.) is amended by adding at the end the following:

''SEC. 764. RURAL MATERNAL AND OBSTETRIC CARE TRAINING DEMONSTRATION.

''(a) IN GENERAL.—The Secretary shall award grants to accredited schools of allopathic medicine, osteo-

pathic medicine, and nursing, and other appropriate health professional training programs, to establish a training demonstration program to support—

''(1) training for physicians, medical residents, fellows, nurse practitioners, physician assistants, nurses, certified nurse midwives, relevant home visiting workforce professionals and paraprofessionals, or other professionals who meet relevant State training and licensing requirements, as applicable, to provide maternal health care services in rural community-based settings; and

''(2) developing recommendations for such training programs.

''(b) APPLICATION.—To be eligible to receive a grant under subsection (a), an entity shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

''(c) ACTIVITIES.—

''(1) TRAINING FOR HEALTH CARE PROFESSIONALS.—A recipient of a grant under subsection (a)—

''(A) shall use the grant funds to plan, develop, and operate a training program to provide maternal health care in rural areas; and

''(B) may use the grant funds to provide additional support for the administration of the program or to meet the costs of projects to establish, maintain, or improve faculty development, or departments, divisions, or other units necessary to implement such training.

''(2) TRAINING PROGRAM REQUIREMENTS.—The recipient of a grant under subsection (a) shall ensure that training programs carried out under the grant are evidence-based and address improving maternal health care in rural areas, and such programs may include training on topics such as—

''(A) maternal mental health, including perinatal depression and anxiety;

''(B) substance use disorders;

''(C) social determinants of health that affect individuals living in rural areas; and

''(D) implicit and explicit bias.

''(d) EVALUATION AND REPORT.—

''(1) EVALUATION.—

''(A) IN GENERAL.—The Secretary shall evaluate the outcomes of the demonstration program under this section.

''(B) DATA SUBMISSION.—Recipients of a grant under subsection (a) shall submit to the

Secretary performance metrics and other related data in order to evaluate the program for the report described in paragraph (2).

''(2) REPORT TO CONGRESS.—Not later than January 1, 2025, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that includes—

''(A) an analysis of the effects of the demonstration program under this section on the quality, quantity, and distribution of maternal health care services, including health care services related to prenatal care, labor care, birthing, and postpartum care, and the demographics of the recipients of those services;

''(B) an analysis of maternal and infant health outcomes (including quality of care, morbidity, and mortality) before and after implementation of the program in the communities served by entities participating in the demonstration program; and

''(C) recommendations on whether the demonstration program should be continued.

''(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $5,000,000 for each of fiscal years 2021 through 2025.''.

TITLE VI—ADDRESSING THE IMPACTS OF COVID–19 ON MENTAL HEALTH

Subtitle A—Creating Resources To Improve Situations of Inherent Severity

SEC. 6001. SET-ASIDE FOR EVIDENCE-BASED CRISIS CARE SERVICES.

Section 1920 of the Public Health Service Act (42 U.S.C. 300x–9) is amended—

(1) in subsection (a), by striking ''$532,571,000 for each of fiscal years 2018 through 2022'' and inserting ''$532,571,000 for each of fiscal years 2018 through 2020, and $758,000,000 for each of fiscal years 2021 through 2022''; and

(2) by adding at the end the following:

''(d) CRISIS CARE.—

''(1) IN GENERAL.—Except as provided in paragraph (3), a State shall expend at least 5 percent of the amount the State receives pursuant to section 1911 for each fiscal year to support evidenced-based programs that address the crisis care needs of indi-

viduals with serious mental disorders, and children with serious mental and emotional disturbances.

''(2) CORE ELEMENTS.—At the discretion of the single State agency responsible for the administration of the program of the State under a grant under section 1911, funds expended pursuant to paragraph (1) may be used to fund some or all of the core crisis care service components, delivered according to evidence-based principles, including the following:

''(A) Crisis call centers.

''(B) 24/7 mobile crisis services.

''(C) Crisis stabilization programs offering acute care or subacute care in a hospital or appropriately licensed facility, as determined by the Substance Abuse and Mental Health Services Administration, with referrals to inpatient or outpatient care.

''(3) STATE FLEXIBILITY.—In lieu of expending 5 percent of the amount the State receives pursuant to section 1911 for a fiscal year to support evidence-based programs as required by paragraph (1), a State may elect to expend not less than 10 percent of such amount to support such programs by the end of two consecutive fiscal years.''.

Subtitle B—Emergency Mental Health and Substance Use Training and Technical Assistance Center

SEC. 6011. EMERGENCY MENTAL HEALTH AND SUBSTANCE USE TRAINING AND TECHNICAL ASSISTANCE CENTER.

Subpart 3 of part B of title V of the Public Health Service Act (42 U.S.C. 290bb–31 et seq.) is amended by inserting after section 520A (42 U.S.C. 290bb–32) the following:

"SEC. 520B. EMERGENCY MENTAL HEALTH AND SUBSTANCE USE TRAINING AND TECHNICAL ASSISTANCE CENTER.

''(a) ESTABLISHMENT.—The Secretary, acting through the Assistant Secretary, shall establish or operate a center to be known as the Emergency Mental Health and Substance Use Training and Technical Assistance Center (referred to in this section as the 'Center') to provide technical assistance and support—

''(1) to public or nonprofit entities seeking to establish or expand access to mental health and substance use prevention, treatment, and recovery support services, and increase awareness of such services; and

''(2) to public health professionals, health care professionals and support staff, essential workers (as defined by a State, Tribe, locality, or territory), and members of the public to address the trauma, stress, and mental health needs associated with an emergency period.

''(b) ASSISTANCE AND SUPPORT.—The assistance and support provided under subsection (a) shall include assistance and support with respect to—

''(1) training on identifying signs of trauma, stress, and mental health needs;

''(2) providing accessible resources to assist individuals and families experiencing trauma, stress, or other mental health needs during and after an emergency period;

''(3) providing resources for substance use disorder prevention, treatment, and recovery designed to assist individuals and families during and after an emergency period;

''(4) the provision of language access services, including translation services, interpretation, or other such services for individuals with limited English speaking proficiency or individuals with disabilities; and

''(5) evaluation and improvement, as necessary, of the effectiveness of such services provided by public or nonprofit entities.

''(c) BEST PRACTICES.—The Center shall periodically issue best practices for use by organizations seeking to provide mental health services or substance use disorder prevention, treatment, or recovery services, including best practices for the following special populations:

''(1) Incarcerated individuals.

''(2) Children.

''(3) Pregnant women.

''(4) Underserved populations.

''(5) Communities of color.

''(6) Health care providers and essential workers.

''(d) EMERGENCY PERIOD.—In this section, the term 'emergency period' has the meaning given such term in section 1135(g)(1)(A) of the Social Security Act.

''(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $20,000,000 for each of fiscal years 2021 and 2022.''.

Subtitle C—Suicide Prevention Grants

SEC. 6021. SYNDROMIC SURVEILLANCE OF SELF-HARM BEHAVIORS PROGRAM.

Title III of the Public Health Service Act is amended by inserting after section 317U of such Act (42 U.S.C. 247b–23) the following:

"SEC. 317V. SYNDROMIC SURVEILLANCE OF SELF-HARM BEHAVIORS PROGRAM.

''(a) IN GENERAL.—The Secretary shall award grants to State, local, Tribal, and territorial public health departments for the expansion of surveillance of self-harm.

''(b) DATA SHARING BY GRANTEES.—As a condition of receipt of such grant under subsection (a), each grantee shall agree to share with the Centers for Disease Control and Prevention in real time, to the extent feasible and as specified in the grant agreement, data on suicides and self-harm for purposes of—

''(1) tracking and monitoring self-harm to inform response activities to suicide clusters;

''(2) informing prevention programming for identified at-risk populations; and

''(3) conducting or supporting research.

''(c) DISAGGREGATION OF DATA.—The Secretary shall provide for the data collected through surveillance

of self-harm under subsection (b) to be disaggregated by the following categories:

''(1) Nonfatal self-harm data of any intent.

''(2) Data on suicidal ideation.

''(3) Data on self-harm where there is no evidence, whether implicit or explicit, of suicidal intent.

''(4) Data on self-harm where there is evidence, whether implicit or explicit, of suicidal intent.

''(5) Data on self-harm where suicidal intent is unclear based on the available evidence.

''(d) PRIORITY.—In making awards under subsection (a), the Secretary shall give priority to eligible entities that are—

''(1) located in a State with an age-adjusted rate of nonfatal suicidal behavior that is above the national rate of nonfatal suicidal behavior, as determined by the Director of the Centers for Disease Control and Prevention;

''(2) serving an Indian Tribe (as defined in section 4 of the Indian Self-Determination and Education Assistance Act) with an age-adjusted rate of nonfatal suicidal behavior that is above the national rate of nonfatal suicidal behavior, as determined through appropriate mechanisms determined by the Secretary in consultation with Indian Tribes; or

''(3) located in a State with a high rate of coverage of statewide (or Tribal) emergency department visits, as determined by the Director of the Centers for Disease Control and Prevention.

''(e) GEOGRAPHIC DISTRIBUTION.—In making grants under this section, the Secretary shall make an effort to ensure geographic distribution, taking into account the unique needs of rural communities, including—

''(1) communities with an incidence of individuals with serious mental illness, demonstrated suicidal ideation or behavior, or suicide rates that are above the national average, as determined by the Assistant Secretary for Mental Health and Substance Use;

''(2) communities with a shortage of prevention and treatment services, as determined by the Assistant Secretary for Mental Health and Substance Use and the Administrator of the Health Resources and Services Administration; and

''(3) other appropriate community-level factors and social determinants of health such as income, employment, and education.

''(f) PERIOD OF PARTICIPATION.—To be selected as a grant recipient under this section, a State, local, Tribal, or territorial public health department shall agree to par-

ticipate in the program for a period of not less than 4 years.

''(g) TECHNICAL ASSISTANCE.—The Secretary shall provide technical assistance and training to grantees for collecting and sharing the data under subsection (b).

''(h) DATA SHARING BY HHS.—Subject to subsection (b), the Secretary shall, with respect to data on self-harm that is collected pursuant to this section, share and integrate such data through—

''(1) the National Syndromic Surveillance Program's Early Notification of Community Epidemics (ESSENCE) platform (or any successor platform);

''(2) the National Violent Death Reporting System, as appropriate; or

''(3) another appropriate surveillance program, including such a program that collects data on suicides and self-harm among special populations, such as members of the military and veterans.

''(i) RULE OF CONSTRUCTION REGARDING APPLICABILITY OF PRIVACY PROTECTIONS.—Nothing in this section shall be construed to limit or alter the application of Federal or State law relating to the privacy of information to data or information that is collected or created under this section.

''(j) REPORT.—

"(1) SUBMISSION.—Not later than 3 years after the date of enactment of this Act, the Secretary shall evaluate the suicide and self-harm syndromic surveillance systems at the Federal, State, and local levels and submit a report to Congress on the data collected under subsections (b) and (c) in a manner that prevents the disclosure of individually identifiable information, at a minimum, consistent with all applicable privacy laws and regulations.

"(2) CONTENTS.—In addition to the data collected under subsections (b) and (c), the report under paragraph (1) shall include—

"(A) challenges and gaps in data collection and reporting;

"(B) recommendations to address such gaps and challenges; and

"(C) a description of any public health responses initiated at the Federal, State, or local level in response to the data collected.

"(k) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $20,000,000 for each of fiscal years 2021 through 2025.".

SEC. 6022. GRANTS TO PROVIDE SELF-HARM AND SUICIDE PREVENTION SERVICES.

Part B of title V of the Public Health Service Act (42 U.S.C. 290aa et seq.) is amended by adding at the end the following:

"SEC. 520N. GRANTS TO PROVIDE SELF-HARM AND SUICIDE PREVENTION SERVICES.

''(a) IN GENERAL.—The Secretary of Health and Human Services shall award grants to hospital emergency departments to provide self-harm and suicide prevention services.

''(b) ACTIVITIES SUPPORTED.—

''(1) IN GENERAL.—A hospital emergency department awarded a grant under subsection (a) shall use amounts under the grant to implement a program or protocol to better prevent suicide attempts among hospital patients after discharge, which may include—

''(A) screening patients for self-harm and suicide in accordance with the standards of practice described in subsection (e)(1) and standards of care established by appropriate medical and advocacy organizations;

''(B) providing patients short-term self-harm and suicide prevention services in accord-

ance with the results of the screenings described in subparagraph (A); and

"(C) referring patients, as appropriate, to a health care facility or provider for purposes of receiving long-term self-harm and suicide prevention services, and providing any additional follow up services and care identified as appropriate as a result of the screenings and short-term self-harm and suicide prevention services described in subparagraphs (A) and (B).

"(2) USE OF FUNDS TO HIRE AND TRAIN STAFF.—Amounts awarded under subsection (a) may be used to hire clinical social workers, mental and behavioral health care professionals, and support staff as appropriate, and to train existing staff and newly hired staff to carry out the activities described in paragraph (1).

"(c) GRANT TERMS.—A grant awarded under subsection (a)—

"(1) shall be for a period of 3 years; and

"(2) may be renewed subject to the requirements of this section.

"(d) APPLICATIONS.—A hospital emergency department seeking a grant under subsection (a) shall submit an application to the Secretary at such time, in such man-

ner, and accompanied by such information as the Secretary may require.

''(e) STANDARDS OF PRACTICE.—

''(1) IN GENERAL.—Not later than 180 days after the date of the enactment of this section, the Secretary shall develop standards of practice for screening patients for self-harm and suicide for purposes of carrying out subsection (b)(1)(C).

''(2) CONSULTATION.—The Secretary shall develop the standards of practice described in paragraph (1) in consultation with individuals and entities with expertise in self-harm and suicide prevention, including public, private, and non-profit entities.

''(f) REPORTING.—

''(1) REPORTS TO THE SECRETARY.—

''(A) IN GENERAL.—A hospital emergency department awarded a grant under subsection (a) shall, at least quarterly for the duration of the grant, submit to the Secretary a report evaluating the activities supported by the grant.

''(B) MATTERS TO BE INCLUDED.—The report required under subparagraph (A) shall include—

''(i) the number of patients receiving—

''(I) screenings carried out at the hospital emergency department;

''(II) short-term self-harm and suicide prevention services at the hospital emergency department; and

''(III) referrals to health care facilities for the purposes of receiving long-term self-harm and suicide prevention;

''(ii) information on the adherence of the hospital emergency department to the standards of practice described in subsection (f)(1); and

''(iii) other information as the Secretary determines appropriate to evaluate the use of grant funds.

''(2) REPORTS TO CONGRESS.—Not later than 2 years after the date of the enactment of the Commitment to Defeat the Virus and Keep America Healthy Act, and biennially thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House

of Representatives a report on the grant program under this section, including—

''(A) a summary of reports received by the Secretary under paragraph (1); and

''(B) an evaluation of the program by the Secretary.

''(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $30,000,000 for each of fiscal years 2021 through 2025.''.

Subtitle D—Effective Suicide Screening in the Emergency Department

SEC. 6031. PROGRAM TO IMPROVE THE CARE PROVIDED TO PATIENTS IN THE EMERGENCY DEPARTMENT WHO ARE AT RISK OF SUICIDE.

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding at the end the following new section:

''SEC. 399V–7. PROGRAM TO IMPROVE THE CARE PROVIDED TO PATIENTS IN THE EMERGENCY DEPARTMENT WHO ARE AT RISK OF SUICIDE.

''(a) IN GENERAL.—The Secretary shall establish a program (in this section referred to as the 'Program') to improve the identification, assessment, and treatment of

patients in emergency departments who are at risk for suicide, including by—

"(1) developing policies and procedures for identifying and assessing individuals who are at risk of suicide; and

"(2) enhancing the coordination of care for such individuals after discharge.

"(b) GRANT ESTABLISHMENT AND PARTICIPATION.—

"(1) IN GENERAL.—In carrying out the Program, the Secretary shall award grants on a competitive basis to not more than 40 eligible health care sites described in paragraph (2).

"(2) ELIGIBILITY.—To be eligible for a grant under this section, a health care site shall—

"(A) submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may specify;

"(B) be a hospital (as defined in section 1861(e) of the Social Security Act);

"(C) have an emergency department; and

"(D) deploy onsite health care or social service professionals to help connect and inte-

grate patients who are at risk of suicide with treatment and mental health support services.

"(3) PREFERENCE.—In awarding grants under this section, the Secretary may give preference to eligible health care sites described in paragraph (2) that meet at least one of the following criteria:

"(A) The eligible health care site is a critical access hospital (as defined in section 1861(mm)(1) of the Social Security Act).

"(B) The eligible health care site is a sole community hospital (as defined in section 1886(d)(5)(D)(iii) of the Social Security Act).

"(C) The eligible health care site is operated by the Indian Health Service, by an Indian tribe or tribal organization (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act), or by an urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act).

"(D) The eligible health care site is located in a geographic area with a suicide rate that is higher than the national rate, as determined by the Secretary based on the most recent data

from the Centers for Disease Control and Prevention.

''(c) PERIOD OF GRANT.—A grant awarded to an eligible health care site under this section shall be for a period of at least 2 years.

''(d) GRANT USES.—

''(1) REQUIRED USES.—A grant awarded under this section to an eligible health care site shall be used for the following purposes:

''(A) To train emergency department health care professionals to identify, assess, and treat patients who are at risk of suicide.

''(B) To establish and implement policies and procedures for emergency departments to improve the identification, assessment and treatment of individuals who are at risk of suicide.

''(C) To establish and implement policies and procedures with respect to care coordination, integrated care models, or referral to evidence-based treatment to be used upon the discharge from the emergency department of patients who are at risk of suicide.

''(2) ADDITIONAL PERMISSIBLE USES.—In addition to the required uses listed in paragraph (1),

a grant awarded under this section to an eligible health care site may be used for any of the following purposes:

"(A) To hire emergency department psychiatrists, psychologists, nurse practitioners, counselors, therapists, or other licensed health care and behavioral health professionals specializing in the treatment of individuals at risk of suicide.

"(B) To develop and implement best practices for the follow-up care and long-term treatment of individuals who are at risk of suicide.

"(C) To increase the availability of and access to evidence-based treatment for individuals who are at risk of suicide, including through telehealth services and strategies to reduce the boarding of these patients in emergency departments.

"(D) To offer consultation with and referral to other supportive services that provide evidence-based treatment and recovery for individuals who are at risk of suicide.

"(e) REPORTING REQUIREMENTS.—

"(1) REPORTS BY GRANTEES.—Each eligible health care site receiving a grant under this section

shall submit to the Secretary an annual report for each year for which the grant is received on the progress of the program funded through the grant. Each such report shall include information on—

''(A) the number of individuals screened in the site's emergency department for being at risk of suicide;

''(B) the number of individuals identified in the site's emergency department as being—

''(i) survivors of an attempted suicide; or

''(ii) are at risk of suicide;

''(C) the number of individuals who are identified in the site's emergency department as being at risk of suicide by a health care or behavioral health professional hired pursuant to subsection (d)(2)(A);

''(D) the number of individuals referred by the site's emergency department to other treatment facilities, the types of such other facilities, and the number of such individuals admitted to such other facilities pursuant to such referrals;

''(E) the effectiveness of programs and activities funded through the grant in preventing suicides and suicide attempts; and

"(F) any other relevant additional data regarding the programs and activities funded through the grant.

"(2) REPORT BY SECRETARY.—Not later than one year after the end of fiscal year 2025, the Secretary shall submit to Congress a report that includes—

"(A) findings on the Program;

"(B) overall patient outcomes achieved through the Program;

"(C) an evaluation of the effectiveness of having a trained health care or behavioral health professional onsite to identify, assess, and treat patients who are at risk of suicide; and

"(D) a compilation of policies, procedures, and best practices established, developed, or implemented by grantees under this section.

"(f) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $20,000,000 for the period of fiscal years 2021 through 2025.".

Subtitle E—Suicide Prevention Lifeline Improvement

SEC. 6041. SUICIDE PREVENTION LIFELINE.

(a) PLAN.—Section 520E–3 of the Public Health Service Act (42 U.S.C. 290bb–36c) is amended—

(1) by redesignating subsection (c) as subsection (e); and

(2) by inserting after subsection (b) the following:

''(c) PLAN.—

''(1) IN GENERAL.—For purposes of maintaining the suicide prevention hotline under subsection (b)(2), the Secretary shall develop and implement a plan to ensure the provision of high-quality service.

''(2) CONTENTS.—The plan required by paragraph (1) shall include the following:

''(A) Quality assurance provisions, including—

''(i) clearly defined and measurable performance indicators and objectives to improve the responsiveness and performance of the hotline, including at backup call centers; and

"(ii) quantifiable timeframes to track the progress of the hotline in meeting such performance indicators and objectives.

"(B) Standards that crisis centers and backup centers must meet—

"(i) to participate in the network under subsection (b)(1); and

"(ii) to ensure that each telephone call, online chat message, and other communication received by the hotline, including at backup call centers, is answered in a timely manner by a person, consistent with the guidance established by the American Association of Suicidology or other guidance determined by the Secretary to be appropriate.

"(C) Guidelines for crisis centers and backup centers to implement evidence-based practices including with respect to followup and referral to other health and social services resources.

"(D) Guidelines to ensure that resources are available and distributed to individuals using the hotline who are not personally in a time of crisis but know of someone who is.

"(E) Guidelines to carry out periodic testing of the hotline, including at crisis centers and backup centers, during each fiscal year to identify and correct any problems in a timely manner.

"(F) Guidelines to operate in consultation with the State department of health, local governments, Indian tribes, and tribal organizations.

"(3) INITIAL PLAN; UPDATES.—The Secretary shall—

"(A) not later than 6 months after the date of enactment of the Commitment to Defeat the Virus and Keep America Healthy Act, complete development of the initial version of the plan required by paragraph (1), begin implementation of such plan, and make such plan publicly available; and

"(B) periodically thereafter, update such plan and make the updated plan publicly available.".

