

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

A BILL

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

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Commitment to Defeat
5 the Virus and Keep America Healthy Act”.

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

7 The table of contents for this Act is as follows:

- Sec. 1. Short title.
 Sec. 2. Table of contents.

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.
 Sec. 1002. Deployment by the Secretary of Health and Human Services of National Strategic Stockpile.
 Sec. 1003. Authority and responsibilities of the Federal Emergency Management Agency regarding the Strategic National Stockpile.

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.

Subtitle C—Protections for Good Samaritan Health Professionals

- Sec. 1021. Limitation on liability for volunteer health care professionals.
 Sec. 1022. Sense of the Congress.

Subtitle D—Medical Sheltering

- Sec. 1031. Reducing the spread of COVID-19 through payments to States to lease hotels to temporarily house eligible individuals.

Subtitle E—CDC Campaign on COVID-19 Awareness

- Sec. 1041. COVID-19 public awareness campaign.

Subtitle F—Protecting Children From COVID-19

- Sec. 1051. Study on children's role in transmitting SARS-CoV-2.

Subtitle G—Ensuring Understanding of COVID-19

- Sec. 1061. Study on the impact of COVID-19.

Subtitle H—Safeguarding Therapeutics

- Sec. 1071. Authority to destroy counterfeit devices.
 Sec. 1072. Determination of budgetary effects.

Subtitle I—Advisory Committee on Immunization Practices

- Sec. 1081. Expedited meeting of ACIP for COVID-19 vaccines.

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.

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.

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

Sec. 2011. Report to Congress on barriers to domestic manufacturing of medical products and supplies.

Sec. 2012. Enhancing intra-agency coordination and public health assessment with regard to compliance activities.

Sec. 2013. Encouraging international harmonization.

Sec. 2014. Mutual recognition agreements for inspections and review activities.

Sec. 2015. Enhancing transparency of drug facility inspection timelines.

Sec. 2016. Advanced manufacturing technologies program.

Subtitle C—Improving the American Drug Supply Chain

Sec. 2021. Study and reporting on domestic and foreign production.

Subtitle D—Essential Medicines Strategic Stockpile

Sec. 2031. Pilot program on ensuring medication supply stability.

Subtitle E—National Centers of Excellence in Continuous Pharmaceutical Manufacturing

Sec. 2041. National Centers of Excellence in Continuous Pharmaceutical Manufacturing.

TITLE III—STRATEGIC NATIONAL STOCKPILE IMPROVEMENTS

Subtitle A—Stockpiling for America’s Future Endeavors

Sec. 3001. Strategic National Stockpile.

Subtitle B—Stockpile Inventory Modernization

Sec. 3011. Reimbursable transfers.

Subtitle C—Equipment Maintenance

Sec. 3021. Equipment maintenance.

Subtitle D—Medical Supplies for Pandemics

Sec. 3031. Supply chain flexibility manufacturing pilot.

Subtitle E—State Stockpile Readiness

Sec. 3041. Grants for State strategic stockpiles.

Subtitle F—Process Improvements and Reports

Sec. 3051. GAO study on the feasibility and benefits of user fee agreements.

Sec. 3052. Action reporting.

Sec. 3053. Improved, transparent processes.

Subtitle G—Strategic National Stockpile Funding

Sec. 3061. Authorization of appropriations.

TITLE IV—PUBLIC HEALTH INFRASTRUCTURE IMPROVEMENTS

Subtitle A—Public Health Infrastructure Modernization

Sec. 4001. Public health data system transformation.

Subtitle B—Modernizing Infectious Disease Data Collection

Sec. 4011. Modernizing infectious disease data collection.

Subtitle C—Diagnostic Testing for Public Health Labs

Sec. 4021. Grants for public health laboratories to acquire high-throughput diagnostic equipment.

Subtitle D—Rapid Testing for Communities

Sec. 4031. Grants for same-day point-of-care clinical laboratory diagnostic testing in communities.

Subtitle E—Public Health Workforce Loan Repayment

Sec. 4041. Public Health Workforce Loan Repayment Program.

Subtitle F—Vaccine Awareness and Disease Prevention

Sec. 4051. Improving awareness of disease prevention.

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

Sec. 4061. National COVID–19 Resource Center for Older Adults.