(b) TRANSMISSION OF DATA TO CDC.—Section 520E–3 of the Public Health Service Act (42 U.S.C. 290bb–36c) is amended by inserting after subsection (c)

of such section, as added by subsection (a) of this section, the following:

''(d) TRANSMISSION OF DATA TO CDC.—The Secretary shall formalize and strengthen agreements between the National Suicide Prevention Lifeline program and the Centers for Disease Control and Prevention to transmit any necessary epidemiological data from the program to the Centers, including local call center data, to assist the Centers in suicide prevention efforts.''.

(c) AUTHORIZATION OF APPROPRIATIONS.—Subsection (e) of section 520E–3 of the Public Health Service Act (42 U.S.C. 290bb–36c) is amended to read as follows:

''(e) AUTHORIZATION OF APPROPRIATIONS.—

''(1) IN GENERAL.—To carry out this section, there are authorized to be appropriated $50,000,000 for each of fiscal years 2021 through 2023.

''(2) ALLOCATION.—Of the amount authorized to be appropriated by paragraph (1) for each of fiscal years 2021 through 2023, at least 80 percent shall be made available to crisis centers.''.

SEC. 6042. PILOT PROGRAM ON INNOVATIVE TECHNOLOGIES.

(a) PILOT PROGRAM.—

(1) IN GENERAL.—The Secretary of Health and Human Services, acting through the Assistant Sec-

retary for Mental Health and Substance Use, shall carry out a pilot program to research, analyze, and employ various technologies and platforms of communication (including social media platforms, texting platforms, and email platforms) for suicide prevention in addition to the telephone and online chat service provided by the Suicide Prevention Lifeline.

(2) AUTHORIZATION OF APPROPRIATIONS.—To carry out paragraph (1), there is authorized to be appropriated $5,000,000 for the period of fiscal years 2021 and 2022.

(b) REPORT.—Not later than 24 months after the date on which the pilot program under subsection (a) commences, the Secretary of Health and Human Services, acting through the Assistant Secretary for Mental Health and Substance Use, shall submit to the Congress a report on the pilot program. With respect to each platform of communication employed pursuant to the pilot program, the report shall include—

(1) a full description of the program;

(2) the number of individuals served by the program;

(3) the average wait time for each individual to receive a response;

(4) the cost of the program, including the cost per individual served; and

(5) any other information the Secretary determines appropriate.

SEC. 6043. HHS STUDY AND REPORT.

Not later than 24 months after the Secretary of Health and Human Services begins implementation of the plan required by section 520E–3(c) of the Public Health Service Act, as added by section 6041(a)(2) of this subtitle, the Secretary shall—

(1) complete a study on—

(A) the implementation of such plan, including the progress towards meeting the objectives identified pursuant to paragraph (2)(A)(i) of such section 520E–3(c) by the timeframes identified pursuant to paragraph (2)(A)(ii) of such section 520E–3(c); and

(B) in consultation with the Director of the Centers for Disease Control and Prevention, options to expand data gathering from calls to the Suicide Prevention Lifeline in order to better track aspects of usage such as repeat calls, consistent with applicable Federal and State privacy laws; and

(2) submit a report to the Congress on the results of such study, including recommendations on whether additional legislation or appropriations are needed.

SEC. 6044. GAO STUDY AND REPORT.

(a) IN GENERAL.—Not later than 24 months after the Secretary of Health and Human Services begins implementation of the plan required by section 520E–3(c) of the Public Health Service Act, as added by section 6041(a)(2) of this subtitle, the Comptroller General of the United States shall—

(1) complete a study on the Suicide Prevention Lifeline; and

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

(b) ISSUES TO BE STUDIED.—The study required by subsection (a) shall address—

(1) the feasibility of geolocating callers to direct calls to the nearest crisis center;

(2) operation shortcomings of the Suicide Prevention Lifeline;

(3) geographic coverage of each crisis call center;

(4) the call answer rate of each crisis call center;

(5) the call wait time of each crisis call center;

(6) the hours of operation of each crisis call center;

(7) funding avenues of each crisis call center;

(8) the implementation of the plan under section 520E–3(c) of the Public Health Service Act, as added by section 6041(a) of this subtitle, including the progress towards meeting the objectives identified pursuant to paragraph (2)(A)(i) of such section 520E–3(c) by the timeframes identified pursuant to paragraph (2)(A)(ii) of such section 520E–3(c); and

(9) service to individuals requesting a foreign language speaker, including—

(A) the number of calls or chats the Lifeline receives from individuals speaking a foreign language;

(B) the capacity of the Lifeline to handle these calls or chats; and

(C) the number of crisis centers with the capacity to serve foreign language speakers, in house.

(c) RECOMMENDATIONS.—The report required by subsection (a) shall include recommendations for improving the Suicide Prevention Lifeline, including recommendations for legislative and administrative actions.

SEC. 6045. DEFINITION.

In this subtitle, the term ''Suicide Prevention Lifeline'' means the suicide prevention hotline maintained pursuant to section 520E–3 of the Public Health Service Act (42 U.S.C. 290bb–36c).

Subtitle F—Campaign To Prevent Suicide

SEC. 6051. NATIONAL SUICIDE PREVENTION LIFELINE.

Section 520E–3(b)(2) of the Public Health Service Act (42 U.S.C. 290bb–36c(b)(2)) is amended by inserting after ''suicide prevention hotline'' the following: '', which, beginning not later than one year after the date of the enactment of the Commitment to Defeat the Virus and Keep America Healthy Act, shall be a 3-digit nationwide toll-free telephone number,''.

SEC. 6052. NATIONAL SUICIDE PREVENTION MEDIA CAMPAIGN.

(a) NATIONAL SUICIDE PREVENTION MEDIA CAMPAIGN.—

(1) IN GENERAL.—Not later than the date that is three years after the date of the enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary''), in coordination with the Assistant Secretary for Mental Health and Substance Use (referred to in this section as the ''Assistant Secretary'') and the Director

of the Centers for Disease Control and Prevention (referred to in this section as the ''Director''), shall conduct a national suicide prevention media campaign (referred to in this section as the ''national media campaign''), in accordance with the requirements of this section, for purposes of—

(A) preventing suicide in the United States;

(B) educating families, friends, and communities on how to address suicide and suicidal thoughts, including when to encourage individuals with suicidal risk to seek help; and

(C) increasing awareness of suicide prevention resources of the Centers for Disease Control and Prevention and the Substance Abuse and Mental Health Services Administration (including the suicide prevention hotline maintained under section 520E–3 of the Public Health Service Act (42 U.S.C. 290bb–36c)), any suicide prevention mobile application of the Centers for Disease Control and Prevention or the Substance Abuse Mental Health Services Administration, and other support resources determined appropriate by the Secretary.

(2) ADDITIONAL CONSULTATION.—In addition to coordinating with the Assistant Secretary and the Director under this section, the Secretary shall consult with, as appropriate, State, local, Tribal, and territorial health departments, primary health care providers, hospitals with emergency departments, mental and behavioral health services providers, crisis response services providers, first responders, suicide prevention and mental health professionals, patient advocacy groups, survivors of suicide attempts, and representatives of television and social media platforms in planning the national media campaign to be conducted under paragraph (1).

(b) TARGET AUDIENCES.—

(1) TAILORING ADVERTISEMENTS AND OTHER COMMUNICATIONS.—In conducting the national media campaign under subsection (a)(1), the Secretary may tailor culturally competent advertisements and other communications of the campaign across all available media for a target audience (such as a particular geographic location or demographic) across the lifespan.

(2) TARGETING CERTAIN LOCAL AREAS.—The Secretary shall, to the maximum extent practicable, use amounts made available under subsection (f) for

media that targets individuals in local areas with higher suicide rates.

(c) USE OF FUNDS.—

(1) REQUIRED USES.—

(A) IN GENERAL.—The Secretary shall, to the extent reasonably feasible with the funds made available under subsection (f), carry out the following, with respect to the national media campaign:

(i) The purchase of advertising time and space, including the strategic planning for, and accounting of, any such purchase.

(ii) Creative services and talent costs.

(iii) Advertising production costs.

(iv) Testing and evaluation of advertising.

(v) Evaluation of the effectiveness of the national media campaign.

(vi) Operational and management expenses.

(vii) The creation of an educational toolkit for television and social media platforms to use in discussing suicide and raising awareness about how to prevent suicide.

(B) SPECIFIC REQUIREMENTS.—

(i) TESTING AND EVALUATION OF ADVERTISING.—In testing and evaluating advertising under subparagraph (A)(iv), the Secretary shall test all advertisements after use in the national media campaign to evaluate the extent to which such advertisements have been effective in carrying out the purposes of the national media campaign.

(ii) EVALUATION OF EFFECTIVENESS OF NATIONAL MEDIA CAMPAIGN.—In evaluating the effectiveness of the national media campaign under subparagraph (A)(v), the Secretary shall take into account—

(I) the number of unique calls that are made to the suicide prevention hotline maintained under section 520E–3 of the Public Health Service Act (42 U.S.C. 290bb–36c) and assess whether there are any State and regional variations with respect to the capacity to answer such calls;

(II) the number of unique encounters with suicide prevention and support resources of the Centers for Disease Control and Prevention and the Substance Abuse and Mental Health Services Administration and assess engagement with such suicide prevention and support resources;

(III) whether the national media campaign has contributed to increased awareness that suicidal individuals should be engaged, rather than ignored; and

(IV) such other measures of evaluation as the Secretary determines are appropriate.

(2) OPTIONAL USES.—The Secretary may use amounts made available under subsection (f) for the following, with respect to the national media campaign:

(A) Partnerships with professional and civic groups, community-based organizations, including faith-based organizations, and Government or Tribal organizations that the Secretary determines have experience in suicide

prevention, including the Substance Abuse and Mental Health Services Administration and the Centers for Disease Control and Prevention.

(B) Entertainment industry outreach, interactive outreach, media projects and activities, public information, news media outreach, outreach through television programs, and corporate sponsorship and participation.

(d) PROHIBITIONS.—None of the amounts made available under subsection (f) may be obligated or expended for any of the following:

(1) To supplant current suicide prevention campaigns.

(2) For partisan political purposes, or to express advocacy in support of or to defeat any clearly identified candidate, clearly identified ballot initiative, or clearly identified legislative or regulatory proposal.

(e) REPORT TO CONGRESS.—Not later than 18 months after implementation of the national media campaign has begun, the Secretary, in coordination with the Assistant Secretary and the Director, shall, with respect to the first year of the national media campaign, submit to Congress a report that describes—

(1) the strategy of the national media campaign and whether specific objectives of such campaign were accomplished, including whether such campaign impacted the number of calls made to lifeline crisis centers and the capacity of such centers to manage such calls;

(2) steps taken to ensure that the national media campaign operates in an effective and efficient manner consistent with the overall strategy and focus of the national media campaign;

(3) plans to purchase advertising time and space;

(4) policies and practices implemented to ensure that Federal funds are used responsibly to purchase advertising time and space and eliminate the potential for waste, fraud, and abuse; and

(5) all contracts entered into with a corporation, a partnership, or an individual working on behalf of the national media campaign.

(f) AUTHORIZATION OF APPROPRIATIONS.—For purposes of carrying out this section, there is authorized to be appropriated $10,000,000 for each of fiscal years 2021 through 2025.

Subtitle G—Helping Emergency Responders Overcome

SEC. 6061. DATA SYSTEM TO CAPTURE NATIONAL PUBLIC SAFETY OFFICER SUICIDE INCIDENCE.

The Public Health Service Act is amended by inserting before section 318 of such Act (42 U.S.C. 247c) the following:

"SEC. 317W. DATA SYSTEM TO CAPTURE NATIONAL PUBLIC SAFETY OFFICER SUICIDE INCIDENCE.

''(a) IN GENERAL.—The Secretary, in coordination with the Director of the Centers for Disease Control and Prevention and other agencies as the Secretary determines appropriate, shall—

''(1) develop and maintain a data system, to be known as the Public Safety Officer Suicide Reporting System, for the purposes of—

''(A) collecting data on the suicide incidence among public safety officers; and

''(B) facilitating the study of successful interventions to reduce suicide among public safety officers; and

''(2) integrate such system into the National Violent Death Reporting System, so long as the Secretary determines such integration to be consistent with the purposes described in paragraph (1).

''(b) DATA COLLECTION.—In collecting data for the Public Safety Officer Suicide Reporting System, the Secretary shall, at a minimum, collect the following information:

''(1) The total number of suicides in the United States among all public safety officers in a given calendar year.

''(2) Suicide rates for public safety officers in a given calendar year, disaggregated by—

''(A) age and gender of the public safety officer;

''(B) State;

''(C) occupation; including both the individual's role in their public safety agency and their primary occupation in the case of volunteer public safety officers;

''(D) where available, the status of the public safety officer as volunteer, paid-on-call, or career; and

''(E) status of the public safety officer as active or retired.

''(c) CONSULTATION DURING DEVELOPMENT.—In developing the Public Safety Officer Suicide Reporting System, the Secretary shall consult with non-Federal experts to determine the best means to collect data regard-

ing suicide incidence in a safe, sensitive, anonymous, and effective manner. Such non-Federal experts shall include, as appropriate, the following:

''(1) Public health experts with experience in developing and maintaining suicide registries.

''(2) Organizations that track suicide among public safety officers.

''(3) Mental health experts with experience in studying suicide and other profession-related traumatic stress.

''(4) Clinicians with experience in diagnosing and treating mental health issues.

''(5) Active and retired volunteer, paid-on-call, and career public safety officers.

''(6) Relevant national police, and fire and emergency medical services, organizations.

''(d) DATA PRIVACY AND SECURITY.—In developing and maintaining the Public Safety Officer Suicide Reporting System, the Secretary shall ensure that all applicable Federal privacy and security protections are followed to ensure that—

''(1) the confidentiality and anonymity of suicide victims and their families are protected, including so as to ensure that data cannot be used to deny benefits; and

''(2) data is sufficiently secure to prevent unauthorized access.

''(e) REPORTING.—

''(1) ANNUAL REPORT.—Not later than 2 years after the date of enactment of the Commitment to Defeat the Virus and Keep America Healthy Act, and biannually thereafter, the Secretary shall submit a report to the Congress on the suicide incidence among public safety officers. Each such report shall—

''(A) include the number and rate of such suicide incidence, disaggregated by age, gender, and State of employment;

''(B) identify characteristics and contributing circumstances for suicide among public safety officers;

''(C) disaggregate rates of suicide by—

''(i) occupation;

''(ii) status as volunteer, paid-on-call, or career; and

''(iii) status as active or retired;

''(D) include recommendations for further study regarding the suicide incidence among public safety officers;

''(E) specify in detail, if found, any obstacles in collecting suicide rates for volunteers and include recommended improvements to overcome such obstacles;

''(F) identify options for interventions to reduce suicide among public safety officers; and

''(G) describe procedures to ensure the confidentiality and anonymity of suicide victims and their families, as described in subsection (d)(1).

''(2) PUBLIC AVAILABILITY.—Upon the submission of each report to the Congress under paragraph (1), the Secretary shall make the full report publicly available on the website of the Centers for Disease Control and Prevention.

''(f) DEFINITION.—In this section, the term 'public safety officer' means—

''(1) a public safety officer as defined in section 1204 of the Omnibus Crime Control and Safe Streets Act of 1968; or

''(2) a public safety telecommunicator as described in detailed occupation 43–5031 in the Standard Occupational Classification Manual of the Office of Management and Budget (2018).

''(g) PROHIBITED USE OF INFORMATION.—Notwithstanding any other provision of law, if an individual is identified as deceased based on information contained in the Public Safety Officer Suicide Reporting System, such information may not be used to deny or rescind life insurance payments or other benefits to a survivor of the deceased individual.''.

SEC. 6062. PEER-SUPPORT BEHAVIORAL HEALTH AND WELLNESS PROGRAMS WITHIN FIRE DEPARTMENTS AND EMERGENCY MEDICAL SERVICE AGENCIES.

(a) IN GENERAL.—Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) is amended by adding at the end the following:

''SEC. 320B. PEER-SUPPORT BEHAVIORAL HEALTH AND WELLNESS PROGRAMS WITHIN FIRE DEPARTMENTS AND EMERGENCY MEDICAL SERVICE AGENCIES.

''(a) IN GENERAL.—The Secretary shall award grants to eligible entities for the purpose of establishing or enhancing peer-support behavioral health and wellness programs within fire departments and emergency medical services agencies.

''(b) PROGRAM DESCRIPTION.—A peer-support behavioral health and wellness program funded under this section shall—

''(1) use career and volunteer members of fire departments or emergency medical services agencies to serve as peer counselors;

''(2) provide training to members of career, volunteer, and combination fire departments or emergency medical service agencies to serve as such peer counselors;

''(3) purchase materials to be used exclusively to provide such training; and

''(4) disseminate such information and materials as are necessary to conduct the program.

''(c) DEFINITION.—In this section:

''(1) The term 'eligible entity' means a nonprofit organization with expertise and experience with respect to the health and life safety of members of fire and emergency medical services agencies.

''(2) The term 'member'—

''(A) with respect to an emergency medical services agency, means an employee, regardless of rank or whether the employee receives compensation (as defined in section 1204(7) of the

Omnibus Crime Control and Safe Streets Act of 1968); and

''(B) with respect to a fire department, means any employee, regardless of rank or whether the employee receives compensation, of a Federal, State, Tribal, or local fire department who is responsible for responding to calls for emergency service.''.

(b) TECHNICAL CORRECTION.—Effective as if included in the enactment of the Children's Health Act of 2000 (Public Law 106–310), the amendment instruction in section 1603 of such Act is amended by striking ''Part B of the Public Health Service Act'' and inserting ''Part B of title III of the Public Health Service Act''.

SEC. 6063. HEALTH CARE PROVIDER BEHAVIORAL HEALTH AND WELLNESS PROGRAMS.

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.), as amended by section 6062, is further amended by adding at the end the following:

''SEC. 320C. HEALTH CARE PROVIDER BEHAVIORAL HEALTH AND WELLNESS PROGRAMS.

''(a) IN GENERAL.—The Secretary shall award grants to eligible entities for the purpose of establishing or enhancing behavioral health and wellness programs for health care providers.

''(b) PROGRAM DESCRIPTION.—A behavioral health and wellness program funded under this section shall—

''(1) provide confidential support services for health care providers to help handle stressful or traumatic patient-related events, including counseling services and wellness seminars;

''(2) provide training to health care providers to serve as peer counselors to other health care providers;

''(3) purchase materials to be used exclusively to provide such training; and

''(4) disseminate such information and materials as are necessary to conduct such training and provide such peer counseling.

''(c) DEFINITIONS.—In this section, the term 'eligible entity' means a hospital, including a critical access hospital (as defined in section 1861(mm)(1) of the Social Security Act) or a disproportionate share hospital (as defined under section 1923(a)(1)(A) of such Act), a federally qualified health center (as defined in section 1905(1)(2)(B) of such Act), or any other health care facility.''.

SEC. 6064. DEVELOPMENT OF RESOURCES FOR EDUCATING MENTAL HEALTH PROFESSIONALS ABOUT TREATING FIRE FIGHTERS AND EMERGENCY MEDICAL SERVICES PERSONNEL.

(a) IN GENERAL.—The Administrator of the United States Fire Administration, in consultation with the Secretary of Health and Human Services, shall develop and make publicly available resources that may be used by the Federal Government and other entities to educate mental health professionals about—

(1) the culture of Federal, State, Tribal, and local career, volunteer, and combination fire departments and emergency medical services agencies;

(2) the different stressors experienced by firefighters and emergency medical services personnel, supervisory firefighters and emergency medical services personnel, and chief officers of fire departments and emergency medical services agencies;

(3) challenges encountered by retired firefighters and emergency medical services personnel; and

(4) evidence-based therapies for mental health issues common to firefighters and emergency medical services personnel within such departments and agencies.

(b) CONSULTATION.—In developing resources under subsection (a), the Administrator of the United States Fire Administration and the Secretary of Health and Human Services shall consult with national fire and emergency medical services organizations.

(c) DEFINITIONS.—In this section:

(1) The term ''firefighter'' means any employee, regardless of rank or whether the employee receives compensation, of a Federal, State, Tribal, or local fire department who is responsible for responding to calls for emergency service.

(2) The term ''emergency medical services personnel'' means any employee, regardless of rank or whether the employee receives compensation, as defined in section 1204(7) of the Omnibus Crime Control and Safe Streets Act of 1968 (34 U.S.C. 10284(7)).

(3) The term ''chief officer'' means any individual who is responsible for the overall operation of a fire department or an emergency medical services agency, irrespective of whether such individual also serves as a firefighter or emergency medical services personnel.

SEC. 6065. BEST PRACTICES AND OTHER RESOURCES FOR ADDRESSING POSTTRAUMATIC STRESS DISORDER IN PUBLIC SAFETY OFFICERS.

(a) DEVELOPMENT; UPDATES.—The Secretary of Health and Human Services shall—

(1) develop and assemble evidence-based best practices and other resources to identify, prevent, and treat posttraumatic stress disorder and co-occurring disorders in public safety officers; and

(2) reassess and update, as the Secretary determines necessary, such best practices and resources, including based upon the options for interventions to reduce suicide among public safety officers identified in the annual reports required by section 317W(e)(1)(F) of the Public Health Service Act, as added by section 6061 of this subtitle.

(b) CONSULTATION.—In developing, assembling, and updating the best practices and resources under subsection (a), the Secretary of Health and Human Services shall consult with, at a minimum, the following:

(1) Public health experts.

(2) Mental health experts with experience in studying suicide and other profession-related traumatic stress.

(3) Clinicians with experience in diagnosing and treating mental health issues.

(4) Relevant national police, fire, and emergency medical services organizations.

(c) AVAILABILITY.—The Secretary of Health and Human Services shall make the best practices and resources under subsection (a) available to Federal, State, and local fire, law enforcement, and emergency medical services agencies.

(d) FEDERAL TRAINING AND DEVELOPMENT PROGRAMS.—The Secretary of Health and Human Services shall work with Federal departments and agencies, including the United States Fire Administration, to incorporate education and training on the best practices and resources under subsection (a) into Federal training and development programs for public safety officers.

(e) DEFINITION.—In this section, the term ''public safety officer'' means—

(1) a public safety officer as defined in section 1204 of the Omnibus Crime Control and Safe Streets Act of 1968 (34 U.S.C. 10284); or

(2) a public safety telecommunicator as described in detailed occupation 43–5031 in the Standard Occupational Classification Manual of the Office of Management and Budget (2018).

Subtitle H—Behavioral Health Intervention Guidelines

SEC. 6071. BEST PRACTICES FOR BEHAVIORAL INTERVENTION TEAMS.

The Public Health Service Act is amended by inserting after section 520G of such Act (42 U.S.C. 290bb–38) the following new section:

"SEC. 520H. BEST PRACTICES FOR BEHAVIORAL INTERVENTION TEAMS.

''(a) IN GENERAL.—The Secretary, acting through the Assistant Secretary, shall develop and periodically update—

''(1) best practices to assist elementary schools, secondary schools, and institutions of higher education in establishing and using behavioral intervention teams; and

''(2) a list of evidence-based threat assessment training providers to assist personnel in elementary schools, secondary schools, and institutions of higher education in implementing such best practices, including with respect to training behavioral intervention teams.

''(b) ELEMENTS.—The best practices under subsection (a)(1) shall include guidance on the following:

''(1) How behavioral intervention teams can operate effectively from an evidence-based, objective perspective while protecting the constitutional and civil rights of individuals, including any individual of concern.

''(2) The use of behavioral intervention teams to identify individuals of concern, implement interventions, and manage risk through the framework of the school's or institution's rules or code of conduct, as applicable.

''(3) How behavioral intervention teams can, when assessing an individual of concern—

''(A) seek training on evidence-based, threat-assessment rubrics;

''(B) ensure that such teams—

''(i) have adequately trained, diverse stakeholders with varied expertise; and

''(ii) use cross validation by a wide-range of individual perspectives on the team; and

''(C) use violence risk assessment.

''(4) How behavioral intervention teams can avoid—

''(A) attempting to predict future behavior by the concept of pre-crime;

"(B) inappropriately using a mental health assessment;

"(C) inappropriately limiting or restricting law enforcement's jurisdiction over criminal matters;

"(D) attempting to substitute the behavioral intervention process in place of a criminal process, or impede a criminal process, when an individual of concern's behavior has potential criminal implications;

"(E) endangering an individual's privacy by failing to ensure that all applicable Federal and State privacy laws are fully complied with; or

"(F) creating school-to-prison pipelines.

"(c) CONSULTATION.—In carrying out subsection (a)(1), the Secretary shall consult with—

"(1) the Secretary of Education;

"(2) the Director of the National Threat Assessment Center of the Department of Homeland Security;

"(3) the Attorney General of the United States; and

"(4) as appropriate, relevant stakeholders including—

"(A) teachers and other educators, principals, school administrators, school board members, school psychologists, mental health professionals, and parents of elementary school and secondary school students;

"(B) local law enforcement agencies and campus law enforcement administrators;

"(C) mental health mobile crisis providers;

"(D) child and adolescent psychiatrists; and

"(E) other education and mental health professionals.

"(d) PUBLICATION.—Not later than 2 years after the date of enactment of this section, the Secretary shall publish the best practices under subsection (a)(1) and the list under subsection (a)(2) on a publicly accessible website of the Department of Health and Human Services.

"(e) TECHNICAL ASSISTANCE.—The Secretary shall provide technical assistance to institutions of higher education, elementary schools, and secondary schools to assist such institutions and schools in implementing the best practices under subsection (a).

"(f) DEFINITIONS.—In this section:

"(1) The term 'behavioral intervention team' means a team of qualified individuals who—

''(A) are responsible for identifying and assessing individuals of concern; and

''(B) develop and facilitate implementation of evidence-based interventions to mitigate the threat of harm to self or others posed by individuals of concern and address the mental and behavioral health needs of individuals of concern to reduce such threat.

''(2) The terms 'elementary school', 'parent', and 'secondary school' have the meanings given to such terms in section 8101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7801).

''(3) The term 'individual of concern' means an individual whose behavior indicates a potential threat to self or others.

''(4) The term 'institution of higher education' has the meaning given to such term in section 102 of the Higher Education Act of 1965 (20 U.S.C. 1002).

''(5) The term 'mental health assessment' means an evaluation, primarily focused on diagnosis, determining the need for involuntary commitment, medication management, and on-going treatment recommendations.

''(6) The term 'pre-crime' means law-enforcement efforts and strategies to deter crime by predicting when and where criminal activity will occur.

''(7) The term 'violence risk assessment' refers to a broad determination of the potential risk of violence based on evidence-based literature.''.

Subtitle I—Suicide Training and Awareness Nationally Delivered for Universal Prevention

SEC. 6081. STUDENT SUICIDE AWARENESS AND PREVENTION TRAINING.

(a) IN GENERAL.—Title V of the Public Health Service Act is amended by inserting after section 520A of such Act (42 U.S.C. 290bb–32) the following:

''SEC. 520B. STUDENT SUICIDE AWARENESS AND PREVENTION TRAINING POLICIES.

''(a) IN GENERAL.—As a condition on receipt of funds under section 520A, each State educational agency, local educational agency, and Tribal educational agency that receives such funds, directly or through a State or Indian Tribe, for activities to be performed within secondary schools, including the Project AWARE State Education Agency Grant Program, shall—

''(1) establish and implement a school-based student suicide awareness and prevention training policy;

''(2) consult with stakeholders (including principals, teachers, parents, local Tribal officials, and other school leaders) in the development of the policy under subsection (a)(1); and

''(3) collect and report information in accordance with subsection (c).

''(b) SCHOOL-BASED STUDENT SUICIDE AWARENESS AND PREVENTION TRAINING POLICY.—A school-based student suicide awareness and prevention training policy implemented pursuant to subsection (a)—

''(1) shall be evidence-based;

''(2) shall be culturally and linguistically appropriate;

''(3) shall provide evidence-based training to students in grades 6 through 12, in coordination with school-based mental health service providers as defined in section 4102(6) of the Elementary and Secondary Education Act of 1965, if applicable, regarding—

''(A) suicide education and awareness, including warning signs of self-harm or suicidal ideation;

"(B) methods that students can use to seek help for themselves and others; and

"(C) student resources for suicide awareness and prevention;

"(4) shall provide for retraining of such students every school year;

"(5) may last for such period as the State educational agency, local educational agency, or Tribal educational agency involved determines to be appropriate;

"(6) may be implemented through any delivery method, including in-person trainings, digital trainings, or train-the-trainer models; and

"(7) may include discussion of comorbidities or risk factors for suicidal ideation or self-harm, including substance misuse, sexual or physical abuse, mental illness, or other evidence-based comorbidities and risk factors.

"(c) COLLECTION OF INFORMATION AND REPORTING.—Each State educational agency, local educational agency, and Tribal educational agency that receives funds under section 520A shall, with respect to each school served by the agency, collect and report to the Secretary the following information:

''(1) The number of student trainings conducted.

''(2) The number of students trained, disaggregated by age and grade level.

''(3) The number of help-seeking reports made by students after implementation of such policy.

''(d) EVIDENCE-BASED PROGRAM LISTING.—The Secretary of Health and Human Services shall coordinate with the Secretary of Education to make publicly available the policies established by State educational agencies, local educational agencies, and Tribal educational agencies pursuant to this section and the training that is available to students and teams pursuant to such policies, including identification of whether such training is available to trainees at no cost.

''(e) IMPLEMENTATION TIMELINE.—A State educational agency, local educational agency, or Tribal educational agency shall establish and begin implementation of the policies required by subsection (a)(1) not later than the beginning of the third fiscal year following the date of enactment of this section for which the agency receives funds under section 520A.

''(f) DEFINITIONS.—In this section and section 520B–1:

''(1) The term 'evidence-based' has the meaning given to such term in section 8101 of the Elementary and Secondary Education Act of 1965.

''(2) The term 'local educational agency' has the meaning given to such term in section 8101 of the Elementary and Secondary Education Act of 1965.

''(3) The term 'State educational agency' has the meaning given to such term in section 8101 of the Elementary and Secondary Education Act of 1965.

''(4) The term 'Tribal educational agency' has the meaning given to the term 'tribal educational agency' in section 6132 of the Elementary and Secondary Education Act of 1965.

''SEC. 520B–1. BEST PRACTICES FOR STUDENT SUICIDE AWARENESS AND PREVENTION TRAINING.

''The Secretary of Health and Human Services, in consultation with the Secretary of Education and the Bureau of Indian Education, shall—

''(1) publish best practices for school-based student suicide awareness and prevention training, pursuant to section 520B, that are based on—

''(A) evidence-based practices; and

''(B) input from relevant Federal agencies, national organizations, Indian Tribes and Tribal organizations, and related stakeholders;

''(2) publish guidance, based on the best practices under paragraph (1), to provide State educational agencies, local educational agencies, and Tribal educational agencies with information on student suicide awareness and prevention best practices;

''(3) disseminate such best practices to State educational agencies, local educational agencies, and Tribal educational agencies; and

''(4) provide technical assistance to State educational agencies, local educational agencies, and Tribal educational agencies.''.

SEC. 6082. EFFECTIVE DATE.

The amendments made by this subtitle shall only apply with respect to applications for assistance under section 520A of the Public Health Service Act (42 U.S.C. 290bb–32) that are submitted after the date of enactment of this Act.

TITLE VII—ADDRESSING THE IMPACTS OF COVID–19 ON SUBSTANCE USE DISORDERS

Subtitle A—Easy Medication Access and Treatment for Opioid Addiction

SEC. 7001. DISPENSATION OF NARCOTIC DRUGS FOR THE PURPOSE OF RELIEVING ACUTE WITHDRAWAL SYMPTOMS FROM OPIOID USE DISORDER.

Not later than 180 days after the date of enactment of this Act, the Attorney General shall revise section 1306.07(b) of title 21, Code of Federal Regulations, so that practitioners, in accordance with applicable State, Federal, or local laws relating to controlled substances, are allowed to dispense not more than a three-day supply of narcotic drugs to one person or for one person's use at one time for the purpose of initiating maintenance treatment or detoxification treatment (or both).

Subtitle B—Access to Remote Behavioral Health Treatment

SEC. 7011. REGISTRATION OF QUALIFIED COMMUNITY MENTAL HEALTH CENTERS.

(a) DEFINITIONS.—Section 102 of the Controlled Substances Act (21 U.S.C. 802) is amended—

(1) by striking paragraph (54)(A)(i) and inserting the following:

''(i) while the patient is being treated by, and physically located in—

''(I) a hospital or clinic registered under section 303(f); or

''(II) a qualified community mental health center registered under section 303(l); and'';

(2) by redesignating paragraph (58) as paragraph (59);

(3) by redesignating the second paragraph (57) (as added by section 401(a) of the First Step Act of 2018 (Public Law 115–391)) as paragraph (58); and

(4) by adding at the end the following:

''(60) The term 'qualified community mental health center' means a facility that—

''(A)(i) meets the criteria specified in section 1913(c) of the Public Health Service Act to be considered a community mental health center; or

''(ii) meets the criteria specified pursuant to section 223 of the Protecting Access to Medicare Act of 2014 to be considered a certified community behavioral health clinic; and

''(B) is licensed, operated, authorized, certified, or otherwise recognized by a State government.''.

(b) REGISTRATION.—Section 303 of the Controlled Substances Act (21 U.S.C. 823) is amended by adding at the end the following:

''(l) QUALIFIED COMMUNITY MENTAL HEALTH CENTERS.—

''(1) REGISTRATION.—The Attorney General shall register qualified community mental health centers to administer controlled substances through the practice of telemedicine.

''(2) DENIAL OF APPLICATIONS.—The Attorney General may deny an application for registration under paragraph (1) if the Attorney General determines that the registration would be inconsistent with the public interest after considering—

''(A) any recommendation by the licensing board or professional disciplinary authority of the State in which the applicant is located;

''(B) the experience of the applicant in treating patients;

''(C) any conviction of an employee of the applicant under Federal or State law relating to treatment of patients;

"(D) the compliance of the applicant with applicable Federal, State, or local laws relating to treatment of patients; and

"(E) any other conduct by the applicant that may threaten the public's health and safety.".

(c) REPORT TO CONGRESS.—Not later than 60 days after the date of enactment of this Act, the Attorney General of the United States shall submit to the Congress a plan for implementation of the amendments made by subsections (a) and (b).

(d) DELAYED APPLICABILITY.—The amendments made by subsections (a) and (b) apply beginning on the date that is 120 days after the date of enactment of this Act.

Subtitle C—PDMP Pilot Program

SEC. 7021. PILOT PROGRAM FOR INTEGRATING SUBSTANCE USE DISORDER AND BEHAVIORAL HEALTH TREATMENT LOCATOR TOOL INTO STATE PRESCRIPTION DRUG MONITORING PROGRAMS.

(a) IN GENERAL.—The Secretary of Health and Human Services, in consultation with the Assistant Secretary for Mental Health and Substance Use, shall establish and implement a pilot program in which the Secretary

awards grants to, or enters into cooperative agreements with, not more than 5 eligible States to test the feasibility and outcomes of integrating a substance use disorder and behavioral health treatment locator tool into the State's prescription drug monitoring program.

(b) GRANT ESTABLISHMENT AND PARTICIPATION.—

(1) IN GENERAL.—In carrying out the pilot program under this section, the Secretary shall, on a competitive basis, award grants to, or enter into cooperative agreements with, not more than 5 eligible States.

(2) ELIGIBILITY.—To be eligible for a grant under this section, a State shall demonstrate to the Secretary's satisfaction that the State is making progress in integrating the State's PDMP with electronic health records and health information technology infrastructure.

(3) PREFERENCE.—In awarding grants under this section, the Secretary shall give preference to eligible States described in paragraph (2) whose rates of death due to drug overdose per population of 100,000 are in the top quartile according to the most recent data of the Centers for Disease Control and Prevention.

(c) PERIOD OF GRANT.—A grant awarded to an eligible entity under this section shall be for a period of 2 years.

(d) GRANT USES.—

(1) REQUIRED USES.—A grant awarded under this section to an eligible State shall be used for both of the following purposes:

(A) To integrate a substance use disorder and behavioral health treatment locator tool into the PDMP.

(B) To develop and disseminate guidance for health care providers on how to consult and share information obtained through the substance use disorder and behavioral health treatment locator tool when a patient's PDMP information indicates possible misuse of a controlled substance.

(2) ADDITIONAL PERMISSIBLE USES.—A grant awarded under this section to an eligible State may be used for any of the following additional purposes:

(A) To integrate a substance use disorder and behavioral health treatment locator tool into the PDMP that incorporates direct referral capabilities that enable the health care provider—

(i) to refer a patient to treatment or for an assessment; and

(ii) consistent with the protection of information by Federal and State privacy laws and security rules, receive feedback about the patient's engagement with such treatment or assessment.

(B) To integrate a substance use disorder and behavioral health treatment locator tool into the PDMP that provides information regarding the current capacity of inpatient or outpatient treatment resources of a health care provider.

(e) REPORTING REQUIREMENTS.—

(1) REPORTS BY STATES.—Each eligible State that participates in the pilot program under this section shall submit to the Secretary an annual report for each year of the pilot program that includes information on—

(A) the number of health care providers and health facilities with access to the substance use disorder and behavioral health treatment locator tool;

(B) the number of individuals referred to treatment with the assistance of the locator tool;

(C) aggregate, de-identified patient data related to the type of treatment located by the locator tool, how often patients followed through on seeking such treatment, and the average duration of such treatment, to the extent collected by the State;

(D) feedback from providers with access to the locator tool on usability and any impact on outcomes;

(E) recommendations to improve the usability and efficacy of a substance use disorder and behavioral health treatment locator tool within the PDMP; and

(F) additional information and reporting metrics as determined by the Secretary.

(2) REPORT BY SECRETARY.—Not less than 180 days after the conclusion of the pilot program under this section, the Secretary shall submit to the Congress a report on the findings of the program, including—

(A) outcomes reported by the participating States;

(B) findings on the suitability of including a substance use disorder and behavioral health treatment locator tool within State PDMPs; and

(C) recommendations on best practices for integrating a substance use disorder and behavioral health treatment locator tool within State PDMPs.

(f) DEFINITIONS.—In this section:

(1) The term ''prescription drug monitoring program'' or ''PDMP'' has the meaning given to the term ''PDMP'' in section 399O of the Public Health Service Act (42 U.S.C. 280g–3).

(2) The term ''Secretary'' means the Secretary of Health and Human Services.

(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $2,500,000 for each of fiscal years 2021 and 2022.

Subtitle D—Family Support Services for Addiction

SEC. 7031. FAMILY SUPPORT SERVICES FOR INDIVIDUALS STRUGGLING WITH SUBSTANCE USE DISORDER.

Part D of title V of the Public Health Service Act (42 U.S.C. 290dd et seq.) is amended by adding at the end the following:

"SEC. 553. FAMILY SUPPORT SERVICES FOR INDIVIDUALS STRUGGLING WITH SUBSTANCE USE DISORDER.

''(a) DEFINITIONS.—In this section—

''(1) the term 'family community organization' means an independent nonprofit organization that—

''(A) mobilizes resources within and outside of the community of families with individuals living with addiction, to provide a support network, education, and evidence-informed tools for families and loved ones of individuals struggling with substance use disorders; and

''(B) is governed by experts in the field of addiction, which may include—

''(i) experts in evidence-informed interventions for family members;

"(ii) experts in the impact of addiction on family systems;

"(iii) families who have experience with substance use disorders and addiction; and

"(iv) other experts in the field of addiction; and

"(2) the term 'family support services' means resources or programs that support families that include an individual with substance use disorder.

"(b) GRANTS AUTHORIZED.—The Secretary shall award grants to family community organizations to enable such organizations to develop, expand, and enhance evidence-informed family support services.

"(c) FEDERAL SHARE.—The Federal share of the costs of a program funded by a grant under this section may not exceed 85 percent.

"(d) USE OF FUNDS.—Grants awarded under subsection (b)—

"(1) shall be used to develop, expand, and enhance community and statewide evidence-informed family support services; and

"(2) may be used to—

"(A) build connections between family support networks, including providing technical as-

sistance between family community organizations and peer support networks, and with other family support services, focused on enhancing knowledge of evidence-informed interventions for family members and loved ones of individuals living with substance use disorders and reducing harm by educating service providers on current evidence regarding addiction and the family, including—

''(i) behavioral health providers, including such providers focused specifically on family and couples therapy in the context of addiction;

''(ii) primary care providers;

''(iii) providers of foster care services or support services for grandparents, guardians, and other extended family impacted by addiction; and

''(iv) other family support services that connect to community resources for individuals with substance use disorders, including non-clinical community services;

''(B) reduce stigma associated with the family of individuals with substance use disorders by improving knowledge about addiction

and its treatment, providing compassionate support, and dispelling myths that perpetuate such stigma;

"(C) conduct outreach on issues relating to substance use disorders and family support, which may include education, training, and resources with respect to—

"(i) building a resilience- and strengths-based approach to prevention of, and living with, addiction in the family;

"(ii) identifying the signs of substance use disorder;

"(iii) adopting an approach that minimizes harm to all family members; and

"(iv) families of individuals with a substance use disorder, including with respect to—

"(I) navigating the treatment and recovery systems;

"(II) paying for addiction treatment;

"(III) education about substance use disorder; and

"(IV) avoiding predatory treatment programs; and

"(D) connect families to evidence-informed peer support programs.

"(e) DATA REPORTING AND PROGRAM OVERSIGHT.—With respect to a grant awarded under subsection (a), not later than 90 days after the end of the first year of the grant period, and annually thereafter for the duration of the grant period, the entity shall submit data, as appropriate and to the extent practicable, to the Secretary regarding—

"(1) the programs and activities funded by the grant;

"(2) health outcomes of the population of individuals with a substance use disorder who received services through programs supported by the grant, as evaluated by an independent program evaluator through the use of outcomes measures, as determined by the Secretary; and

"(3) any other information that the secretary may require for the purpose of ensuring that the grant recipient is complying with all the requirements of the grant.

"(f) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $5,000,000 for each of fiscal years 2021 through 2025.".

Subtitle E—Block, Report, And Suspend Suspicious Shipments

SEC. 7041. CLARIFICATION OF PROCESS FOR REGISTRANTS TO EXERCISE DUE DILIGENCE UPON DISCOVERING A SUSPICIOUS ORDER.

(a) IN GENERAL.—Paragraph (3) of section 312(a) of the Controlled Substances Act (21 U.S.C. 832(a)) is amended to read as follows:

''(3) upon discovering a suspicious order or series of orders—

''(A) exercise due diligence;

''(B) establish and maintain (for not less than a period to be determined by the Administrator of the Drug Enforcement Administration) a record of the due diligence that was performed;

''(C) decline to fill the order or series of orders if the due diligence fails to resolve all of the indicators that gave rise to the suspicion that filling the order or series of orders would cause a violation of this title by the registrant or the prospective purchaser; and

''(D) notify the Administrator of the Drug Enforcement Administration and the Special Agent in Charge of the Division Office of the

Drug Enforcement Administration for the area in which the registrant is located or conducts business of—

"(i) each suspicious order or series of orders discovered by the registrant; and

"(ii) the indicators giving rise to the suspicion that filling the order or series of orders would cause a violation of this title by the registrant or the prospective purchaser.".

(b) APPLICABILITY.—Section 312(a)(3) of the Controlled Substances Act, as amended by subsection (a), shall apply beginning on the day that is 6 months after the date of enactment of this Act. Until such day, section 312(a)(3) of the Controlled Substances Act shall apply as such section 312(a)(3) was in effect on the day before the date of enactment of this Act.

(c) REGULATIONS.—The Attorney General shall, issue regulations specifying, for purposes of paragraph (3) of section 312(a) of the Controlled Substances Act, as added by subsection (a), the indicators that give rise to a suspicion that filling an order or series of orders would cause a violation of title III of the Controlled Substances Act (21 U.S.C. 801 et seq.) by a registrant or a prospective purchaser.