Sec. 4062. Healthy Aging Program.

Sec. 4063. Authorization of appropriations.

Subtitle H—Expanding Capacity for Health Outcomes

Sec. 4071. Expanding capacity for health outcomes.

Subtitle I—Community Readiness

Sec. 4081. Grants for research on, or establishing, wastewater surveillance and other early warning systems.

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.

Sec. 5002. Improving health statistics reporting with respect to Indian Tribes.

Subtitle B—Tribal Medical Supplies Stockpile Access

Sec. 5011. Provision of items to Indian programs and facilities.

Subtitle C—Native American Suicide Prevention

Sec. 5021. Native American suicide prevention.

Subtitle D—Pursuing Equity in Mental Health

PART 1—HEALTH EQUITY AND ACCOUNTABILITY

- Sec. 5031. Integrated Health Care Demonstration Program.
- Sec. 5032. Addressing racial and ethnic minority mental health disparities research gaps.
- Sec. 5033. Health professions competencies to address racial and ethnic minority mental health disparities.
- Sec. 5034. Racial and ethnic minority behavioral and mental health outreach and education strategy.
- Sec. 5035. Additional funds for National Institutes of Health.
- Sec. 5036. Additional funds for National Institute on Minority Health and Health Disparities.

PART 2—OTHER PROVISIONS

- Sec. 5037. Reauthorization of Minority Fellowship Program.
- Sec. 5038. Study on the Effects of Smartphone and Social Media Use on Adolescents.
- Sec. 5039. Technical correction.

Subtitle E—Maternal Health Quality Improvement

- Sec. 5041. Innovation for maternal health.
- Sec. 5042. Training for health care providers.
- Sec. 5043. Study on training to reduce and prevent discrimination.
- Sec. 5044. Perinatal quality collaboratives.
- Sec. 5045. Integrated services for pregnant and postpartum women.
- Sec. 5046. Improving rural maternal and obstetric care data.
- Sec. 5047. Rural obstetric network grants.
- Sec. 5048. Telehealth network and telehealth resource centers grant programs.
- Sec. 5049. Rural maternal and obstetric care training demonstration.

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.

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.

Subtitle C—Suicide Prevention Grants

- Sec. 6021. Syndromic surveillance of self-harm behaviors program.
- Sec. 6022. Grants to provide self-harm and suicide prevention services.

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.

Subtitle E—Suicide Prevention Lifeline Improvement

- Sec. 6041. Suicide Prevention Lifeline.
- Sec. 6042. Pilot program on innovative technologies.
- Sec. 6043. HHS study and report.
- Sec. 6044. GAO study and report.
- Sec. 6045. Definition.

Subtitle F—Campaign To Prevent Suicide

- Sec. 6051. National Suicide Prevention Lifeline.
- Sec. 6052. National suicide prevention media campaign.

Subtitle G—Helping Emergency Responders Overcome

- Sec. 6061. Data system to capture national public safety officer suicide incidence.
- Sec. 6062. Peer-support behavioral health and wellness programs within fire departments and emergency medical service agencies.
- Sec. 6063. Health care provider behavioral health and wellness programs.
- Sec. 6064. Development of resources for educating mental health professionals about treating fire fighters and emergency medical services personnel.
- Sec. 6065. Best practices and other resources for addressing posttraumatic stress disorder in public safety officers.

Subtitle H—Behavioral Health Intervention Guidelines

- Sec. 6071. Best practices for behavioral intervention teams.

Subtitle I—Suicide Training and Awareness Nationally Delivered for Universal Prevention

- Sec. 6081. Student suicide awareness and prevention training.
- Sec. 6082. Effective date.

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.

Subtitle B—Access to Remote Behavioral Health Treatment

- Sec. 7011. Registration of qualified community mental health centers.

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.

Subtitle D—Family Support Services for Addiction

- Sec. 7031. Family support services for individuals struggling with substance use disorder.

Subtitle E—Block, Report, And Suspend Suspicious Shipments

Sec. 7041. Clarification of process for registrants to exercise due diligence upon discovering a suspicious order.

Subtitle F—Debarment Enforcement of Bad Actor Registrants

Sec. 7051. Debarment of certain registrants.