Subtitle F—Debarment Enforcement of Bad Actor Registrants

SEC. 7051. DEBARMENT OF CERTAIN REGISTRANTS.

Section 304 of the Controlled Substances Act (21 U.S.C. 824) is amended by adding at the end the following:

''(h) The Attorney General may issue an order to prohibit, conditionally or unconditionally, and permanently or for such period as the Attorney General may determine, any person from being registered under this title to manufacture, distribute, or dispense a controlled substance or a list I chemical, if the Attorney General finds that—

''(1) such person meets or has met any of the conditions for suspension or revocation of registration under subsection (a); and

''(2) such person has a history of prior suspensions or revocations of registration.''.

Subtitle G—Ensuring Compliance Against Opioid Diversion

SEC. 7061. MODIFICATION, TRANSFER, AND TERMINATION OF REGISTRATION TO MANUFACTURE, DISTRIBUTE, OR DISPENSE CONTROLLED SUBSTANCES.

Subsection (a) of section 302 of the Controlled Substances Act (21 U.S.C. 822) is amended by adding at the end the following new paragraph:

''(3)(A) Except as provided in subparagraph (C), the registration of any registrant under this title to manufacture, distribute, or dispense controlled substances or list I chemicals terminates if and when such registrant—

''(i) dies;

''(ii) ceases legal existence;

''(iii) discontinues business or professional practice; or

''(iv) surrenders such registration.

''(B) In the case of such a registrant who ceases legal existence or discontinues business or professional practice, such registrant shall promptly notify the Attorney General in writing of such fact.

''(C) No registration under this title to manufacture, distribute, or dispense controlled substances or list I chemicals, and no authority conferred thereby, may be as-

signed or otherwise transferred except upon such conditions as the Attorney General may specify and then only pursuant to written consent. A registrant to whom a registration is assigned or transferred pursuant to the preceding sentence may not manufacture, distribute, or dispense controlled substances or list I chemicals pursuant to such registration until the Attorney General receives such written consent.

''(D) In the case of a registrant under this title to manufacture, distribute, or dispense controlled substances or list I chemicals desiring to discontinue business or professional practice altogether or with respect to controlled substances and list I chemicals (without assigning or transferring such business or professional practice to another entity), such registrant shall return to the Attorney General for cancellation—

''(i) the registrant's certificate of registration;

''(ii) any unexecuted order forms in the registrant's possession; and

''(iii) any other documentation that the Attorney General may require.''.

Subtitle H—Opioid Prescription Verification

SEC. 7071. MATERIALS FOR TRAINING PHARMACISTS ON CERTAIN CIRCUMSTANCES UNDER WHICH A PHARMACIST MAY DECLINE TO FILL A PRESCRIPTION.

(a) UPDATES TO MATERIALS.—Section 3212(a) of the SUPPORT for Patients and Communities Act (Public Law 115–271) is amended by striking ''Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services, in consultation with the Administrator of the Drug Enforcement Administration, Commissioner of Food and Drugs, Director of the Centers for Disease Control and Prevention, and Assistant Secretary for Mental Health and Substance Use, shall develop and disseminate'' and inserting ''The Secretary of Health and Human Services, in consultation with the Administrator of the Drug Enforcement Administration, Commissioner of Food and Drugs, Director of the Centers for Disease Control and Prevention, and Assistant Secretary for Mental Health and Substance Use, shall develop and disseminate not later than 1 year after the date of enactment of this Act, and update periodically thereafter''.

(b) MATERIALS INCLUDED.—Section 3212(b) of the SUPPORT for Patients and Communities Act (Public Law 115–271) is amended—

(1) by redesignating paragraphs (1) and (2) as paragraphs (2) and (3), respectively; and

(2) by inserting before paragraph (2), as so redesignated, the following new paragraph:

''(1) pharmacists on how to verify the identity of individuals picking up prescriptions;''.

(c) MATERIALS FOR TRAINING ON VERIFICATION OF IDENTITY.—Section 3212 of the SUPPORT for Patients and Communities Act (Public Law 115–271) is amended by adding at the end the following new subsection:

''(d) MATERIALS FOR TRAINING ON VERIFICATION OF IDENTITY OF INDIVIDUALS PICKING UP PRESCRIBED MEDICATIONS.—Not later than 6 months after the date of enactment of this subsection, the Secretary of Health and Human Services, after seeking stakeholder input in accordance with subsection (c), shall—

''(1) update the materials developed under subsection (a) to include information for pharmacists on how to verify the identity of individuals picking up prescribed medications; and

''(2) disseminate, as appropriate, the updated materials.''.

SEC. 7072. INCENTIVIZING STATES TO FACILITATE RESPONSIBLE, INFORMED DISPENSING OF CONTROLLED SUBSTANCES.

(a) IN GENERAL.—Section 392A of the Public Health Service Act (42 U.S.C. 280b–1) is amended—

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

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

''(c) PREFERENCE.—In determining the amounts of grants awarded to States under subsections (a) and (b), the Director of the Centers for Disease Control and Prevention may give preference to States in accordance with such criteria as the Director may specify and may choose to give preference to States that—

''(1) maintain a prescription drug monitoring program;

''(2) require dispensers of controlled substances in schedule II, III, or IV to verify the identity of the person who picks up a prescribed medication by requiring such person to present a photo identification card that is valid as determined by the respective State; and

''(3) require dispensers of such controlled substances to enter certain information about the purchase of such controlled substances into the respec-

tive State's prescription drug monitoring program, including—

"(A) the National Drug Code or, in the case of compounded medications, compound identifier;

"(B) the quantity dispensed;

"(C) the name of the patient;

"(D) the name of the ultimate user;

"(E) the name of the person who picks up the controlled substance, if different from the patient and ultimate user; and

"(F) the date filled.".

(b) DEFINITIONS.—Subsection (d) of section 392A of the Public Health Service Act (42 U.S.C. 280b–1), as redesignated by subsection (a)(1), is amended to read as follows:

"(d) DEFINITIONS.—In this section:

"(1) CONTROLLED SUBSTANCE.—The term 'controlled substance' has the meaning given that term in section 102 of the Controlled Substances.

"(2) DISPENSER.—The term 'dispenser' means a physician, pharmacist, or other person that dispenses a controlled substance to an ultimate user.

"(3) INDIAN TRIBE.—The term 'Indian tribe' has the meaning given that term in section 4 of the

Indian Self-Determination and Education Assistance Act.

''(4) STATE.—The term 'State' means each of the 50 States, the District of Columbia, and any commonwealth or territory of the United States.

''(5) ULTIMATE USER.—The term 'ultimate user' means a person who has obtained from a dispenser, and who possesses, a controlled substance for the person's own use, for the use of a member of the person's household, or for the use of an animal.''.

Subtitle I—Suspicious Order Identification

SEC. 7081. STRENGTHENING ARCOS.

Section 307(d) of the Controlled Substances Act (21 U.S.C. 827(d)) is amended to read as follows:

''(1)(A) Every registrant under section 303 shall and in such form as the Attorney General may require, make reports in electronic format to the Attorney General of every sale, delivery, or other disposal (other than by dispensing by a practitioner) by the registrant of any controlled substance, identifying by the registration number assigned under this title the person or establishment (unless exempt from registration under section 302(d)) to whom such sale, delivery, or other disposal was made.

''(B) Every registrant shall make each report required under subparagraph (A)—

''(i) not later than 30 days after the sale, delivery, or other disposal; or

''(ii) after the date on which the real-time reporting system is established under section 7082(e)(3) of the Commitment to Defeat the Virus and Keep America Healthy Act is implemented, in real time.''.

SEC. 7082. SUSPICIOUS ORDERS TASK FORCE.

(a) DEFINITIONS.—In this section:

(1) ADMINISTRATOR.—The term ''Administrator'' means the Administrator of the Drug Enforcement Administration.

(2) CONTROLLED SUBSTANCE; DISTRIBUTOR; MANUFACTURER.—The terms ''controlled substance'', ''distributor'', and ''manufacturer'' have the meanings given those terms in section 102 of the Controlled Substances Act (21 U.S.C. 802).

(3) REAL TIME.—The term ''real time'' means with as little delay as technically and economically feasible, as determined by the Attorney General following the program designed under subsection (e)(1), but not to exceed 24 hours.

(4) REGISTRANT.—The term ''registrant''—

(A) means a person registered under section 303 of the Controlled Substances Act (21 U.S.C. 823); and

(B) does not include practitioner.

(b) ESTABLISHMENT.—The Attorney General, in consultation with the Director of the Office of National Drug Control Policy and the Secretary of Health and Human Services, shall establish a Suspicious Order Monitoring Task Force (referred to in this section as the ''Task Force'').

(c) COMPOSITION.—

(1) IN GENERAL.—The Task Force shall be composed of appropriate personnel from—

(A) the Department of Justice;

(B) the Drug Enforcement Administration;

(C) the Office of National Drug Control Policy;

(D) the National Institute of Standards and Technology; and

(E) other appropriate Federal, State, and local law enforcement and regulatory agencies with experience in investigating and prosecuting illegal transactions of controlled substances as determined by the Attorney General, in con-

sultation with the Secretary of Health and Human Services.

(2) CONSULTANTS.—The Task Force shall consult with—

(A) industry members, including—

(i) data analytic professionals;

(ii) community pharmacies that dispense controlled substances;

(iii) chain pharmacies that dispense controlled substances;

(iv) distributors of controlled substances;

(v) manufacturers of controlled substances;

(vi) State and local public health officials; and

(vii) other relevant industry professionals; and

(B) relevant industry regulators and entities that utilize real-time reporting of transactions, orders, or other activities with the goal of identifying suspicious activity, such as appropriate personnel from the Financial Crimes Enforcement Network and money transfer industry professionals.

(d) MEETINGS.—

(1) IN GENERAL.—The Task Force shall meet not less frequently than 4 times per year and at such other times as may be determined necessary by the Task Force.

(2) INITIAL MEETING.—Not later than 60 days after the date of enactment of this Act, the Task Force shall hold the initial meeting of the Task Force.

(e) PRELIMINARY ORDER EVALUATION PROGRAM.—

(1) IN GENERAL.—

(A) DESIGN.—Not later than 60 days after the date on which the Task Force holds the initial meeting required under subsection (d)(2), the Task Force shall begin to design a program in accordance with paragraph (2).

(B) PURPOSE.—The program described in subparagraph (A) shall be designed to share necessary data, in a limited capacity, with registrants in order to provide registrants with information to identify suspicious ordering in real time.

(C) DEADLINE FOR COMPLETION.—Not later than 8 months after the date of enactment

of this Act, the Task Force shall complete the design required under subparagraph (A).

(2) REQUIREMENTS.—

(A) IN GENERAL.—The program required under paragraph (1) shall establish a process for—

(i) transitioning to a requirement to report in real time to the Attorney General under section 307(d) of the Controlled Substances Act (21 U.S.C. 827(d)) every sale, delivery, or other disposal by a registrant of any controlled substance;

(ii) limited sharing in real time of Automation of Reports and Consolidated Orders System (commonly known as ''ARCOS'') data with registrants to share necessary data, in a limited capacity, with registrants in order to provide registrants with information to identify suspicious ordering in real time; and

(iii) ensuring data privacy, data de-identification, protection of trade secrets and purchasing history.

(B) OTHER CONSIDERATIONS.—In designing the program under paragraph (1), the Task Force shall take into consideration—

(i) the inclusion of a waiver process for pharmacies and other registrants unable to transmit orders electronically on the date of enactment of this Act;

(ii) a mechanism to ensure that the costs of running the program are not passed through to customers of registrants, unless the registrants are customers of other registrants;

(iii) technical requirements for ensuring that registrants may access all relevant de-identified data, with output provided in a standard database file format; and

(iv) a mechanism to ensure that the program required to be designed under subparagraph (A) is updated based on feedback from industry members and other relevant entities.

(3) IMPLEMENTATION.—Not later than 1 year after the date of enactment of this Act, the Attorney General shall—

(A) implement the program designed under paragraph (1) to collect and share in real time data for registrants to evaluate the orders of controlled substances from distributors to manufacturers and from pharmacies to distributors; or

(B) otherwise implement a program to collect and share in real time data for drug manufacturers and distributors, by providing access to anonymized information to help drug manufacturers and distributors identify, report, and stop suspicious orders of controlled substances and reduce diversion rates.

(4) RECOMMENDED STATUTORY AND REGULATORY CHANGES.—In designing the program required under paragraph (1), the Task Force—

(A) shall submit to the Attorney General any recommendations for necessary amendments to regulations of the Department of Justice relating to the requirements for ordering schedule II controlled substances, so as to allow uniform electronic ordering of controlled substances in schedules II, III, IV, and V electronically through the program; and

(B) may submit to Congress any recommendations for necessary legislative changes so that a real-time data analytics solution can be used across the United States.

(5) RESPONSIBILITY OF REGISTRANTS.—All registered drug manufacturers and distributors shall be responsible for reviewing any information made available by the Attorney General and complying with any regulations regarding the program designed under paragraph (1) and implemented under paragraph (3).

(f) FUNDING.—

(1) IN GENERAL.—The Attorney General, acting through the Administrator, shall use amounts collected as fees for distributors and registrants under section 303 of the Controlled Substances Act (21 U.S.C. 823) and section 1007 of the Controlled Substances Import and Export Act (21 U.S.C. 957) to carry out this section.

(2) OFFSET.—

(A) IN GENERAL.—The Administrator may, on an equal basis and in accordance with subparagraph (B), increase the fees described in paragraph (1) for distributors and reg-

istrants to the extent necessary to defray the costs of this section.

(B) TIERED FEE.—The Administrator shall establish a tiered user fee for distributors and registrants in proportion to the volume of sales and purchases.

(g) APPLICABILITY OF FACA.—

(1) IN GENERAL.—Except as provided in paragraph (2), the Federal Advisory Committee Act (5 U.S.C. App.) shall apply to the Task Force.

(2) TERMINATION.—The Task Force shall terminate on the date on which the program is fully implemented under subsection (e)(3).

(h) RULES OF CONSTRUCTION.—Nothing in this subtitle shall be construed as relieving any manufacturer, distributor, or other registrant from the responsibilities of the manufacturer, distributor, or other registrant, as the case may be, to—

(1) identify, stop, and report suspicious orders;

(2) maintain effective controls against diversion in accordance with section 303 of the Controlled Substances Act (21 U.S.C. 823); and

(3) comply with the requirements established in section 1301.74(b) of title 21, Code of Federal Reg-

ulations, or any successor regulation thereto, with respect to suspicious orders.

Subtitle J—Stop the Importation and Manufacturing of Synthetic Analogues

SEC. 7091. ESTABLISHMENT OF SCHEDULE A.

Section 202 of the Controlled Substances Act (21 U.S.C. 812) is amended—

(1) in subsection (a), by striking ''five schedules of controlled substances, to be known as schedules I, II, III, IV, and V'' and inserting ''six schedules of controlled substances, to be known as schedules I, II, III, IV, V, and A'';

(2) in subsection (b), by adding at the end the following:

''(6) SCHEDULE A.—

''(A) IN GENERAL.—The drug or substance—

''(i) is or has been imported, or is offered for import, into the United States;

''(ii) has—

''(I) a chemical structure that is substantially similar to the chemical structure of a controlled substance in schedule I, II, III, IV, or V; and

"(II) an actual or predicted stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I, II, III, IV, or V; and

"(iii) is not—

"(I) listed or otherwise included in any other schedule in this section or by regulation of the Attorney General; and

"(II) with respect to a particular person, subject to an exemption that is in effect for investigational use, for that person, under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) to the extent conduct with respect to such substance is pursuant to such exemption.

"(B) PREDICTED STIMULANT, DEPRESSANT, OR HALLUCINOGENIC EFFECT.—For purposes of this paragraph, a predicted stimulant, depressant, or hallucinogenic effect on the central nervous system may be based on—

"(i)(I) the chemical structure; and

''(II)(aa) the structure activity relationships; or

''(bb) binding receptor assays and other relevant scientific information about the substance;

''(ii)(I) the current or relative potential for abuse of the substance; and

''(II) the clandestine importation, manufacture, or distribution, or diversion from legitimate channels, of the substance; or

''(iii) the capacity of the substance to cause a state of dependence, including physical or psychological dependence that is similar to or greater than that of a controlled substance in schedule I, II, III, IV, or V.''; and

(3) in subsection (c)—

(A) in the matter preceding schedule I, by striking ''IV, and V'' and inserting ''IV, V, and A''; and

(B) by adding at the end the following:

''SCHEDULE A

''Any substance temporarily or permanently scheduled by the Attorney General in accordance with section 201(k).''.

SEC. 7092. TEMPORARY AND PERMANENT SCHEDULING OF SCHEDULE A SUBSTANCES.

Section 201 of the Controlled Substances Act (21 U.S.C. 811) is amended by adding at the end the following:

''(k) TEMPORARY AND PERMANENT SCHEDULING OF SCHEDULE A SUBSTANCES.—

''(1) IN GENERAL.—The Attorney General may issue a temporary order adding a drug or substance to schedule A if the Attorney General finds that—

''(A) the drug or other substance satisfies the criteria for being considered a schedule A substance; and

''(B) adding such drug or substance to schedule A will assist in preventing abuse of the drug or other substance.

''(2) DURATION OF TEMPORARY SCHEDULING ORDER.—A temporary scheduling order issued under paragraph (1) shall—

''(A) not take effect until 30 days after the date of the publication by the Attorney General of a notice in the Federal Register of the intention to issue such order and the grounds upon which such order is to be issued; and

''(B) expire not later than 5 years after the date on which the order becomes effective,

except that the Attorney General may, during the pendency of proceedings under paragraph (5), extend the temporary scheduling order for up to 180 days.

''(3) EFFECT OF ISSUANCE OF PERMANENT SCHEDULING ORDER.—A temporary scheduling order issued under paragraph (1) shall be vacated upon the issuance of a permanent order issued under paragraph (5) with regard to the same substance, or upon the subsequent issuance of any scheduling order under this section.

''(4) LIMITATION ON JUDICIAL REVIEW.—A temporary scheduling order issued under paragraph (1) shall not be subject to judicial review.

''(5) PERMANENT SCHEDULING ORDER.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), not earlier than 3 years after the date on which the Attorney General issues an order temporarily scheduling a drug or substance under this subsection, the Attorney General may, by rule, issue a permanent order adding the drug or other substance to schedule A if such drug or substance satisfies the criteria for being considered a schedule A substance.

''(B) LIMITATION.—If the Secretary of Health and Human Services has determined, based on relevant scientific studies and necessary data requested by the Secretary of Health and Human Services and gathered by the Attorney General, that a drug or other substance that has been temporarily placed in schedule A does not have sufficient potential for abuse to warrant control in any schedule, and provides written notice of such determination to the Attorney General, the Attorney General—

''(i) may not issue a permanent scheduling order under subparagraph (A); and

''(ii) not later than 30 days after the date on which the Attorney General receives such notice, shall issue an order immediately terminating the temporary scheduling order for the drug or other substance.

''(6) NOTICE TO HHS.—Before initiating proceedings under paragraph (1), the Attorney General shall transmit notice of a temporary order proposed to be issued to the Secretary of Health and Human Services. In issuing an order under paragraph (1), the Attorney General shall take into consideration

any comments submitted by the Secretary of Health and Human Services in response to a notice transmitted pursuant to this paragraph.''.

SEC. 7093. PENALTIES.

Section 1010 of the Controlled Substances Import and Export Act (21 U.S.C. 960) is amended—

(1) in subsection (a), by inserting ''or a drug or substance in schedule A'' after ''controlled substance'' each place it appears; and

(2) in subsection (b), by adding at the end the following:

''(8) In the case of a violation under subsection (a) involving a controlled substance in schedule A, the person committing such violation shall be sentenced to a term of imprisonment of not more than 20 years and if death or serious bodily injury results from the use of such substance shall be sentenced to a term of imprisonment for any term of years or for life, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18, United States Code, or $1,000,000 if the defendant is an individual or $5,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment of not more than 30 years and

if death or serious bodily injury results from the use of such substance shall be sentenced to a term of imprisonment for any term of years or for life, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18, United States Code, or $2,000,000 if the defendant is an individual or $10,000,000 if the defendant is other than an individual, or both. Notwithstanding section 3583 of title 18, United States Code, any sentence imposing a term of imprisonment under this paragraph shall, in the absence of such a prior conviction, impose a term of supervised release of not less than 3 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of not less than 6 years in addition to such term of imprisonment. Notwithstanding the prior sentence, and notwithstanding any other provision of law, the court shall not place on probation or suspend the sentence of any person sentenced under the provisions of this paragraph which provide for a mandatory term of imprisonment if death or serious bodily injury results.''.

SEC. 7094. FALSE LABELING OF SCHEDULE A CONTROLLED SUBSTANCES.

(a) IN GENERAL.—Section 305 of the Controlled Substances Act (21 U.S.C. 825) is amended by adding at the end the following:

''(f) FALSE LABELING OF SCHEDULE A CONTROLLED SUBSTANCES.—

''(1) It shall be unlawful to import or export, with intent to manufacture, distribute, or dispense, a schedule A substance or product containing a schedule A substance, unless the substance or product bears a label clearly identifying a schedule A substance or product containing a schedule A substance by the nomenclature used by the International Union of Pure and Applied Chemistry (IUPAC).

''(2)(A) A product described in subparagraph (B) is exempt from the International Union of Pure and Applied Chemistry nomenclature requirement of this subsection if such product is labeled in the manner required under the Federal Food, Drug, and Cosmetic Act.

''(B) A product is described in this subparagraph if the product—

"(i) is the subject of an approved application as described in section 505(b) or (j) of the Federal Food, Drug, and Cosmetic Act; or

"(ii) is exempt from the provisions of section 505 of such Act relating to new drugs because—

"(I) it is intended solely for investigational use as described in section 505(i) of such Act; and

"(II) such product is being used exclusively for purposes of a clinical trial that is the subject of an effective investigational new drug application.".