Subtitle G—Ensuring Compliance Against Opioid Diversion

Sec. 7061. Modification, transfer, and termination of registration to manufacture, distribute, or dispense controlled substances.

Subtitle H—Opioid Prescription Verification

Sec. 7071. Materials for training pharmacists on certain circumstances under which a pharmacist may decline to fill a prescription.

Sec. 7072. Incentivizing States to facilitate responsible, informed dispensing of controlled substances.

Subtitle I—Suspicious Order Identification

Sec. 7081. Strengthening ARCOS.

Sec. 7082. Suspicious Orders Task Force.

Subtitle J—Stop the Importation and Manufacturing of Synthetic Analogues

Sec. 7091. Establishment of schedule A.

Sec. 7092. Temporary and permanent scheduling of schedule A substances.

Sec. 7093. Penalties.

Sec. 7094. False labeling of schedule A controlled substances.

Sec. 7095. Registration requirements for importers and exporters of schedule A substances.

Sec. 7096. Additional conforming amendments.

Sec. 7097. Sentencing review.

Sec. 7098. Rules of construction.

Sec. 7099. Clarification of certain registration requirements related to research.

Sec. 7100. Review of research registration process.

TITLE VIII—TAX INCENTIVES TO IMPROVE HEALTH CARE

Sec. 8001. Domestic medical and drug manufacturing credit.

Sec. 8002. Qualifying advanced medical manufacturing equipment credit.

Sec. 8003. New medical research expenditure component of credit for increasing research activities.

Sec. 8004. Refundable portion of research credit for small businesses engaging in specified medical research.

Sec. 8005. Exception from passive loss rules for investments in specified medical research small business pass-thru entities.

Sec. 8006. Temporary carryover for health and dependent care flexible spending arrangements.

Sec. 8007. Increase in exclusion for employer-provided dependent care assistance.

Sec. 8008. Temporary increase in contribution limits for health savings accounts.

Sec. 8009. Temporary allowance of payments for employment-related expenses under health savings accounts.

Sec. 8010. Treatment of direct primary care service arrangements.

- Sec. 8011. Allow both spouses to make catch-up contributions to the same HSA account.
- Sec. 8012. Repeal of ceiling on deductible and out-of-pocket expenses under a high deductible health plan.
- Sec. 8013. On-site employee clinics.
- Sec. 8014. Adjustment of medical expense deduction.
- Sec. 8015. Healthy workplace tax credit.

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.
- Sec. 9002. Making permanent FQHC and RHC telehealth payments.
- Sec. 9003. Expanding the list of practitioners eligible to furnish telehealth services.
- Sec. 9004. Allowing for the provision of telehealth services via audio-only telecommunications systems.
- Sec. 9005. Making permanent the safe harbor for absence of deductible for telehealth.
- Sec. 9006. Removing requirement for face-to-face visits between home dialysis patients and physicians.
- Sec. 9007. Report on telehealth payment integrity.
- Sec. 9008. Increasing funding for review of telehealth claims.
- Sec. 9009. Telehealth resources.

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.

Subtitle C—Reducing Unnecessary Senior Hospitalizations

- Sec. 9021. SNF-based provision of preventive acute care and hospitalization reduction program.

TITLE X—APPROPRIATIONS

- Sec. 10001. Appropriations.

Subtitle A—Health Programs

Subtitle B—General Provisions—This Title

1 **TITLE I—PANDEMIC**
2 **PREPAREDNESS AND RESPONSE**
3 **Subtitle A—Clarifying the Role of**
4 **the Department of Health and**
5 **Human Services During Public**
6 **Health Emergencies**

7 **SEC. 1001. LEAD AGENCY FOR FEDERAL PUBLIC HEALTH**
8 **AND MEDICAL RESPONSE TO PUBLIC**
9 **HEALTH EMERGENCIES.**

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

12 (1) in subsection (a), by inserting after “shall
13 lead all Federal public health and medical response
14 to public health emergencies and incidents” the fol-
15 lowing: “(including emergencies and disasters de-
16 clared by the President pursuant to the National
17 Emergencies Act or the Robert T. Stafford Disaster
18 Relief and Emergency Assistance Act)”; and

19 (2) in subsection (b), by inserting after “shall
20 assume operational control of emergency public
21 health and medical response assets, as necessary, in
22 the event of a public health emergency” the fol-
23 lowing: “or in the event of an emergency or disaster
24 declared by the President under the National Emer-

1 agencies Act or the Robert T. Stafford Disaster Re-
2 lief and Emergency Assistance Act”.