(b) PENALTIES.—Section 402 of the Controlled Substances Act (21 U.S.C. 842) is amended—

(1) in subsection (a)—

(A) in paragraph (16), by striking "or" at the end;

(B) by redesignating paragraph (17) as paragraph (18); and

(C) by inserting after paragraph (16) the following:

"(17) to violate section 305(f); or"; and

(2) in subsection (c)—

(A) in paragraph (1)—

(i) in subparagraph (B)(i), by striking ''(17)'' and inserting ''(18)''; and

(ii) in subparagraph (C), by inserting ''or (17)'' after ''paragraph (16)'' each place it appears; and

(B) in paragraph (2)(D), by striking ''(17)'' and inserting ''(18)''.

SEC. 7095. REGISTRATION REQUIREMENTS FOR IMPORTERS AND EXPORTERS OF SCHEDULE A SUBSTANCES.

Section 1008 of the Controlled Substances Import and Export Act (21 U.S.C. 958) is amended by adding at the end the following:

''(j)(1) The Attorney General shall register an applicant to import or export a schedule A substance if—

''(A) the applicant demonstrates that the schedule A substance will be used for research, analytical, or industrial purposes approved by the Attorney General; and

''(B) the Attorney General determines that such registration is consistent with the public interest and with the United States obligations under international treaties, conventions, or protocols in effect on the date of enactment of this subsection.

''(2) In determining the public interest under paragraph (1)(B), the Attorney General shall consider—

''(A) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule A compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;

''(B) compliance with applicable State and local law;

''(C) promotion of technical advances in the art of manufacturing substances described in subparagraph (A) and the development of new substances;

''(D) prior conviction record of applicant under Federal and State laws relating to the importation, manufacture, distribution, or dispensing of substances described in subparagraph (A);

''(E) past experience in the importation and manufacture of controlled substances, and the exist-

ence in the establishment of effective control against diversion; and

''(F) such other factors as may be relevant to and consistent with the public health and safety.

''(3) If an applicant is registered to import or export a controlled substance in schedule I or II under subsection (a), the applicant shall not be required to apply for a separate registration under this subsection.''.

SEC. 7096. ADDITIONAL CONFORMING AMENDMENTS.

The Controlled Substances Import and Export Act (21 U.S.C. 951 et seq.) is amended—

(1) in section 1002(a) (21 U.S.C. 952(a))—

(A) in the matter preceding paragraph (1), by inserting ''or drug or substance in schedule A'' after ''schedule I or II''; and

(B) in paragraph (2), by inserting ''or drug or substances in schedule A'' after ''schedule I or II'';

(2) in section 1003 (21 U.S.C. 953)—

(A) in subsection (c), in the matter preceding paragraph (1), by inserting ''or drug or substance in schedule A'' after ''schedule I or II''; and

(B) in subsection (d), by inserting ''or drug or substance in schedule A'' after ''schedule I or II'';

(3) in section 1004(1) (21 U.S.C. 954(1)), in the matter preceding subparagraph (A), by inserting ''or drug or substance in schedule A'' after ''schedule I'';

(4) in section 1005 (21 U.S.C. 955), by inserting ''or drug or substance in schedule A'' after ''schedule I or II''; and

(5) in section 1009(a) (21 U.S.C. 959(a)), by inserting ''or drug or substance in schedule A'' after ''schedule I or II''.

SEC. 7097. SENTENCING REVIEW.

(a) COVERED OFFENSE DEFINED.—In this section, the term ''covered offense'' means an offense involving a schedule A substance for which the penalty was established under section 7093 or 7094 of this subtitle.

(b) SENTENCING REVIEW.—

(1) PETITION FOR REVIEW.—If a schedule A substance that is temporarily or permanently scheduled under section 201(k) of the Controlled Substances Act, as added by this subtitle, is subsequently descheduled or rescheduled on a schedule with lower penalties, any individual convicted of a

covered offense involving such schedule A substance who is awaiting sentencing or is still serving a term of imprisonment for such covered offense on the date of the descheduling or rescheduling may petition the court that imposed the sentence for a sentencing reduction hearing for such covered offense.

(2) SENTENCING REVIEW.—Not later than 30 days after the date on which a petition is filed under paragraph (1), the court shall conduct a sentencing reduction hearing and may modify the sentence of the petitioner as if the descheduling or rescheduling described in paragraph (1) had been in effect on the date the covered offense was committed.

SEC. 7098. RULES OF CONSTRUCTION.

Nothing in this subtitle, or the amendments made by this subtitle, may be construed to limit—

(1) the prosecution of offenses involving controlled substance analogues under the Controlled Substances Act (21 U.S.C. 801 et seq.); or

(2) the authority of the Attorney General to temporarily or permanently schedule, reschedule, or decontrol controlled substances under provisions of section 201 of the Controlled Substances Act (21 U.S.C. 811) that are in effect on the day before the date of enactment of this Act.

SEC. 7099. CLARIFICATION OF CERTAIN REGISTRATION REQUIREMENTS RELATED TO RESEARCH.

(a) EXCEPTION FOR AGENTS OR EMPLOYEES OF REGISTERED RESEARCHERS.—Section 302(c) of the Controlled Substances Act (21 U.S.C. 822(c)) is amended in paragraph (1) by striking ''or dispenser'' and inserting ''dispenser, or researcher''.

(b) CONFORMING AMENDMENT.—Section 102(3) of the Controlled Substances Act (21 U.S.C. 802(3)) is amended by striking ''or dispenser'' and inserting ''dispenser, or researcher''.

(c) SINGLE REGISTRATION FOR CONTIGUOUS RESEARCH SITES.—Section 302(e) of the Controlled Substances Act (21 U.S.C. 822(e)) is amended by adding at the end the following new paragraph:

''(3) Notwithstanding paragraph (1), a person registered to conduct research with a controlled substance under section 303(f) may conduct such research under a single registration if such research occurs exclusively on a single, contiguous campus and the registrant notifies the Attorney General in writing of all sites on the campus where the research will be conducted or where the controlled substance will be stored or administered. The registrant must so notify the Attorney General prior to conducting research at such additional sites.''.

(d) NEW INSPECTION NOT REQUIRED IN CERTAIN SITUATIONS.—Section 303(f) of the Controlled Substances Act (21 U.S.C. 823(f)) is amended—

(1) by redesignating paragraphs (1) through (5) as subparagraphs (A) through (E), respectively, and by moving the margins of such subparagraphs two ems to the right;

(2) by striking ''(f) The'' and inserting ''(f)(1) The''; and

(3) by adding at the end, after the matter following subparagraph (E), as so redesignated, the following new paragraph:

''(2)(A) If a person is registered to conduct research with a controlled substance and applies for a registration, or a modification of a registration to conduct research with a second controlled substance that is in the same schedule or in a schedule with a higher numerical designation, a new inspection by the Attorney General of the registered location is not required.

''(B) Nothing in this paragraph shall prohibit the Attorney General from conducting any inspection if the Attorney General deems it necessary.''.

(e) CONTINUATION OF RESEARCH ON SUBSTANCES NEWLY ADDED TO SCHEDULE I; AUTHORITY TO CONDUCT RESEARCH WITH OTHER SUBSTANCES IN SCHED-

ULE I.—Section 302 of the Controlled Substances Act (21 U.S.C. 822) is amended by adding at the end the following new subsection:

"(h) CONTINUATION OF RESEARCH ON SUBSTANCES NEWLY ADDED TO SCHEDULE I; AUTHORITY TO CONDUCT RESEARCH WITH OTHER SUBSTANCES IN SCHEDULE I.—

"(1) If a person is conducting research on a substance at the time the substance is added to schedule I, and such person is already registered to conduct research with a controlled substance in schedule I or II then—

"(A) the person shall, within 30 days of the scheduling of the newly scheduled substance, submit a completed application for registration or modification of existing registration, to conduct research on such substance, in accordance with the regulations issued by the Attorney General;

"(B) the person may, notwithstanding subsections (a) and (b), continue to conduct the research on such substance until the application referred to in subparagraph (A) is withdrawn by the applicant or until the Attorney General serves on the applicant an order to show cause

proposing the denial of the application pursuant to section 304(c); and

''(C) if the Attorney General serves such an order to show cause and the applicant requests a hearing, such hearing shall be held on an expedited basis and not later than 45 days after the request is made, except that the hearing may be held at a later time if so requested by the applicant.

''(2)(A) A person who is registered to conduct research with a controlled substance in schedule I may, notwithstanding subsections (a) and (b), conduct research with another controlled substance in schedule I, provided the following conditions are met:

''(i) The person has applied for a modification of the person's registration to authorize research with such other controlled substance in accordance with the regulations issued by the Attorney General.

''(ii) The Attorney General has obtained verification from the Secretary that the research protocol submitted with the application is meritorious.

''(iii) The Attorney General has determined that such activity is consistent with United States obligations under the Single Convention on Narcotic Drugs, 1961. The Attorney General shall make such determination not later than 30 days after receiving the application referred to in clause (i).

''(B) Nothing in this section shall be construed to alter the authority of the Attorney General to initiate proceedings to deny, suspend, or revoke any registration in accordance with sections 303 and 304.''.

(f) TREATMENT OF CERTAIN ACTIVITIES AS COINCIDENT TO RESEARCH.—Section 302 of the Controlled Substances Act (21 U.S.C. 822), as amended by subsection (d), is further amended by adding at the end the following new subsection:

''(i) TREATMENT OF CERTAIN ACTIVITIES AS COINCIDENT TO RESEARCH.—

''(1) IN GENERAL.—Except as specified in paragraph (2), a person who is registered to perform research with a controlled substance may perform the following activities with small quantities of that substance, as set forth in the relevant statement or protocol filed with the application for registration

approved by the Attorney General without being required to obtain a manufacturing registration:

"(A) Processing the substance to create extracts, tinctures, oils, solutions, derivatives, or other forms of the substance consistent with the approved research protocol.

"(B) Dosage form development for the purpose of satisfying regulatory requirements implemented by the Food and Drug Administration for submitting an investigational new drug application.

"(2) EXCEPTION REGARDING MARIHUANA.—The authority under paragraph (1) does not include authority to grow marihuana.".

SEC. 7100. REVIEW OF RESEARCH REGISTRATION PROCESS.

(a) REVIEW.—Not later than one year after the date of the enactment of this section, the Attorney General and the Secretary of Health and Human Services shall conduct a review of the processes used to obtain or modify Federal authorization to conduct research with controlled substances, including—

(1) an evaluation of the impacts of the amendments made by section 7099 on the risk of the diversion of controlled substances used in research and related public safety considerations; and

(2) identification of opportunities to reduce any unnecessary burden on persons seeking registration, potential redundancies, and inefficiencies in the process to obtain or modify Federal authorization to conduct research with controlled substances, including the process for obtaining a registration under section 303 of the Controlled Substances Act (21 U.S.C. 823) and the process by which the Secretary of Health and Human Services reviews research protocols.

(b) GUIDANCE.—Following the review described in subsection (a), the Attorney General and the Secretary of Health and Human Services shall, as appropriate, jointly issue guidance to registrants and potential registrants clarifying the process for registration under section 303 of the Controlled Substances Act (21 U.S.C. 823).

TITLE VIII—TAX INCENTIVES TO IMPROVE HEALTH CARE

SEC. 8001. DOMESTIC MEDICAL AND DRUG MANUFACTURING CREDIT.

(a) IN GENERAL.—Subpart D of part IV of subchapter A of chapter 1 of the Internal Revenue Code of 1986 is amended by adding at the end the following new section:

"SEC. 45U. DOMESTIC MEDICAL AND DRUG MANUFACTURING CREDIT.

''(a) IN GENERAL.—For purposes of section 38, the domestic medical and drug manufacturing credit determined under this section for any taxable year is an amount equal to 10.5 percent of the lesser of—

''(1) the qualified medical and drug manufacturing income of the taxpayer for the taxable year, or

''(2) taxable income of the taxpayer for the taxable year.

''(b) CREDIT LIMITED TO WAGES PAID.—

''(1) IN GENERAL.—The amount of the credit allowable under subsection (a) for any taxable year shall not exceed 50 percent of the W–2 wages of the taxpayer for the taxable year.

''(2) W–2 WAGES.—For purposes of this section—

''(A) IN GENERAL.—The term 'W–2 wages' means, with respect to any person for any taxable year of such person, the sum of the amounts described in paragraphs (3) and (8) of section 6051(a) paid by such person with respect to employment of employees by such person during the calendar year ending during such taxable year.

"(B) LIMITATION TO WAGES ATTRIBUTABLE TO DOMESTIC PRODUCTION.—Such term shall not include any amount which is not properly allocable to domestic medical and drug manufacturing gross receipts for purposes of subsection (c)(1).

"(C) RETURN REQUIREMENT.—Such term shall not include any amount which is not properly included in a return filed with the Social Security Administration on or before the 60th day after the due date (including extensions) for such return.

"(3) ACQUISITIONS, DISPOSITIONS, AND SHORT TAXABLE YEARS.—The Secretary shall provide for the application of this subsection in cases of a short taxable year or where the taxpayer acquires, or disposes of, the major portion of a trade or business or the major portion of a separate unit of a trade or business during the taxable year.

"(c) QUALIFIED MEDICAL AND DRUG MANUFACTURING INCOME.—For purposes of this section—

"(1) IN GENERAL.—The term 'qualified medical and drug manufacturing income' for any taxable year means an amount equal to the excess (if any) of—

"(A) the taxpayer's domestic medical and drug manufacturing gross receipts for the taxable year, over

"(B) the sum of—

"(i) the cost of goods sold that are allocable to such receipts, and

"(ii) other expenses, losses, or deductions which are properly allocable to such receipts.

"(2) ALLOCATION METHOD.—The Secretary shall prescribe rules for the proper allocation of items described in paragraph (1)(B) for purposes of determining qualified medical and drug manufacturing income. Such rules shall provide for the proper allocation of items whether or not such items are directly allocable to domestic medical and drug manufacturing gross receipts.

"(3) SPECIAL RULES FOR DETERMINING COSTS.—

"(A) IN GENERAL.—For purposes of determining costs under clause (i) of paragraph (1)(B), any item or service brought into the United States shall be treated as acquired by purchase, and its cost shall be treated as not

less than its value immediately after it entered the United States.

"(B) EXPORTS FOR FURTHER MANUFACTURE.—In the case of any property described in subparagraph (A) that had been exported by the taxpayer for further manufacture, the increase in cost or adjusted basis under subparagraph (A) shall not exceed the difference between the value of the property when exported and the value of the property when brought back into the United States after the further manufacture.

"(4) DOMESTIC MEDICAL AND DRUG MANUFACTURING GROSS RECEIPTS.—

"(A) IN GENERAL.—The term 'domestic medical and drug manufacturing gross receipts' means the gross receipts of the taxpayer which are derived from any sale, exchange, or other disposition of—

"(i) any active pharmaceutical ingredient, or

"(ii) any qualified countermeasure,

which was manufactured or produced by the taxpayer in whole or in significant part within the United States.

"(B) ACTIVE PHARMACEUTICAL INGREDIENT.—The term 'active pharmaceutical ingredient' means any substance or mixture of substances intended to be used in the manufacture of a drug product and (when so used) becomes an active ingredient in the drug product.

"(C) QUALIFIED COUNTERMEASURE.—The term 'qualified countermeasure' has the meaning given such term in section 319F–1(a)(2) of the Public Health Service Act (42 U.S.C. 247d–6a(a)(2))."

"(D) PARTNERSHIPS OWNED BY EXPANDED AFFILIATED GROUPS.—For purposes of this paragraph, if all of the interests in the capital and profits of a partnership are owned by members of a single expanded affiliated group at all times during the taxable year of such partnership, the partnership and all members of such group shall be treated as a single taxpayer during such period.

"(d) DEFINITIONS AND SPECIAL RULES.—For purposes of this section—

"(1) APPLICATION OF SECTION TO PASS-THRU ENTITIES.—

"(A) PARTNERSHIPS AND S CORPORATIONS.—In the case of a partnership or S corporation—

"(i) this section shall be applied at the partner or shareholder level,

"(ii) each partner or shareholder shall take into account such person's allocable share of each item described in subparagraph (A) or (B) of subsection (c)(1) (determined without regard to whether the items described in such subparagraph (A) exceed the items described in such subparagraph (B)), and

"(iii) each partner or shareholder shall be treated for purposes of subsection (b) as having W–2 wages for the taxable year in an amount equal to such person's allocable share of the W–2 wages of the partnership or S corporation for the taxable year (as determined under regulations prescribed by the Secretary).

"(B) TRUSTS AND ESTATES.—In the case of a trust or estate—

"(i) the items referred to in subparagraph (A)(ii) (as determined therein) and

the W–2 wages of the trust or estate for the taxable year, shall be apportioned between the beneficiaries and the fiduciary (and among the beneficiaries) under regulations prescribed by the Secretary, and

''(ii) for purposes of paragraph (2), adjusted gross income of the trust or estate shall be determined as provided in section 67(e) with the adjustments described in such paragraph.

''(C) REGULATIONS.—The Secretary may prescribe rules requiring or restricting the allocation of items and wages under this paragraph and may prescribe such reporting requirements as the Secretary determines appropriate.

''(2) APPLICATION TO INDIVIDUALS.—In the case of an individual, subsection (a)(2) shall be applied by substituting 'adjusted gross income' for 'taxable income'. For purposes of the preceding sentence, adjusted gross income shall be determined after application of sections 86, 135, 137, 219, 221, 222, and 469.

''(3) SPECIAL RULE FOR AFFILIATED GROUPS.—

"(A) IN GENERAL.—All members of an expanded affiliated group shall be treated as a single corporation for purposes of this section.

"(B) EXPANDED AFFILIATED GROUP.—For purposes of this section, the term 'expanded affiliated group' means an affiliated group as defined in section 1504(a), determined—

"(i) by substituting 'more than 50 percent' for 'at least 80 percent' each place it appears, and

"(ii) without regard to paragraphs (2) and (4) of section 1504(b).

"(C) ALLOCATION OF CREDIT.—Except as provided in regulations, the credit under subsection (a) shall be allocated among the members of the expanded affiliated group in proportion to each member's respective amount (if any) of qualified medical and drug manufacturing income.

"(4) TRADE OR BUSINESS REQUIREMENT.—This section shall be applied by only taking into account items which are attributable to the actual conduct of a trade or business.

''(5) COORDINATION WITH MINIMUM TAX.—For purposes of determining alternative minimum taxable income under section 55, qualified medical and drug manufacturing income shall be determined without regard to any adjustments under sections 56 through 59.

''(6) UNRELATED BUSINESS TAXABLE INCOME.—For purposes of determining the tax imposed by section 511, subsection (a)(1)(B) shall be applied by substituting 'unrelated business taxable income' for 'taxable income'.

''(7) REGULATIONS.—The Secretary shall prescribe such regulations as are necessary to carry out the purposes of this section, including regulations which prevent more than 1 taxpayer from being allowed a credit under this section with respect to any activity described in subsection (c)(4)(A).''.

(b) TREATMENT UNDER BASE EROSION TAX.—Section 59A(b)(1)(B)(ii) of such Code is amended by striking ''plus'' at the end of subclause (I), by redesignating subclause (II) as subclause (III), and by inserting after subclause (I) the following new subclause:

''(II) the credit allowed under section 38 for the taxable year which is properly allocable to the domestic

medical and drug manufacturing credit determined under section 45U(a), plus''.

(c) PART OF GENERAL BUSINESS CREDIT.—Section 38(b) of such Code is amended by striking ''plus'' at the end of paragraph (32), by striking the period at the end of paragraph (33) and inserting '', plus'', and by adding at the end the following new paragraph:

''(34) the domestic medical and drug manufacturing credit determined under section 45U(a).''.

(d) CREDIT ALLOWED AGAINST ALTERNATIVE MINIMUM TAX.—Section 38(c)(4)(B) of such Code is amended by redesignating clauses (x) through (xii) as clauses (xi) through (xiii), respectively, and by inserting after clause (ix) the following new clause:

''(x) the credit determined under section 45U,''.

(e) CLERICAL AMENDMENT.—The table of sections for subpart D of part IV of subchapter A of chapter 1 of such Code is amended by adding at the end the following new item:

''Sec. 45U. Domestic medical and drug manufacturing credit.''.

(f) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2020.

SEC. 8002. QUALIFYING ADVANCED MEDICAL MANUFACTURING EQUIPMENT CREDIT.

(a) IN GENERAL.—Subpart E of part IV of subchapter A of chapter 1 of the Internal Revenue Code of 1986 is amended by adding at the end the following new section:

"SEC. 48D. QUALIFYING ADVANCED MEDICAL MANUFACTURING EQUIPMENT CREDIT.

''(a) IN GENERAL.—For purposes of section 46, the qualifying advanced medical manufacturing equipment credit determined under this section for any taxable year is the applicable percentage of the basis of any qualifying advanced medical manufacturing equipment placed in service during such taxable year.

''(b) APPLICABLE PERCENTAGE.—For purposes of subsection (a), the applicable percentage is—

''(1) 30 percent in the case of equipment which is placed in service before January 1, 2028,

''(2) 20 percent in the case of equipment which is placed in service during calendar year 2028,

''(3) 10 percent in the case of equipment which is placed in service during calendar year 2029, and

''(4) 0 percent in the case of equipment which is placed in service after December 31, 2029.

''(c) QUALIFYING ADVANCED MEDICAL MANUFACTURING EQUIPMENT.—For purposes of this section, the

term 'qualifying advanced medical manufacturing equipment' means property of a character subject to the allowance for depreciation—

"(1) which is machinery or equipment that is designed and used to manufacture a—

"(A) drug (as such term is defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act),

"(B) device (as such term is defined in section 201(h) of such Act), or

"(C) biological product (as such term is defined in section 351(i) of the Public Health Service Act),

"(2) which has been identified by the Secretary (after consultation with the Secretary of Health and Human Services) as machinery or equipment that—

"(A) incorporates novel technology or uses an established technique or technology in a new or innovative way, or

"(B) that can improve medical product quality, address shortages of medicines, and speed time-to-market,

"(3) which is placed in service in the United States by the taxpayer, and

''(4) with respect to which depreciation is allowable.