3 **SEC. 1002. DEPLOYMENT BY THE SECRETARY OF HEALTH**
4 **AND HUMAN SERVICES OF NATIONAL STRA-**
5 **TEGIC STOCKPILE.**

6 Section 319F–2(a)(3)(F) of the Public Health Serv-
7 ice Act (42 U.S.C. 247d–6b(a)(3)(F)) is amended by
8 striking “as required by” and inserting “in consultation
9 with”.

10 **SEC. 1003. AUTHORITY AND RESPONSIBILITIES OF THE**
11 **FEDERAL EMERGENCY MANAGEMENT AGEN-**
12 **CY REGARDING THE STRATEGIC NATIONAL**
13 **STOCKPILE.**

14 The Homeland Security Act of 2002 is amended—

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

18 (2) in subparagraph (D) of section 504(a)(3) (6
19 U.S.C. 314(a)(3)), by striking “requiring” and in-
20 sserting “, at the direction of the Secretary of Health
21 and Human Services, assisting in”.

1 **Subtitle B—Reagan-Udall Founda-**
2 **tion and Foundation for the Na-**
3 **tional Institutes of Health**

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

6 (a) REAGAN-UDALL FOUNDATION FOR THE FOOD
7 AND DRUG ADMINISTRATION.—Section 770(n) of the
8 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
9 379dd(n)) is amended by striking “\$500,000 and not
10 more than \$1,250,000” and inserting “\$1,250,000 and
11 not more than \$5,000,000”.

12 (b) FOUNDATION FOR THE NATIONAL INSTITUTES
13 OF HEALTH.—Section 499(l) of the Public Health Service
14 Act (42 U.S.C. 290b(l)) is amended by striking “\$500,000
15 and not more than \$1,250,000” and inserting
16 “\$1,250,000 and not more than \$5,000,000”.

17 **Subtitle C—Protections for Good**
18 **Samaritan Health Professionals**

19 **SEC. 1021. LIMITATION ON LIABILITY FOR VOLUNTEER**
20 **HEALTH CARE PROFESSIONALS.**

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

1 **“SEC. 224A. LIMITATION ON LIABILITY FOR VOLUNTEER**
2 **HEALTH CARE PROFESSIONALS.**

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

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

10 “(2) the act or omission occurs—

11 “(A) during the period of the disaster, as
12 determined under the laws listed in subsection
13 (d)(1);

14 “(B) in the State or States for which the
15 disaster is declared;

16 “(C) in the health care professional’s ca-
17 pacity as a volunteer;

18 “(D) in the course of providing services
19 that are within the scope of the license, reg-
20 istration, or certification of the volunteer, as de-
21 fined by the State of licensure, registration, or
22 certification; and

23 “(E) in a good faith belief that the indi-
24 vidual being treated is in need of health care
25 services.

1 “(b) EXCEPTIONS.—Subsection (a) does not apply
2 if—

3 “(1) the harm was caused by an act or omission
4 constituting willful or criminal misconduct, gross
5 negligence, reckless misconduct, or a conscious fla-
6 grant indifference to the rights or safety of the indi-
7 vidual harmed by the health care professional; or

8 “(2) the health care professional rendered the
9 health care services under the influence (as deter-
10 mined pursuant to applicable State law) of alcohol
11 or an intoxicating drug.

12 “(c) PREEMPTION.—

13 “(1) IN GENERAL.—This section preempts the
14 laws of a State or any political subdivision of a State
15 to the extent that such laws are inconsistent with
16 this section, unless such laws provide greater protec-
17 tion from liability.

18 “(2) VOLUNTEER PROTECTION ACT.—Protec-
19 tions afforded by this section are in addition to those
20 provided by the Volunteer Protection Act of 1997.