''(d) CERTAIN QUALIFIED PROGRESS EXPENDITURES RULES MADE APPLICABLE.—Rules similar to the rules of subsections (c)(4) and (d) of section 46 (as in effect on the day before the enactment of the Revenue Reconciliation Act of 1990) shall apply for purposes of this section.

''(e) REGULATIONS.—The Secretary shall prescribe such regulations or other guidance as may be necessary to carry out the purposes of this section, including regulations which prevent abuse or fraud.''.

(b) TREATMENT UNDER BASE EROSION TAX.—Section 59A(b)(1)(B)(ii) of such Code, as amended by section 8001 of this Act, is further amended by striking ''plus'' at the end of subclause (II), by redesignating subclause (III) as subclause (IV), and by inserting after subclause (II) the following new subclause:

''(III) the credit allowed under section 46 for the taxable year which is properly allocable to the qualifying advanced medical manufacturing equipment credit determined under section 48D(a), plus''.

(c) PART OF INVESTMENT CREDIT.—Section 46 of such Code is amended by striking ''and'' at the end of paragraph (5), by striking the period at the end of paragraph (6) and inserting '', and'', and by adding at the end the following new paragraph:

''(7) the qualifying advanced medical manufacturing equipment credit.''.

(d) CLERICAL AMENDMENT.—The table of sections for subpart D of part IV of subchapter A of chapter 1 of such Code is amended by adding at the end the following new item:

''Sec. 48D. Qualifying advanced medical manufacturing equipment credit.''.

(e) EFFECTIVE DATE.—The amendments made by this section shall apply to periods after the date of the enactment of this section under rules similar to the rules of section 48(m) of the Internal Revenue Code of 1986 (as in effect on the date of the enactment fo the Revenue Reconciliation Act of 1990).

SEC. 8003. NEW MEDICAL RESEARCH EXPENDITURE COMPONENT OF CREDIT FOR INCREASING RESEARCH ACTIVITIES.

(a) IN GENERAL.—Section 41(a) of the Internal Revenue Code of 1986 is amended by striking ''and'' at the end of paragraph (2), by striking the period at the end of paragraph (3) and inserting '', and'', and by adding at the end the following new paragraph:

''(4) 14 percent of specified medical research expenditures.''.

(b) SPECIFIED MEDICAL RESEARCH EXPENDITURES.—Section 41(f) of such Code is amended by adding at the end the following new paragraph:

''(7) SPECIFIED MEDICAL RESEARCH EXPENDITURES.—

''(A) IN GENERAL.—The term 'specified medical research expenditures' means amounts paid or incurred for qualified research with respect to any qualified countermeasure.

''(B) QUALIFIED COUNTERMEASURE.—The term 'qualified countermeasure' has the meaning given to such term in section 319F–1(a)(2) of the Public Health Service Act (42 U.S.C. 247d–6a(a)(2)).''.

(c) DENIAL OF DOUBLE BENEFIT.—

(1) TAXABLE YEARS BEGINNING BEFORE JANUARY 1, 2021.—In the case of specified medical research expenditures (as defined in section 41(f)(7) of such Code (as added by this section)) paid or incurred in taxable years beginning before January 1, 2021—

(A) such expenditures shall be treated in the same manner as qualified research expenses

and basic research expenses under section 280C(c)(1) of such Code (as in effect on the day before the enactment of the Tax Cuts and Jobs Act), and

(B) the amount determined under section 280C(c)(2)(A) (as in effect on such day) for the taxable year shall be increased by the amount of credit determined for the taxable year under section 41(a)(4) (as added by this section).

(2) TAXABLE YEARS BEGINNING AFTER DECEMBER 31, 2020.—Section 280C(c)(1) of such Code is amended by striking ''section 41(a)(1)'' and inserting ''paragraphs (1) and (4) of section 41(a)''.

(d) CONFORMING AMENDMENT.—Section 41(f)(1) of such Code is amended by striking ''and amounts paid or incurred to energy research consortiums'' each place it appears and inserting '', amounts paid or incurred to energy research consortiums, and specified medical research expenditures''.

(e) EFFECTIVE DATE.—The amendments made by this section shall apply to amounts paid or incurred after the date of the enactment of this Act, in taxable years ending after such date.

SEC. 8004. REFUNDABLE PORTION OF RESEARCH CREDIT FOR SMALL BUSINESSES ENGAGING IN SPECIFIED MEDICAL RESEARCH.

(a) IN GENERAL.—Section 41 of the Internal Revenue Code of 1986 is amended by adding at the end the following new subsection:

''(i) REFUNDABLE PORTION FOR SMALL BUSINESSES ENGAGING IN SPECIFIED MEDICAL RESEARCH.—

''(1) IN GENERAL.—At the election of a medical research small business, the portion of the credit determined under this section for the taxable year which is properly allocable to specified medical research shall be treated (other than for purposes of section 280C) as a credit allowed under subpart C (and not this subpart).

''(2) MEDICAL RESEARCH SMALL BUSINESS.—For purposes of this subsection, the term 'medical research small business' means any domestic C corporation—

''(A) which conducts any specified medical research during the taxable year, and

''(B) the gross receipts of which (determined under the rules of subsection (c)) for the taxable year do not exceed $1,000,000.

''(3) SPECIFIED MEDICAL RESEARCH.—For purposes of this subsection, the term 'specified med-

ical research' means any qualified research with respect to qualified countermeasures (as defined in section 319F–1(a)(2) of the Public Health Service Act (42 U.S.C. 247d–6a(a)(2))).

''(4) ELECTION.—Any election under this subsection for any taxable year—

''(A) shall specify the amount of the credit to which such election applies,

''(B) shall be made on or before the due date (including extensions) of the return of tax for the taxable year,

''(C) may not be made for any taxable year with respect to any portion of the credit determined under this section with respect to which an election is made under subsection (h), and

''(D) may be revoked only with the consent of the Secretary.

''(5) REGULATIONS.—The Secretary shall prescribe such regulations for purposes of this subsection as may be necessary or appropriate for determining proper allocation to specified medical research of the portion of any credit allowed to a taxpayer for a taxable year under this section.''.

(b) CONFORMING AMENDMENT.—Section 1324(b) of title 31, United States Code, is amended by inserting ''41(i),'' after ''6428,''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2020.

SEC. 8005. EXCEPTION FROM PASSIVE LOSS RULES FOR INVESTMENTS IN SPECIFIED MEDICAL RESEARCH SMALL BUSINESS PASS-THRU ENTITIES.

(a) IN GENERAL.—Subsection (c) of section 469 of the Internal Revenue Code of 1986 is amended by redesignating paragraphs (4) through (7) as paragraphs (5) through (8), respectively, and by inserting after paragraph (3) the following new paragraph:

''(4) SPECIFIED MEDICAL RESEARCH ACTIVITIES.—

''(A) IN GENERAL.—The term 'passive activity' shall not include any qualified medical research activity of the taxpayer carried on by a specified medical research small business pass-thru entity.

''(B) TREATMENT OF LOSSES AND DEDUCTIONS.—

"(i) IN GENERAL.—Losses or deductions of a taxpayer in connection with qualified medical research activities carried on by a specified medical research small business pass-thru entity shall not be treated as losses or deductions, respectively, from a passive activity except as provided in clause (ii) and subparagraph (C).

"(ii) LIMITATION.—Clause (i) shall apply to losses and deductions of a taxpayer in connection with a specified medical small business pass-thru entity for a taxable year only to the extent that the aggregate losses and deductions of the taxpayer in connection with qualified medical research activities of such entity for such taxable year do not exceed the portion of the taxpayer's adjusted basis in the taxpayer's ownership interest in such entity that is attributable to money or other property contributed—

"(I) in exchange for such ownership interest, and

''(II) specifically for use in connection with qualified medical research activities.

For purposes of the preceding sentence, the taxpayer's basis shall not include any portion of such basis which is attributable to an increase in a partner's share of the liabilities of a partnership that is considered under section 752(a) as a contribution of money.

''(C) TREATMENT OF CARRYOVERS.—Subparagraph (B)(i) shall not apply to the portion of any loss or deduction that is carried over under subsection (b) into a taxable year other than the taxable year in which such loss or deduction arose.

''(D) QUALIFIED MEDICAL RESEARCH ACTIVITY.—For purposes of this paragraph, the term 'qualified medical research activity' means any qualified research (within the meaning of section 41(d)) with respect to qualified countermeasures (as defined in section 319F–1(a)(2) of the Public Health Service Act (42 U.S.C. 247d–6a(a)(2))).

''(E) SPECIFIED MEDICAL RESEARCH SMALL BUSINESS PASS-THRU ENTITY.—For purposes of this paragraph, the term 'specified medical research small business pass-thru entity' means any domestic pass-thru entity for any taxable year if—

''(i) more than 80 percent of such entity's expenditures on qualified research for such taxable year are paid or incurred in connection with qualified medical research activities, and

''(ii) the gross receipts (as determined under the rules of section 41(h)(3)) of such entity for the taxable year (and each preceding taxable year) is less than $1,000,000.

''(F) CAPITAL EXPENDITURES TAKEN INTO ACCOUNT FOR EXPENDITURES TEST.—An expenditure shall not fail to be taken into account under subparagraph (E)(i) merely because such expenditure is chargeable to capital account.

''(G) PASS-THRU ENTITY.—For purposes of this paragraph, the term 'pass-thru entity' means any partnership, S corporation, or other

entity identified by the Secretary as a pass-thru entity for purposes of this paragraph.

''(H) AGGREGATION RULES.—

''(i) IN GENERAL.—All persons treated as a single employer under subsection (a) or (b) of section 52, or subsection (m) or (o) of section 414, shall be treated as a single entity for purposes of subparagraphs (E) and (F)(iii).

''(ii) LIMITATION WHERE ENTITY WOULD NOT QUALIFY.—No entity shall be treated as a specified medical research small business pass-thru entity unless such entity qualifies as such both with and without the application of clause (i).''.

(b) MATERIAL PARTICIPATION NOT REQUIRED.—Paragraph (5) of section 469(c) of the Internal Revenue Code of 1986, as redesignated by subsection (a), is amended by striking ''and (3)'' in the heading and text and inserting '', (3), and (4)''.

(c) CERTAIN RESEARCH-RELATED DEDUCTIONS AND CREDITS OF SPECIFIED MEDICAL RESEARCH SMALL BUSINESS PASS-THRU ENTITIES ALLOWED FOR PURPOSES OF DETERMINING ALTERNATIVE MINIMUM TAX.—

(1) DEDUCTION FOR RESEARCH AND EXPERIMENTAL EXPENDITURES.—Paragraph (2) of section 56(b) of the Internal Revenue Code of 1986 is amended by adding at the end the following new subparagraph:

"(E) EXCEPTION FOR SPECIFIED MEDICAL RESEARCH SMALL BUSINESS PASS-THRU ENTITIES.—In the case of a specified medical research small business pass-thru entity (as defined in section 469(c)(4)), this paragraph shall not apply to any amount allowable as a deduction under section 174(a).".

(2) ALLOWANCE OF CERTAIN RESEARCH-RELATED CREDITS.—Subparagraph (B) of section 38(c)(4) of such Code is amended by redesignating clauses (ii) through (ix) as clauses (iii) through (x), respectively, and by inserting after clause (i) the following new clause:

"(ii) the credit of an individual taxpayer determined under section 41 to the extent attributable to a specified medical research small business pass-thru entity (as defined in section 469(c)(4)),".

(d) EXCEPTION TO LIMITATION ON PASS-THRU OF RESEARCH CREDIT.—Subsection (g) of section 41 of such

Code is amended by adding at the end the following: ''Paragraphs (2) and (4) shall not apply with respect to any specified medical research small business pass-thru entity (as defined in section 469(c)(4)).''.

(e) EFFECTIVE DATE.—The amendments made by this section shall apply to losses and credits arising in taxable years beginning after December 31, 2020.

SEC. 8006. TEMPORARY CARRYOVER FOR HEALTH AND DEPENDENT CARE FLEXIBLE SPENDING ARRANGEMENTS.

(a) IN GENERAL.—With respect to the 2020 plan year for any health flexible spending arrangement or any dependent care flexible spending arrangement, an employer may elect to amend its cafeteria plan to permit any unused amounts remaining in such flexible spending arrangement at the end of such plan year to be carried over to the 2021 plan year, pursuant to rules similar to the rules established for health flexible spending arrangements under Internal Revenue Service Notice 2013–71.

(b) RETROACTIVE APPLICATION.—An employer shall be permitted to amend its cafeteria plan to effectuate the rule described in subsection (a), provided that such amendment—

(1) is adopted before January 1, 2021; and

(2) provides that the rule described in such subsection shall be in effect as of the first day of the 2020 plan year.

(c) DEFINITIONS.—Any term used in this section which is also used in section 125 of the Internal Revenue Code of 1986 or the regulations thereunder shall have the same meaning as when used in such section or regulations.

SEC. 8007. INCREASE IN EXCLUSION FOR EMPLOYER-PROVIDED DEPENDENT CARE ASSISTANCE.

(a) IN GENERAL.—Section 129(a)(2) of the Internal Revenue Code of 1986 is amended by adding at the end the following new subparagraph:

''(D) SPECIAL RULE FOR 2020 AND 2021.—In the case of any taxable year beginning during 2020 or 2021, subparagraph (A) shall be applied by substituting '$10,500 ($5,250' for '$5,000 ($2,500'.''.

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to taxable years beginning after December 31, 2019.

(c) RETROACTIVE PLAN AMENDMENTS.—A plan or other arrangement that otherwise satisfies all applicable requirements of sections 106, 125, and 129 of the Internal Revenue Code of 1986 (including any rules or regulations thereunder) shall not fail to be treated as a cafeteria plan

or dependent care flexible spending arrangement merely because such plan or arrangement is amended pursuant to a provision under this section and such amendment is retroactive, if—

(1) such amendment is adopted no later than the last day of the plan year in which the amendment is effective, and

(2) the plan or arrangement is operated consistent with the terms of such amendment during the period beginning on the effective date of the amendment and ending on the date the amendment is adopted.

SEC. 8008. TEMPORARY INCREASE IN CONTRIBUTION LIMITS FOR HEALTH SAVINGS ACCOUNTS.

(a) IN GENERAL.—Section 223(b) of the Internal Revenue Code of 1986 is amended by adding at the end the following new paragraph:

''(9) INCREASE IN MONTHLY LIMITATIONS FOR TAXABLE YEARS 2020 AND 2021.—In the case of any month during a taxable year which begins after December 31, 2019, and before January 1, 2022, the dollar amount in effect under subparagraph (A) or (B) of paragraph (2) for such month shall be twice the amount otherwise applicable under such subparagraph, as determined—

"(A) before application of paragraph (3),

"(B) after application of subsection (g), and

"(C) without regard to this paragraph.".

(b) EFFECTIVE DATE.—The amendment made by this section shall apply with respect to taxable years beginning after December 31, 2019.

SEC. 8009. TEMPORARY ALLOWANCE OF PAYMENTS FOR EMPLOYMENT-RELATED EXPENSES UNDER HEALTH SAVINGS ACCOUNTS.

(a) IN GENERAL.—Section 223(d)(2) of the Internal Revenue Code of 1986 is amended by adding at the end the following new subparagraph:

"(E) INCLUSION OF EMPLOYMENT-RELATED EXPENSES FOR TAXABLE YEARS 2020 AND 2021.—In the case of any taxable year which begins after December 31, 2019, and before January 1, 2022, the term 'qualified medical expenses' includes, with respect to an account beneficiary, any amounts paid by such beneficiary for employment-related expenses (as defined in section 21(b)(2)) which are incurred during such taxable year.".

(b) CONFORMING AMENDMENT.—Section 21(c) of the Internal Revenue Code of 1986 is amended by insert-

ing ''and any amounts paid or distributed out of a health savings account which are used exclusively to pay expenses described in section 223(d)(2)(E) which are incurred by the taxpayer during such taxable year'' before the period at the end of the second sentence.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to taxable years beginning after December 31, 2019.

SEC. 8010. TREATMENT OF DIRECT PRIMARY CARE SERVICE ARRANGEMENTS.

(a) IN GENERAL.—Section 223(c)(1) of the Internal Revenue Code of 1986 is amended by adding at the end the following new subparagraph:

''(D) TREATMENT OF DIRECT PRIMARY CARE SERVICE ARRANGEMENTS.—

''(i) IN GENERAL.—A direct primary care service arrangement shall not be treated as a health plan for purposes of subparagraph (A)(ii).

''(ii) DIRECT PRIMARY CARE SERVICE ARRANGEMENT.—For purposes of this paragraph—

''(I) IN GENERAL.—The term 'direct primary care service arrangement' means, with respect to any indi-

vidual, an arrangement under which such individual is provided medical care (as defined in section 213(d)) consisting solely of primary care services provided by primary care practitioners (as defined in section 1833(x)(2)(A) of the Social Security Act, determined without regard to clause (ii) thereof), if the sole compensation for such care is a fixed periodic fee.

''(II) LIMITATION.—With respect to any individual for any month, such term shall not include any arrangement if the aggregate fees for all direct primary care service arrangements (determined without regard to this subclause) with respect to such individual for such month exceed $150 (twice such dollar amount in the case of an individual with any direct primary care service arrangement (as so determined) that covers more than one individual).

''(iii) CERTAIN SERVICES SPECIFICALLY EXCLUDED FROM TREATMENT AS PRIMARY CARE SERVICES.—For purposes of this subparagraph, the term 'primary care services' shall not include—

''(I) procedures that require the use of general anesthesia, and

''(II) laboratory services not typically administered in an ambulatory primary care setting.

The Secretary, after consultation with the Secretary of Health and Human Services, shall issue regulations or other guidance regarding the application of this clause.''.

(b) DIRECT PRIMARY CARE SERVICE ARRANGEMENT FEES TREATED AS MEDICAL EXPENSES.—Section 223(d)(2)(C) of the Internal Revenue Code of 1986 is amended by striking ''or'' at the end of clause (iii), by striking the period at the end of clause (iv) and inserting '', or'', and by adding at the end the following new clause:

''(v) any direct primary care service arrangement.''.

(c) INFLATION ADJUSTMENT.—Section 223(g)(1) of the Internal Revenue Code of 1986 is amended—

(1) by inserting '', (c)(1)(D)(ii)(II),'' after ''(b)(2),'' each place such term appears, and

(2) in subparagraph (B), by inserting ''and (iii)'' after ''clause (ii)'' in clause (i), by striking ''and'' at the end of clause (i), by striking the period at the end of clause (ii) and inserting '', and'', and by inserting after clause (ii) the following new clause:

''(iii) in the case of the dollar amount in subsection (c)(1)(D)(ii)(II) for taxable years beginning in calendar years after 2020, 'calendar year 2019'.''.

(d) REPORTING OF DIRECT PRIMARY CARE SERVICE ARRANGEMENT FEES ON W–2.—Section 6051(a) of the Internal Revenue Code of 1986 is amended by striking ''and'' at the end of paragraph (16), by striking the period at the end of paragraph (17) and inserting '', and'', and by inserting after paragraph (17) the following new paragraph:

''(18) in the case of a direct primary care service arrangement (as defined in section 223(c)(1)(D)(ii)) which is provided in connection with employment, the aggregate fees for such arrangement for such employee.''.

(e) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided under paragraph (2), the amendments made by this section

shall apply to months beginning after December 31, 2019, in taxable years ending after such date.

(2) INFLATION ADJUSTMENT.—The amendments made by subsection (c) shall apply to taxable years beginning in calendar years beginning after December 31, 2020.

SEC. 8011. ALLOW BOTH SPOUSES TO MAKE CATCH-UP CONTRIBUTIONS TO THE SAME HSA ACCOUNT.

(a) IN GENERAL.—Paragraph (5) of section 223(b) of the Internal Revenue Code of 1986 is amended to read as follows:

''(5) SPECIAL RULE FOR MARRIED INDIVIDUALS WITH FAMILY COVERAGE.—

''(A) IN GENERAL.—In the case of individuals who are married to each other, if both spouses are eligible individuals and either spouse has family coverage under a high deductible health plan as of the first day of any month—

''(i) the limitation under paragraph (1) shall be applied by not taking into account any other high deductible health plan coverage of either spouse (and if such spouses both have family coverage under separate high deductible health plans, only

one such coverage shall be taken into account),

"(ii) such limitation (after application of clause (i)) shall be reduced by the aggregate amount paid to Archer MSAs of such spouses for the taxable year, and

"(iii) such limitation (after application of clauses (i) and (ii)) shall be divided equally between such spouses unless they agree on a different division.

"(B) TREATMENT OF ADDITIONAL CONTRIBUTION AMOUNTS.—If both spouses referred to in subparagraph (A) have attained age 55 before the close of the taxable year, the limitation referred to in subparagraph (A)(iii) which is subject to division between the spouses shall include the additional contribution amounts determined under paragraph (3) for both spouses. In any other case, any additional contribution amount determined under paragraph (3) shall not be taken into account under subparagraph (A)(iii) and shall not be subject to division between the spouses.".

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to taxable years beginning after December 31, 2019.

SEC. 8012. REPEAL OF CEILING ON DEDUCTIBLE AND OUT-OF-POCKET EXPENSES UNDER A HIGH DEDUCTIBLE HEALTH PLAN.

(a) IN GENERAL.—Subparagraph (A) of section 223(c)(2) of the Internal Revenue Code of 1986 is amended to read as follows:

"(A) HIGH DEDUCTIBLE HEALTH PLAN.—The term 'high deductible health plan' means a health plan which has an annual deductible which is not less than—

"(i) $1,000 for self-only coverage, and

"(ii) twice the dollar amount in clause (i) for family coverage.".

(b) CONFORMING AMENDMENTS.—

(1) Subparagraph (D) of section 223(c)(2) of the Internal Revenue Code of 1986 is amended to read as follows:

"(D) SPECIAL RULE FOR NETWORK PLANS.—In the case of a plan using a network of providers, such plan's annual deductible for services provided outside of such network shall

not be taken into account for purposes of subsection (b)(2).''.