21 “(d) DEFINITIONS.—In this section:

22 “(1) The term ‘disaster’ means—

23 “(A) a national emergency declared by the
24 President under the National Emergencies Act;

1 “(B) an emergency or major disaster de-
2 clared by the President under the Robert T.
3 Stafford Disaster Relief and Emergency Assist-
4 ance Act; or

5 “(C) a public health emergency that is de-
6 termined by the Secretary under section 319 of
7 this Act with respect to one or more States
8 specified in such determination—

9 “(i) during only the initial period cov-
10 ered by such determination; and

11 “(ii) excluding any period covered by
12 a renewal of such determination.

13 “(2) The term ‘harm’ includes physical, non-
14 physical, economic, and noneconomic losses.

15 “(3) The term ‘health care professional’ means
16 an individual who is licensed, registered, or certified
17 under Federal or State law to provide health care
18 services.

19 “(4) The term ‘health care services’ means any
20 services provided by a health care professional, or by
21 any individual working under the supervision of a
22 health care professional, that relate to—

23 “(A) the diagnosis, prevention, or treat-
24 ment of any human disease or impairment; or

1 “(B) the assessment or care of the health
2 of a human being.

3 “(5) The term ‘State’ includes each of the sev-
4 eral States, the District of Columbia, the Common-
5 wealth of Puerto Rico, the Virgin Islands, Guam,
6 American Samoa, the Northern Mariana Islands,
7 and any other territory or possession of the United
8 States.

9 “(6)(A) The term ‘volunteer’ means a health
10 care professional who, with respect to the health
11 care services rendered, does not receive—

12 “(i) compensation; or

13 “(ii) any other thing of value in lieu of
14 compensation, in excess of \$500 per year.

15 “(B) For purposes of subparagraph (A), the
16 term ‘compensation’—

17 “(i) includes payment under any insurance
18 policy or health plan, or under any Federal or
19 State health benefits program; and

20 “(ii) excludes—

21 “(I) reasonable reimbursement or al-
22 lowance for expenses actually incurred;

23 “(II) receipt of paid leave; and

24 “(III) receipt of items to be used ex-
25 clusively for rendering the health services

1 in the health care professional’s capacity
2 as a volunteer described in subsection
3 (a)(1).”.

4 (b) EFFECTIVE DATE.—

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

9 (2) APPLICATION.—Section 224A of the Public
10 Health Service Act, as added by subsection (a), ap-
11 plies to a claim for harm only if the act or omission
12 that caused such harm occurred on or after the ef-
13 fective date described in paragraph (1).

14 **SEC. 1022. SENSE OF THE CONGRESS.**

15 It is the sense of Congress that—

16 (1) health care professionals should be encour-
17 aged to register with the Emergency System for Ad-
18 vance Registration of Volunteer Health Professionals
19 (ESAR–VHP), and States should employ online reg-
20 istration with the promptest processing possible of
21 such registrations to foster the rapid deployment
22 and utilization of volunteer health care professionals
23 following a disaster;

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

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

3 (3) the appropriate licensing entities should
4 verify the licenses of volunteer health care profes-
5 sionals serving disaster victims as soon as is reason-
6 ably practical following a disaster.

7 **Subtitle D—Medical Sheltering**

8 **SEC. 1031. REDUCING THE SPREAD OF COVID-19 THROUGH** 9 **PAYMENTS TO STATES TO LEASE HOTELS TO** 10 **TEMPORARILY HOUSE ELIGIBLE INDIVID-** 11 **UALS.**

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

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

19 (1) distributes the amount among the States
20 that—

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

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

25 (2) takes into consideration—

1 (A) the number of active cases of individ-
2 uals infected with COVID-19 in the applying
3 State relative to the overall population of the
4 State; and

5 (B) the average income of individuals in
6 the applying State relative to the average in-
7 come of individuals in the United States.

8 (c) APPLICATIONS.—

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

14 (2) PROCESS.—The Secretary shall—

15 (A) not later than 15 days after the date
16 of enactment of this Act, publish the process
17 for States to apply for payments under this sec-
18 tion; and

19 (B) not later than 15 days after the sub-
20 mission of an application in accordance with
21 such process, approve or disapprove the applica-
22 tion.

23 (3) CONTENTS.—The Secretary shall require
24 the application of a State under this section to in-
25 clude—

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

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

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

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

9 (i) workplace safety standards for
10 their staff;

11 (ii) proper personal protective equip-
12 ment and sanitation supplies;

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

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

19 (E) a plan to feed and provide other nec-
20 essary materials to individuals described in sub-
21 section (a) at the hotels, including medications
22 and hygiene products, without letting such indi-
23 viduals leave their rooms or accept visitors;

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

4 (G) a plan for hospital networks, local
5 health departments, and the hotels to coordi-
6 nate on the exchange and protection of patient
7 information in accordance with other applicable
8 law;

9 (H) a plan to effectively communicate the
10 State's program funded through this section to
11 racial and ethnic minority groups and low-in-
12 come communities; and

13 (I) each funding assurance listed in sub-
14 section (e).

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

21 (e) FUNDING ASSURANCES.—As a condition on re-
22 ceipt of a payment of this section, a State shall give such
23 assurances as the Secretary may require that—

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

1 untary basis, and no hotel will be required by the
2 State to participate in the program under this sec-
3 tion;

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

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

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

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

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

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

9 (B) all of the costs of having one or more
10 qualified health care professionals described in
11 subsection (c)(3)(D)(iii) for the provision of
12 monitoring described in such subsection (wheth-
13 er by being onsite or on call).

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

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

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

21 (A) the Committee on Energy and Com-
22 merce and the Committee on Ways and Means
23 of the House of Representatives; and

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

4 (g) LIABILITY PROTECTION.—

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

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

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

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

22 (h) DEFINITIONS.—In this section:

23 (1) The term “eligible individual” means an in-
24 dividual who is unable to self-isolate at home, does

1 not require inpatient or outpatient health care treat-
2 ment, and—

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

5 (B) has a presumptive positive case of
6 COVID-19; or

7 (C) is a person under investigation who is
8 displaying symptoms of COVID-19.

9 (2) The terms “Indian tribe” and “tribal orga-
10 nization” have the meanings given to those terms in
11 section 4 of the Indian Self-Determination and Edu-
12 cation Assistance Act (25 U.S.C. 5304).

13 (3) The term “Secretary” means the Secretary
14 of Health and Human Services.

15 (4) The term “State” includes each of 50
16 States, the District of Columbia, each Indian Tribe
17 and tribal organization, Guam, American Samoa, the
18 United States Virgin Islands, the Commonwealth of
19 Puerto Rico, and the Commonwealth of the North-
20 ern Mariana Islands.

21 (i) FUNDING.—To carry out this section, there is au-
22 thorized to be appropriated \$1,000,000,000, to remain
23 available through the earlier of—

24 (1) the end of calendar year 2021; or

1 (2) the end of the emergency period (as defined
2 in section 1135(g)(1)(B) of the Social Security Act
3 (42 U.S.C. 1320b-5(g)(1)(B))).

4 **Subtitle E—CDC Campaign on**
5 **COVID-19 Awareness**

6 **SEC. 1041. COVID-19 PUBLIC AWARENESS CAMPAIGN.**

7 The Secretary of Health and Human Services, acting
8 through the Director of the Centers for Disease Control
9 and Prevention and in coordination with other offices and
10 agencies, as appropriate, shall award competitive grants
11 or contracts to one or more public or private entities to
12 carry out a national campaign that is multilingual and cul-
13 turally competent and based on available scientific evi-
14 dence to increase awareness and knowledge of COVID-
15 19, including reducing stigma associated with COVID-19
16 and improving information on the availability of diagnostic
17 testing and other related services at community health
18 centers.

19 **Subtitle F—Protecting Children**
20 **From COVID-19**

21 **SEC. 1051. STUDY ON CHILDREN'S ROLE IN TRANSMITTING**
22 **SARS-COV-2.**

23 (a) STUDY.—

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

1 “Secretary”), in coordination with the heads of
2 agencies of the Department of Health and Human
3 Services and experts from outside of the Depart-
4 ment, as appropriate, shall complete a study on chil-
5 dren’s role in transmitting SARS–CoV–2.

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

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

10 (B) the vulnerability of children, especially
11 those with underlying health conditions, to se-
12 vere illness as such vulnerability relates to
13 COVID–19;

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

17 (D) the vulnerability of adults, especially
18 those with underlying health conditions, who
19 interact with children who may be asymp-
20 tomatic but infectious.