(2) Clause (ii) of section 223(g)(1)(B) of such Code is amended by striking ''each dollar amount in subsection (c)(2)(A)'' and inserting ''the dollar amount in subsection (c)(2)(A)(i)''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to taxable years beginning after December 31, 2019.

SEC. 8013. ON-SITE EMPLOYEE CLINICS.

(a) IN GENERAL.—Paragraph (1) of section 223(c) of the Internal Revenue Code of 1986, as amended by section 8010 of this Act, is amended by adding at the end the following new subparagraph:

''(E) SPECIAL RULE FOR QUALIFIED ITEMS AND SERVICES.—

''(i) IN GENERAL.—For purposes of subparagraph (A)(ii), an individual shall not be treated as covered under a health plan described in subclauses (I) and (II) of such subparagraph merely because the individual is eligible to receive, or receives, qualified items and services—

''(I) at a healthcare facility located at a facility owned or leased by

the employer of the individual (or of the individual's spouse), or

"(II) at a healthcare facility operated primarily for the benefit of employees of the employer of the individual (or of the individual's spouse).

"(ii) QUALIFIED ITEMS AND SERVICES DEFINED.—For purposes of this subparagraph, the term 'qualified items and services' means the following:

"(I) Physical examination.

"(II) Immunizations, including injections of antigens provided by employees.

"(III) Drugs or biologicals other than a prescribed drug (as such term is defined in section 213(d)(3)).

"(IV) Treatment for injuries occurring in the course of employment.

"(V) Preventive care for chronic conditions (as defined in clause (iv)).

"(VI) Drug testing.

"(VII) Hearing or vision screenings and related services.

"(iii) AGGREGATION.—For purposes of clause (i), all persons treated as a single employer under subsection (b), (c), (m), or (o) of section 414 shall be treated as a single employer.

"(iv) PREVENTIVE CARE FOR CHRONIC CONDITIONS.—For purposes of this subparagraph, the term 'preventive care for chronic conditions' means any item or service specified in the Appendix of Internal Revenue Service Notice 2019–45 which is prescribed to treat an individual diagnosed with the associated chronic condition specified in such Appendix for the purpose of preventing the exacerbation of such chronic condition or the development of a secondary condition, including any amendment, addition, removal, or other modification made by the Secretary (pursuant to the authority granted to the Secretary under paragraph (2)(C)) to the items or services specified in such Appendix subsequent to the date of enactment of this subparagraph.".

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to months in taxable years beginning after the date of enactment of this Act.

SEC. 8014. ADJUSTMENT OF MEDICAL EXPENSE DEDUCTION.

(a) IN GENERAL.—Section 213 of the Internal Revenue Code of 1986 is amended—

(1) in subsection (a), by striking ''10 percent'' and inserting ''7.5 percent'', and

(2) by striking subsection (f) and inserting the following:

''(f) TEMPORARY SPECIAL RULE.—In the case of any taxable year beginning after December 31, 2019, and ending before January 1, 2022, subsection (a) shall be applied with respect to a taxpayer by substituting '5 percent' for '7.5 percent'.''.

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2019.

SEC. 8015. HEALTHY WORKPLACE TAX CREDIT.

(a) IN GENERAL.—In the case of an employer, there shall be allowed as a credit against applicable employment taxes for each calendar quarter an amount equal to 50 percent of the sum of—

(1) the qualified employee protection expenses paid or incurred by the employer during such calendar quarter,

(2) the qualified workplace reconfiguration expenses paid or incurred by the employer during such calendar quarter,

(3) the qualified workplace technology expenses paid or incurred by the employer during such calendar quarter, and

(4) the qualified workplace training expenses paid or incurred by the employer during such calendar quarter.

(b) LIMITATIONS AND REFUNDABILITY.—

(1) OVERALL DOLLAR LIMITATION ON CREDIT.—

(A) IN GENERAL.—The amount of the credit allowed under subsection (a) with respect to any employer for any calendar quarter shall not exceed the excess (if any) of—

(i) the applicable dollar limit with respect to such employer for such calendar quarter, over

(ii) the aggregate credits allowed under subsection (a) with respect to such

employer for all preceding calendar quarters.

(B) APPLICABLE DOLLAR LIMIT.—The term ''applicable dollar limit'' means, with respect to any employer for any calendar quarter, the sum of—

(i) $1,000, multiplied so much of the average number of employees employed by such employer during such calendar quarter as does not exceed 500, plus

(ii) $750, multiplied by so much of such average number of employees as exceeds 500 but does not exceed 1,000, plus

(iii) $500, multiplied by so much of such average number of employees as exceeds 1,000.

(2) CREDIT LIMITED TO EMPLOYMENT TAXES.—The credit allowed by subsection (a) with respect to any calendar quarter shall not exceed the applicable employment taxes (reduced by any credits allowed under subsections (e) and (f) of section 3111 of the Internal Revenue Code of 1986, sections 7001 and 7003 of the Families First Coronavirus Response Act, and section 2301 of the CARES Act) on the wages paid with respect to the employment

of all the employees of the eligible employer for such calendar quarter.

(3) REFUNDABILITY OF EXCESS CREDIT.—

(A) IN GENERAL.—If the amount of the credit under subsection (a) exceeds the limitation of paragraph (2) for any calendar quarter, such excess shall be treated as an overpayment that shall be refunded under sections 6402(a) and 6413(b) of the Internal Revenue Code of 1986.

(B) TREATMENT OF PAYMENTS.—For purposes of section 1324 of title 31, United States Code, any amounts due to the employer under this paragraph shall be treated in the same manner as a refund due from a credit provision referred to in subsection (b)(2) of such section.

(c) QUALIFIED EMPLOYEE PROTECTION EXPENSES.—For purposes of this section, the term ''qualified employee protection expenses'' means amounts paid or incurred by the employer for—

(1) testing employees of the employer for COVID–19 (including on a periodic basis),

(2) equipment to protect employees of the employer from contracting COVID–19, including masks, gloves, and disinfectants, and

(3) cleaning products or services (whether provided by an employee of the taxpayer or a cleaning service provider) related to preventing the spread of COVID–19.

(d) QUALIFIED WORKPLACE RECONFIGURATION EXPENSES.—For purposes of this section—

(1) IN GENERAL.—The term ''qualified workplace reconfiguration expenses'' means amounts paid or incurred by the employer to design and reconfigure retail space, work areas, break areas, or other areas that employees or customers regularly use in the ordinary course of the employer's trade or business if such design and reconfiguration—

(A) has a primary purpose of preventing the spread of COVID–19,

(B) is with respect to an area that is located in the United States and that is leased or owned by the employer,

(C) is consistent with the purpose of the property immediately before the reconfiguration,

(D) is commensurate with the risks faced by the employees or customers or is consistent with recommendations made by the Centers for

Disease Control and Prevention or the Occupational Safety and Health Administration,

(E) is completed pursuant to a reconfiguration plan and no comparable reconfiguration plan was in place before March 13, 2020, and

(F) is completed before January 1, 2021.

(2) REGULATIONS.—The Secretary shall prescribe such regulations and other guidance as may be necessary or appropriate to carry out the purposes of this subsection, including guidance defining primary purpose and reconfiguration plan.

(e) QUALIFIED WORKPLACE TECHNOLOGY EXPENSES.—For purposes of this section—

(1) IN GENERAL.—The term ''qualified workplace technology expenses'' means amounts paid or incurred by the employer for technology systems that employees or customers use in the ordinary course of the employer's trade or business if such technology system—

(A) has a primary purpose of preventing the spread of COVID–19,

(B) is used for limiting physical contact between customers and employees in the United States,

(C) is commensurate with the risks faced by the employees or customers or is consistent with recommendations made by the Centers for Disease Control and Prevention or the Occupational Safety and Health Administration,

(D) is acquired by the taxpayer after March 12, 2020, and is not acquired pursuant to a written binding contract entered into before such date, and

(E) is placed in service by the taxpayer before January 1, 2021.

(2) TECHNOLOGY SYSTEMS.—The term ''technology systems'' means computer software (as defined in section 167(f)(1)) and qualified technological equipment (as defined in section 168(i)(2)).

(3) REGULATIONS.—The Secretary shall prescribe such regulations and other guidance as may be necessary or appropriate to carry out the purposes of this subsection, including guidance defining primary purpose.

(f) QUALIFIED WORKPLACE TRAINING EXPENSES.—For purposes of this section, the term ''qualified workplace training expenses'' means amounts paid or incurred by the employer for education and training with respect to industry best practices that ensure—

(1) the health and safety of employees in the workplace with respect to COVID–19, and

(2) the prevention of the spread of COVID–19 in the workplace.

(g) OTHER DEFINITIONS.—For purposes of this section—

(1) APPLICABLE EMPLOYMENT TAXES.—The term ''applicable employment taxes'' means the following:

(A) The taxes imposed under section 3111(a) of the Internal Revenue Code of 1986.

(B) So much of the taxes imposed under section 3221(a) of such Code as are attributable to the rate in effect under section 3111(a) of such Code.

(2) COVID–19.—Except where the context clearly indicates otherwise, any reference in this section to COVID–19 shall be treated as including a reference to the virus which causes COVID–19.

(3) SECRETARY.—The term ''Secretary'' means the Secretary of the Treasury or the Secretary's delegate.

(4) OTHER TERMS.—Any term used in this section (other than subsection (b)(1)(B)) which is also used in chapter 21 or 22 of the Internal Revenue

Code of 1986 shall have the same meaning as when used in such chapter.

(h) CERTAIN GOVERNMENTAL EMPLOYERS.—This credit shall not apply to the Government of the United States, the government of any State or political subdivision thereof, or any agency or instrumentality of any of the foregoing.

(i) SPECIAL RULES.—

(1) AGGREGATION RULE.—All persons treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986, or subsection (m) or (o) of section 414 of such Code, shall be treated as one employer for purposes of this section.

(2) DENIAL OF DOUBLE BENEFIT.—

(A) IN GENERAL.—Rules similar to the rules of paragraphs (1) and (2) of section 280C(b) shall apply for purposes of this section.

(B) EXPENSES NOT TAKEN INTO ACCOUNT MORE THAN ONCE.—Any qualified workplace reconfiguration expense or qualified workplace technology expense shall not be treated as a qualified employee protection expense and any qualified workplace technology expense shall not

be treated as a qualified workplace reconfiguration expense.

(3) THIRD-PARTY PAYORS.—Any credit allowed under this section shall be treated as a credit described in section 3511(d)(2) of such Code.

(4) ELECTION NOT TO HAVE SECTION APPLY.—This section shall not apply with respect to any eligible employer for any calendar quarter if such employer elects (at such time and in such manner as the Secretary may prescribe) not to have this section apply.

(j) TRANSFERS TO CERTAIN TRUST FUNDS.—There are hereby appropriated to the Federal Old-Age and Survivors Insurance Trust Fund and the Federal Disability Insurance Trust Fund established under section 201 of the Social Security Act (42 U.S.C. 401) and the Social Security Equivalent Benefit Account established under section 15A(a) of the Railroad Retirement Act of 1974 (45 U.S.C. 231n–1(a)) amounts equal to the reduction in revenues to the Treasury by reason of this section (without regard to this subsection). Amounts appropriated by the preceding sentence shall be transferred from the general fund at such times and in such manner as to replicate to the extent possible the transfers which would have oc-

curred to such Trust Fund or Account had this section not been enacted.

(k) TREATMENT OF DEPOSITS.—The Secretary shall waive any penalty under section 6656 of the Internal Revenue Code of 1986 for any failure to make a deposit of any applicable employment taxes if the Secretary determines that such failure was due to the reasonable anticipation of the credit allowed under this section.

(l) REGULATIONS AND GUIDANCE.—The Secretary shall prescribe such regulations and other guidance as may be necessary or appropriate to carry out the purposes of this section, including—

(1) with respect to the application of the credit under subsection (a) to third-party payors (including professional employer organizations, certified professional employer organizations, or agents under section 3504 of the Internal Revenue Code of 1986), regulations or other guidance allowing such payors to submit documentation necessary to substantiate the amount of the credit allowed under subsection (a), and

(2) regulations or other guidance to prevent abusive transactions.

(m) APPLICATION.—This section shall only apply to amounts paid or incurred after March 12, 2020, and before January 1, 2021.

TITLE IX—MEDICARE PROVISIONS

Subtitle A—Telehealth

SEC. 9001. REMOVING CERTAIN GEOGRAPHIC AND ORIGINATING SITE RESTRICTIONS ON THE FURNISHING OF TELEHEALTH SERVICES UNDER THE MEDICARE PROGRAM.

Section 1834(m)(4)(C) of the Social Security Act (42 U.S.C. 1395m(m)(4)(C)) is amended—

(1) in clause (i), by inserting ", with respect to services furnished on or after January 1, 2024," after "telecommunications system and"; and

(2) in clause (ii)(X), by inserting ", with respect to services furnished on or after January 1, 2024," after "but".

SEC. 9002. MAKING PERMANENT FQHC AND RHC TELEHEALTH PAYMENTS.

Section 1834(m)(6) of the Social Security Act (42 U.S.C. 1395m(m)(8)), as so redesignated by section 2(7), is amended—

(1) in the header, by striking "DURING EMERGENCY PERIOD";

(2) in subparagraph (A), in the matter preceding clause (i), by striking ''During'' and inserting ''With respect to services furnished on or after the first day of''; and

(3) in subparagraph (B)(i), by striking ''during such emergency period''.

SEC. 9003. EXPANDING THE LIST OF 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 ''as defined in paragraph (4)(E)'';

(2) in paragraph (3)(B), by inserting ''described in subparagraph (C) of such section'' after ''practitioners''; and

(3) in paragraph (4), by amending subparagraph (E) to read as follows:

''(E) PRACTITIONER.—The term 'practitioner' means a practitioner described in section 1842(b)(18)(C) and includes, with respect to services furnished before January 1, 2024, any supplier (other than a physician) permitted to receive payment for a telehealth service under this section as of the date of the enactment of

this subparagraph pursuant to a waiver in effect as of such date under section 1135.''.

SEC. 9004. ALLOWING FOR THE PROVISION OF TELEHEALTH SERVICES VIA AUDIO-ONLY TELECOMMUNICATIONS SYSTEMS.

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

''(G) TELECOMMUNICATIONS SYSTEM.—

''(i) IN GENERAL.—The term 'telecommunications system' includes, in the case of a telehealth service furnished by a qualified provider (as defined in clause (ii)) to an individual located at an originating site before January 1, 2024, a communications system consisting of only audio capabilities, but only if such individual does not have access to a communications system with audio-visual capabilities at such site.

''(ii) QUALIFIED PROVIDER.—For purposes of clause (i), the term 'qualified provider' means, with respect a telehealth service furnished to an individual, a physician or practitioner who—

''(I) furnished to such individual an item or service (other than such telehealth service) for which payment was made under any group health plan (as defined in section 2791 of the Public Health Service Act), health insurance coverage (as so defined), Federal health care program (as defined in section 1128B(f)), or the health care program under chapter 89 of title 5, United States Code, during the 3-year period ending on the date such telehealth service was furnished; or

''(II) is in the same practice (as determined by tax identification number) of a physician or practitioner who furnished such an item or service to such individual during such period.''.

SEC. 9005. MAKING PERMANENT THE SAFE HARBOR FOR ABSENCE OF DEDUCTIBLE FOR TELEHEALTH.

(a) IN GENERAL.—Section 223(c)(2)(E) of the Internal Revenue Code of 1986 is amended by striking ''In the case of plan years beginning on or before December 31, 2021, a'' and inserting ''A''.

(b) CERTAIN COVERAGE DISREGARDED.—Section 223(c)(1)(B)(ii) of the Internal Revenue Code of 1986 is amended by striking ''(in the case of plan years beginning on or before December 31, 2021)''.

SEC. 9006. REMOVING REQUIREMENT FOR FACE-TO-FACE VISITS BETWEEN HOME DIALYSIS PATIENTS AND PHYSICIANS.

(a) IN GENERAL.—Section 1881(b)(3)(B) of the Social Security Act (42 U.S.C. 1395rr(b)(3)(B)) is amended—

(1) in clause (i), by striking ''clauses (ii) and (iii)'' and inserting ''clause (ii)'';

(2) in clause (ii), by inserting ''or (iv)'' after ''clause (iii)'';

(3) by moving clause (iii) 6 ems to the left; and

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

''(iv) Clause (ii) shall not apply to monthly end stage renal disease-related clinical assessments furnished before January 1, 2024, in the case of an individual who has received in-person training with respect to home dialysis.''.

(b) WAIVER AUTHORITY.—

(1) IN GENERAL.—Notwithstanding any provision of section 1135 of the Social Security Act (42 U.S.C. 1320b–5), the Secretary of Health and

Human Services may, with respect to a specified waiver (as defined in paragraph (2)), continue such waiver in effect for any period of time before January 1, 2024.

(2) DEFINITION.—In this subsection, the term ''specified waiver'' means a waiver in effect on the date of the enactment of this Act that, with respect to any provision of title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) that requires an in-person visit with a provider of services or supplier (as such terms are defined in section 1861 of such Act (42 U.S.C. 1395x)) as a prerequisite for payment of any item or service under such title or for any other purpose, modifies such provision to allow such visit to be conducted through the use of telehealth.

SEC. 9007. REPORT ON TELEHEALTH PAYMENT INTEGRITY.

Not later than 1 year after the date of the enactment of this Act, the Inspector General of the Department of Health and Human Services shall review claims for payment for telehealth services furnished under the Medicare program 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)) and submit to Congress a report on any instances of waste, fraud, or abuse identified through such review.

SEC. 9008. INCREASING FUNDING FOR REVIEW OF TELEHEALTH CLAIMS.

There are authorized to be appropriated to the Inspector General of the Department of Health and Human Services $10,000,000 for fiscal years 2021 through 2023 for purposes of conducting audits and other oversight activities with respect to payments made under section 1834(m) of the Social Security Act (42 U.S.C. 1395m(m)).

SEC. 9009. TELEHEALTH RESOURCES.

Not later than 6 months after the last day of the emergency period described in section 1135(g)(1)(B) of the Social Security Act (42 U.S.C. 1320b–5(g)(1)(B)), the Secretary of Health and Human Services shall develop and make available to physicians (as defined in section 1861(r) of such Act (42 U.S.C. 1395x(r))) and practitioners (as defined in section 1834(m)(4)(E) of such Act (42 U.S.C. 1395m(m)(4)(E))) educational resources and training sessions on requirements relating to the furnishing of telehealth services under section 1834(m) of such Act (42 U.S.C. 1395m(m)).

Subtitle B—Protecting Access to Innovation During COVID–19

SEC. 9011. AUTHORIZING THE EXTENSION OF PASS-THROUGH STATUS UNDER THE MEDICARE PROGRAM FOR CERTAIN DRUGS AND DEVICES IMPACTED BY COVID–19.

Section 1833(t)(6) of the Social Security Act (42 U.S.C. 1395l(t)(6)) is amended by adding at the end the following new subparagraph:

"(K) AUTHORITY TO EXTEND PASS-THROUGH STATUS FOR CERTAIN DRUGS AND DEVICES IMPACTED BY COVID–19.—

"(i) IN GENERAL.—Notwithstanding the preceding provisions of this paragraph, in the case of an eligible drug or device (as defined in clause (iv)), if the Secretary determines, prior to or on the date of the expiration of pass-through status for such drug or device (or, in the case of such a drug or device whose pass-through status expired before the date of the enactment of this subparagraph, not later than 30 days after such date), that the cost of such drug or device is unable to be accurately calculated due to the effects of COVID–19,

the Secretary may extend the pass-through status of such eligible drug or device in accordance with clause (ii).

''(ii) EXTENSION.—The Secretary may extend the pass-through status of an eligible drug or device described in clause (i) with respect to which a determination has been made under such clause—

''(I) in the case of a drug or device whose period of pass-through status expired during the emergency period described in section 1135(g)(1)(B) before the date of the enactment of this subparagraph, for a period beginning on the first day after such period of up to the number of days occurring during such period during which such drug or device had pass-through status;

''(II) in the case of a drug or device whose period of pass-through status would otherwise expire during such emergency period on or after such date of enactment—

"(aa) for the remainder of such period; and

"(bb) for a period beginning on the first day after such period of up to the number of days occurring during such period during which such drug or device had pass-through status (not taking into account any extension of such status pursuant to this subclause); and

"(III) in the case of a drug or device not described in subclause (I) or (II), by the number of days occurring during such emergency period during which such drug or device had pass-through status.

"(iii) SPECIAL RULES FOR ALREADY-EXPIRED DRUGS AND DEVICES.—In the case of an eligible drug or device described in clause (ii)(I) for which payment under this subsection was packaged into a payment for a covered OPD service (or group of services) and whose period of pass-

through status is extended in accordance with such clause, the Secretary—

"(I) shall, for the period during which such extension is in effect for such drug or device—

"(aa) remove, during such period, the packaged costs of such drug or device (as determined by the Secretary) from the payment amount under this subsection for the covered OPD service (or group of services) with which it is packaged; and

"(bb) not make any adjustments to payment amounts under this subsection for a covered OPD service (or group of services) for which no costs were removed under subclause (I); and

"(II) may not, when calculating the cost of such drug or device at the end of such extension, take into account claims for such drug or device made while such drug or device was so packaged.

''(iv) ELIGIBLE DRUG OR DEVICE DEFINED.—For purposes of this subparagraph, the term 'eligible drug or device' means a drug, biological, or device with pass-through status in effect during any portion of the emergency period described in section 1135(g)(1)(B) that will not be (or was not) separately payable upon the expiration of such status, but only if, in the case of a drug or biological, such drug or biological—

''(I) was payable based upon the wholesale acquisition cost of such drug or biological in lieu of the average sales price of such drug or biological on the first date of such emergency period; and

''(II) will be (or was) packaged into a payment for a covered OPD service (or group of services) upon expiration of such status.''.

Subtitle C—Reducing Unnecessary Senior Hospitalizations

SEC. 9021. SNF-BASED PROVISION OF PREVENTIVE ACUTE CARE AND HOSPITALIZATION REDUCTION PROGRAM.

Title XVIII of the Social Security Act is amended by adding at the end the following new section:

"SEC. 1899C. SNF-BASED PROVISION OF PREVENTIVE ACUTE CARE AND HOSPITALIZATION REDUCTION PROGRAM.

''(a) ESTABLISHMENT.—There is established a program to be known as the 'SNF-based Provision of Preventive Acute Care and Hospitalization Reduction Program' (in this section referred to as the 'Program'), to be administered by the Secretary, for purposes of reducing unnecessary hospitalizations and emergency department visits by allowing qualified group practices (as defined in section 1877(h)(4)) on or after January 1, 2022, to furnish items and services identified under subsection (b)(3) to individuals entitled to benefits under part A and enrolled under part B residing in qualified skilled nursing facilities.

''(b) OPERATION OF PROGRAM.—Under the Program, the Secretary shall provide for the following:

''(1) Certification of skilled nursing facilities as qualified skilled nursing facilities under subsection (c)(1).

''(2) Certification of group practices as qualified group practices under subsection (c)(2).

''(3) Identification of minimum required non-surgical items and services furnished at a hospital emergency department that may be safely furnished by a qualified group practice at a qualified skilled nursing facility under the Program, as determined as clinically appropriate by the Secretary, and that such qualified group practice shall offer to furnish under the Program.

''(4) Annual identification of additional items and services furnished at a hospital emergency department that may be safely furnished by a qualified group practice at a qualified skilled nursing facility under the Program during a year and that such qualified group practice may offer to furnish under the Program during such year.

''(5) Establishment of qualifications for non-physician employees who may furnish such items and services at a qualified skilled nursing facility. Such qualifications shall include the requirement that such an employee—

''(A) be certified in basic life support by a nationally recognized specialty board of certification or equivalent certification board; and

''(B) have—

''(i) clinical experience furnishing medical care—

''(I) in a skilled nursing facility;

''(II) in a hospital emergency department setting; or

''(III) as an employee of a provider or supplier of ambulance services; or

''(ii) a certification in paramedicine.

''(6) Payment under this title for items and services identified under paragraph (3) or (4) furnished by such qualified group practices at such a facility in amounts determined under subsection (d).

''(c) CERTIFICATIONS.—

''(1) QUALIFIED SKILLED NURSING FACILITIES.—For purposes of this section, the Secretary shall certify a skilled nursing facility as a qualified skilled nursing facility if the facility submits an application in a time and manner specified by the Secretary and meets the following requirements:

"(A) The facility has on-site diagnostic equipment necessary for a qualified group practice to furnish items and services under the Program and real-time audio and visual capabilities.

"(B) The facility has at least one individual who meets the qualifications described in paragraph (5) or a physician present 24 hours a day and 7 days a week to work with the qualified group practice. Such individual may be a member of the staff of the qualified skilled nursing facility or of the qualified group practice.

"(C) The facility ensures that residents of such facility, upon entering such facility, are allowed to specify in an advanced care directive whether the resident wishes to receive items and services furnished at the facility under the Program in a case where communication with the resident is not possible.

"(D) The facility ensures that individuals to be furnished such items and services under the Program at such facility have the opportunity, at their request, to instead be transported to a hospital emergency department.

''(E) The facility is not part of the Special Focus Facility program of the Centers for Medicare & Medicaid Services (although the facility may, at the discretion of the Secretary, be a candidate for selection under such program).

Nothing in this paragraph shall affect the requirements under section 1819(b)(4).

''(2) QUALIFIED GROUP PRACTICES.—For purposes of this section, the Secretary shall certify a group practice as a qualified group practice for a period of 3 years if the group practice submits an application in a time and manner specified by the Secretary and meets the following requirements:

''(A) The group practice offers to furnish all minimum required items and services identified under subsection (b)(3) under the Program.

''(B) The group practice submits a notification to the Secretary annually specifying which (if any) additional items and services identified under subsection (b)(4) for a year the group practice will offer to furnish for such year under the Program.

''(C) The group practice ensures that only individuals who meet the qualifications estab-

lished under subsection (b)(5) or a physician who is part of such group practice may furnish such minimum required items and services and such additional items and services.

''(D) The group practice ensures that, in the case where such minimum required items and services or such additional items and services are furnished by such an individual, such individual furnishes such minimum required items and services or additional items and services under the supervision, either in-person or through the use of telehealth (not including store-and-forward technologies), of—

''(i) a physician—

''(I) who is board certified or board eligible in emergency medicine, family medicine, geriatrics, or internal medicine; or

''(II) who has been certified by a nationally recognized specialty board of certification or equivalent certification board in basic life support;

''(ii) a nurse practitioner who has been certified by a nationally recognized specialty board of certification or equiva-

lent certification board in basic life support; or

''(iii) a physician assistant who has been certified by a nationally recognized specialty board of certification or equivalent certification board in basic life support.

''(E) With respect to any year in which the qualified group practice would participate in the Program, the Chief Actuary for the Centers for Medicare & Medicaid Services determines that such participation during such year will not result in total estimated expenditures under this title for such year being greater than total estimated expenditures under such title for such year without such participation.

''(d) PAYMENTS.—

''(1) IN GENERAL.—For 2022 and each subsequent year, the Secretary shall develop a schedule of payments to apply for items and services identified under paragraph (3) or paragraph (4) of subsection (b) furnished during such year under the Program. Such payments shall be in lieu of any other payments that may be made under this title for such items and services.

''(2) SHARED SAVINGS.—In the case of a year for which the Secretary determines that participation in the Program resulted in a reduction in expenditures under this title compared to what such expenditures would have been without such participation, the Secretary shall—

''(A) pay to such qualified group practice an amount equal to 37.5 percent of the estimated amount of such reduction; and

''(B) in the case of each qualified skilled nursing facility where such qualified group practice furnished items and services under the Program during such year—

''(i) if the qualified skilled nursing facility has at least a three-star rating under the Five Star Quality Rating System (or a successor system), pay to the facility an amount that bears the same ratio to 12.5 percent of the estimated amount of such reduction as the amount of expenditures under the Program for such items and services furnished with respect to individuals at such facility by such qualified group practice during such year bears to the total amount of expenditures under the

Program for such items and services furnished with respect to all individuals by such qualified group practice during such year; and

''(ii) in the case of a qualified skilled nursing facility that is not described in clause (i), retain in the Federal Hospital Insurance Trust Fund under section 1817 the amount that the facility would have been paid pursuant to clause (i) if the facility were described in such clause until such time as the facility has at least a three-star rating under the Five Star Quality Rating System (or a successor system), at which point the Secretary shall pay such amount to the facility.

''(3) ADVANCED ALTERNATIVE PAYMENT MODELS.—Paragraph (2) shall not apply to items and services furnished to an individual entitled to benefits under part A and enrolled under part B for whom shared savings would otherwise be attributed through an advanced alternative payment model as authorized under section 1115A or section 1899.

''(e) EVALUATION.—

''(1) IN GENERAL.—With respect to a qualified group practice and a qualified skilled nursing facility, not later than 6 months after such group practice begins furnishing items and services under the Program (or, in the case of a qualified skilled nursing facility, not less than 6 months after a qualified group practice first furnishes such items and services at such facility), and not less than once every 2 years thereafter, the Secretary shall evaluate such qualified group practice and such qualified facility using information received under paragraph (2) on such criteria as determined appropriate by the Secretary.

''(2) REPORTING OF INFORMATION.—In a time and manner specified by the Secretary, a qualified group practice and a qualified skilled nursing facility shall submit to the Secretary a report containing the following information with respect to items and services furnished under the Program during a reporting period (as specified by the Secretary):

''(A) The number of individuals with respect to whom such group practice furnished such items and services in such period (or, in the case of a qualified skilled nursing facility, the number of individuals with respect to whom

such a group practice furnished such items and services at such facility in such period).

''(B) The number of such individuals who were admitted to a hospital or treated in the emergency department of a hospital within 24 hours of being furnished such items and services.

''(C) Other information determined appropriate by the Secretary.

''(3) LOSS OF QUALIFIED CERTIFICATION.—

''(A) IN GENERAL.—Not later than 3 months after a determination described in this sentence is made, the Secretary may revoke the certification of a qualified skilled nursing facility or a qualified group practice made under subsection (c) if—

''(i) the Chief Actuary of the Centers for Medicare & Medicaid Services determines that the participation of such skilled nursing facility or such group practice in the Program during a year resulted in total expenditures under this title for such period being greater than total expenditures under such title would have been

during such period without such participation; or

''(ii) a facility is selected for the Special Focus Facility program or, if the facility is a candidate for the Special Focus Facility program, the Secretary determines that the participation of such facility in the Program should be terminated.

''(B) EXCLUSION FROM CERTIFICATION.—

''(i) IN GENERAL.—In the case that the Secretary revokes the certification of a qualified skilled nursing facility or a qualified group practice under subparagraph (A), such skilled nursing facility or such group practice shall be ineligible for certification as a qualified skilled nursing facility or a qualified group practice (as applicable) under subsection (c) for the applicable period (as defined under clause (ii)).

''(ii) APPLICABLE PERIOD DEFINED.—In this subparagraph, the term 'applicable period' means—

''(I) if the revocation of a facility or group practice under subparagraph (A) is due to the application of clause

(i) of such subparagraph, a 1-year period beginning on the date of such revocation; and

''(II) in the revocation of a facility under subparagraph (A) is due to the application of clause (ii) of such subparagraph, the period beginning on the date of such revocation and ending on the date on which the facility graduates from the Special Focus Facility program (or, in the case of a facility that is a candidate for such program, the date on which the facility is no longer such a candidate, as determined by the Secretary).

''(f) DETERMINATION OF BUDGET NEUTRALITY; TERMINATION OF PROGRAM.—

''(1) DETERMINATION.—Not later than July 1, 2027, the Chief Actuary of the Centers for Medicare & Medicaid Services shall determine whether the Program has resulted in an increase in total expenditures under this title with respect to the period beginning on January 1, 2022, and ending on December 31, 2026, compared to what such expenditures

would have been during such period had the Program not been in operation.

''(2) TERMINATION.—If the Chief Actuary makes a determination under paragraph (1) that the Program has resulted in an increase in total expenditures under this title, the Secretary shall terminate the Program as of January 1 of the first year beginning after such determination.''.

TITLE X—APPROPRIATIONS

APPROPRIATIONS

SEC. 10001. The following sums are hereby appropriated, out of any money in the Treasury not otherwise appropriated, for the fiscal year ending September 30, 2021, and for other purposes, namely:

Subtitle A—Health Programs

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF THE SECRETARY

PUBLIC HEALTH AND SOCIAL SERVICES EMERGENCY FUND

(INCLUDING TRANSFER OF FUNDS)

For an additional amount for ''Public Health and Social Services Emergency Fund'', $31,000,000,000, to remain available until September 30, 2025, to prevent, prepare for, and respond to coronavirus, domestically or

internationally, including the development of necessary countermeasures and vaccines, prioritizing platform-based technologies with United States-based manufacturing capabilities, the purchase of vaccines, therapeutics, diagnostics, necessary medical supplies, as well as medical surge capacity, addressing blood supply chain, workforce modernization, telehealth access and infrastructure, initial advanced manufacturing, novel dispensing, enhancements to the United States Commissioned Corps, and other preparedness and response activities: *Provided*, That funds appropriated under this paragraph in this title may be used to develop and demonstrate innovations and enhancements to manufacturing platforms to support such capabilities: *Provided further*, That the Secretary of Health and Human Services shall purchase vaccines developed using funds made available under this paragraph in this title to respond to an outbreak or pandemic related to coronavirus in quantities determined by the Secretary to be adequate to address the public health need: *Provided further*, That products purchased by the Federal Government with funds made available under this paragraph in this title, including vaccines, therapeutics, and diagnostics, shall be purchased in accordance with Federal Acquisition Regulation guidance on fair and reasonable pricing: *Provided further*, That the Secretary may take such measures

authorized under current law to ensure that vaccines, therapeutics, and diagnostics developed from funds provided in this title will be affordable in the commercial market: *Provided further*, That in carrying out the previous proviso, the Secretary shall not take actions that delay the development of such products: *Provided further*, That the Secretary shall ensure that protections remain for individuals enrolled in group or individual health care coverage with pre-existing conditions, including those linked to coronavirus: *Provided further*, That products purchased with funds appropriated under this paragraph in this title may, at the discretion of the Secretary of Health and Human Services, be deposited in the Strategic National Stockpile under section 319F–2 of the Public Health Service Act: *Provided further*, That of the amount appropriated under this paragraph in this title, not more than $2,000,000,000 shall be for the Strategic National Stockpile under section 319F–2(a) of such Act: *Provided further*, That funds appropriated under this paragraph in this title may be transferred to, and merged with, the fund authorized by section 319F–4, the Covered Counter measure Process Fund, of the Public Health Service Act: *Provided further*, That of the amount appropriated under this paragraph in this title, not more than $2,000,000,000, to remain available until September 30, 2023, shall be for

activities to improve and sustain State medical stockpiles: *Provided further*, That of the amount appropriated under this paragraph in this title, $20,000,000,000 shall be available to the Biomedical Advanced Research and Development Authority for necessary expenses of manufacturing, production, and purchase, at the discretion of the Secretary, of vaccines, therapeutics, diagnostics, and small molecule active pharmaceutical ingredients, including the development, translation, and demonstration at scale of innovations in manufacturing platforms: *Provided further*, That funds in the previous proviso may be used for the construction or renovation of United States-based next generation manufacturing facilities, other than facilities owned by the United States Government: *Provided further*, That amounts provided in the eleventh proviso may be for necessary expenses related to the sustained on-shore manufacturing capacity for public health emergencies: *Provided further*, That of the amount appropriated under this paragraph in this title, $6,000,000,000 shall be for activities to plan, prepare for, promote, distribute, administer, monitor, and track coronavirus vaccines to ensure broad-based distribution, access, and vaccine coverage: *Provided further*, That the Secretary shall coordinate funding and activities outlined in the previous proviso through the Director of the Centers for Disease Control and Prevention:

Provided further, That the Secretary, through the Director of the Centers for Disease Control and Prevention, shall report to the Committees on Appropriations of the House of Representatives and the Senate within 60 days of the date of enactment of this title on a comprehensive coronavirus vaccine distribution strategy and spend plan that includes how existing infrastructure will be leveraged, enhancements or new infrastructure that may be built, considerations for moving and storing vaccines, guidance for how States and health care providers should prepare for, store, and administer vaccines, nationwide vaccination targets, funding that will be distributed to States, how an informational campaign to both the public and health care providers will be executed, and how the vaccine distribution plan will focus efforts on high risk, underserved, and minority populations: *Provided further*, That such plan shall be updated and provided to the Committees on Appropriations of the House of Representatives and the Senate 90 days after submission of the first plan: *Provided further*, That the Secretary shall notify the Committees on Appropriations of the House of Representatives and the Senate 2 days in advance of any obligation in excess of $50,000,000, including contracts and interagency agreements, from funds provided in this paragraph in this title: *Provided further*, That funds appropriated under this

paragraph in this title may be used for the construction, alteration, or renovation of nonfederally owned facilities for the production of vaccines, therapeutics, diagnostics, and medical supplies where the Secretary determines that such a contract is necessary to secure sufficient amounts of such supplies: *Provided further*, That not later than 30 days after enactment of this title, and every 30 days thereafter until funds are expended, the Secretary shall report to the Committees on Appropriations of the House of Representatives and the Senate on uses of funding for Operation Warp Speed, detailing current obligations by Department or Agency, or component thereof broken out by the coronavirus supplemental appropriations Act that provided the source of funds: *Provided further*, That the plan outlined in the previous proviso shall include funding by contract, grant, or other transaction in excess of $20,000,000 with a notation of which Department or Agency, and component thereof is managing the contract: *Provided further*, That such amount is designated by the Congress as being for an emergency requirement pursuant to section 251(b)(2)(A)(i) of the Balanced Budget and Emergency Deficit Control Act of 1985.

For an additional amount for ''Public Health and Social Services Emergency Fund'', $16,000,000,000, to remain available until September 30, 2023, to prevent, pre-

pare for, and respond to coronavirus, domestically or internationally, which shall be for necessary expenses for testing, contact tracing, surveillance, containment, and mitigation to monitor and suppress COVID–19, including tests for both active infection and prior exposure, including molecular, antigen, and serological tests, the manufacturing, procurement and distribution of tests, testing equipment and testing supplies, including personal protective equipment needed for administering tests, the development and validation of rapid, molecular point-of-care tests, and other tests, support for workforce, epidemiology, to scale up academic, commercial, public health, and hospital laboratories, to conduct surveillance and contact tracing, support development of COVID–19 testing plans, and other related activities related to COVID–19 testing: *Provided*, That of the amount appropriated under this paragraph in this title, not less than $15,000,000,000 shall be for States, localities, territories, Tribes, Tribal organizations, urban Indian health organizations, or health service providers to Tribes for necessary expenses for testing, contact tracing, surveillance, containment, and mitigation, including support for workforce, epidemiology, use by employers, elementary and secondary schools, child care facilities, institutions of higher education, long-term care facilities, or in other settings, scale up of testing by

public health, academic, commercial, and hospital laboratories, and community-based testing sites, health care facilities, and other entities engaged in COVID–19 testing, and other related activities related to COVID–19 testing, contact tracing, surveillance, containment, and mitigation: *Provided further*, That the amount provided in the preceding proviso shall be made available within 30 days of the date of enactment of this title: *Provided further*, That the amount identified in the first proviso under this paragraph in this title shall be allocated to States, localities, and territories according to the formula that applied to the Public Health Emergency Preparedness cooperative agreement in fiscal year 2019: *Provided further*, That not less than $500,000,000 shall be allocated in coordination with the Director of the Indian Health Service, to Tribes, Tribal organizations, urban Indian health organizations, or health service providers to Tribes: *Provided further*, That the Secretary of Health and Human Services (referred to in this paragraph as the ''Secretary'') may satisfy the funding thresholds outlined in the first and fourth provisos under this paragraph in this title by making awards through other grant or cooperative agreement mechanisms: *Provided further*, That the Governor or designee of each State, locality, territory, Tribe, or Tribal organization receiving funds pursuant to this title shall up-

date their plans, as applicable, for COVID–19 testing and contact tracing submitted to the Secretary pursuant to the Paycheck Protection Program and Health Care Enhancement Act (Public Law 116–139) and submit such updates to the Secretary not later than 60 days after funds appropriated in this paragraph in this title have been awarded to such recipient: *Provided further*, That not later than 60 days after the date of enactment, and every quarter thereafter until funds are expended, the Governor or designee of each State, locality, territory, Tribe, or Tribal organization receiving funds shall report to the Secretary on uses of funding, detailing current commitments and obligations broken out by the coronavirus supplemental appropriations Act that provided the source of funds: *Provided further*, That not later than 15 days after receipt of such reports, the Secretary shall summarize and report to the Committees on Appropriations of the House of Representatives and the Senate on States' commitments and obligations of funding: *Provided further*, That funds an entity receives from amounts described in the first proviso in this paragraph may also be used for the rent, lease, purchase, acquisition, construction, alteration, renovation, or equipping of nonfederally owned facilities to improve coronavirus preparedness and response capability at the State and local level: *Provided further*, That such amount

is designated by the Congress as being for an emergency requirement pursuant to section 251(b)(2)(A)(i) of the Balanced Budget and Emergency Deficit Control Act of 1985.

Subtitle B—General Provisions–This Title

SEC. 10101. Each amount appropriated or made available by this title is in addition to amounts otherwise appropriated for the fiscal year involved.

SEC. 10102. No part of any appropriation contained in this title shall remain available for obligation beyond the current fiscal year unless expressly so provided herein.

SEC. 10103. Unless otherwise provided for by this title, the additional amounts appropriated by this title to appropriations accounts shall be available under the authorities and conditions applicable to such appropriations accounts for fiscal year 2020.

SEC. 10104. In this title, the term ''coronavirus'' means SARS–CoV–2 or another coronavirus with pandemic potential.

SEC. 10105. Each amount designated in this title by the Congress as being for an emergency requirement pursuant to section 251(b)(2)(A)(i) of the Balanced Budget and Emergency Deficit Control Act of 1985 shall be available (or rescinded or transferred, if applicable) only if the

President subsequently so designates all such amounts and transmits such designations to the Congress.

SEC. 10106. Any amount appropriated by this title, designated by the Congress as an emergency requirement pursuant to section 251(b)(2)(A)(i) of the Balanced Budget and Emergency Deficit Control Act of 1985 and subsequently so designated by the President, and transferred pursuant to transfer authorities provided by this title shall retain such designation.

SEC. 10107. (a) STATUTORY PAYGO SCORECARDS.—The budgetary effects of this title shall not be entered on either PAYGO scorecard maintained pursuant to section 4(d) of the Statutory Pay As-You-Go Act of 2010.

(b) SENATE PAYGO SCORECARDS.—The budgetary effects of this title shall not be entered on any PAYGO scorecard maintained for purposes of section 4106 of H. Con. Res. 71 (115th Congress).

(c) CLASSIFICATION OF BUDGETARY EFFECTS.—Notwithstanding Rule 3 of the Budget Scorekeeping Guidelines set forth in the joint explanatory statement of the committee of conference accompanying Conference Report 105–217 and section 250(c)(7) and (c)(8) of the Balanced Budget and Emergency Deficit Control Act of 1985, the budgetary effects of this title shall be estimated for purposes of section 251 of such Act.

(d) ENSURING NO WITHIN-SESSION SEQUESTRATION.—Solely for the purpose of calculating a breach within a category for fiscal year 2020 pursuant to section 251(a)(6) or section 254(g) of the Balanced Budget and Emergency Deficit Control Act of 1985, and notwithstanding any other provision of this title, the budgetary effects from this title shall be counted as amounts designated as being for an emergency requirement pursuant to section 251(b)(2)(A) of such Act.

This title may be cited as the ''Coronavirus Response Additional Supplemental Appropriations Act, 2020''.

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