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

23 (A) take into consideration the best avail-
24 able science, including as provided by the Na-
25 tional Academy of Sciences; and

1 (B) ensure that such study includes con-
2 sideration of children who are members of ra-
3 cial or ethnic minority groups.

4 (b) REPORTING.—The Secretary shall submit a re-
5 port to the Congress on children’s role in transmitting
6 SARS–CoV–2. The report shall include the results of the
7 study under subsection (a).

8 (c) DISSEMINATION OF BEST PRACTICES.—The Sec-
9 retary shall disseminate to stakeholders best practices for
10 protecting children and adults in educational settings. The
11 first best practices disseminated pursuant to the preceding
12 sentence shall include any best practices for protecting
13 children and adults in educational settings identified
14 through the study under subsection (a).

15 (d) DEFINITION.—In this section, the term “emer-
16 gency period” has the meaning given to such term in sec-
17 tion 1135(g)(1)(B) of the Social Security Act (42 U.S.C.
18 1320b–5(g)(1)(B)).

19 **Subtitle G—Ensuring** 20 **Understanding of COVID–19**

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

22 Part A of title IV of the Public Health Service Act
23 (42 U.S.C. 281 et seq.) is amended by adding at the end
24 the following:

1 **“SEC. 4040. STUDY ON THE IMPACT OF COVID-19.**

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

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

9 “(c) REQUIREMENTS.—The study under this section
10 shall—

11 “(1) be nationwide;

12 “(2) include diversity of enrollees to account for
13 gender, age, race, ethnicity, geography,
14 comorbidities, and underrepresented populations, in-
15 cluding pregnant and lactating women;

16 “(3) study individuals who were infected with
17 COVID-19 who experienced mild symptoms, such
18 individuals who experienced moderate symptoms,
19 and such individuals who experienced severe symp-
20 toms;

21 “(4) monitor the health outcomes and symp-
22 toms of individuals who were infected with COVID-
23 19, or had prenatal exposure to COVID-19, includ-
24 ing lung capacity and function, and immune re-
25 sponse, taking into account any pharmaceutical
26 interventions such individuals may have received;

1 “(5) monitor the mental health outcomes of in-
2 dividuals infected with COVID–19, taking into ac-
3 count any interventions that affected mental health;
4 and

5 “(6) monitor individuals enrolled in the study
6 not less frequently than twice per year after the first
7 year of the individual’s infection with COVID–19.

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

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

22 “(f) AUTHORIZATION OF APPROPRIATIONS.—There
23 are authorized to be appropriated such sums as may be
24 necessary to carry out this section.”.

1 **Subtitle H—Safeguarding**
2 **Therapeutics**

3 **SEC. 1071. AUTHORITY TO DESTROY COUNTERFEIT DE-**
4 **VICES.**

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

8 (1) in the fourth sentence, by inserting “or
9 counterfeit device” after “counterfeit drug”; and

10 (2) by striking “The Secretary of the Treasury
11 shall cause the destruction of” and all that follows
12 through “liable for costs pursuant to subsection
13 (c).” and inserting the following: “The Secretary of
14 the Treasury shall cause the destruction of any such
15 article refused admission unless such article is ex-
16 ported, under regulations prescribed by the Sec-
17 retary of the Treasury, within 90 days of the date
18 of notice of such refusal or within such additional
19 time as may be permitted pursuant to such regula-
20 tions, except that the Secretary of Health and
21 Human Services may destroy, without the oppor-
22 tunity for export, any drug or device refused admis-
23 sion under this section, if such drug or device is val-
24 ued at an amount that is \$2,500 or less (or such
25 higher amount as the Secretary of the Treasury may

1 set by regulation pursuant to section 498(a)(1) of
2 the Tariff Act of 1930 (19 U.S.C. 1498(a)(1))) and
3 was not brought into compliance as described under
4 subsection (b). The Secretary of Health and Human
5 Services shall issue regulations providing for notice
6 and an opportunity to appear before the Secretary
7 of Health and Human Services and introduce testi-
8 mony, as described in the first sentence of this sub-
9 section, on destruction of a drug or device under the
10 seventh sentence of this subsection. The regulations
11 shall provide that prior to destruction, appropriate
12 due process is available to the owner or consignee
13 seeking to challenge the decision to destroy the drug
14 or device. Where the Secretary of Health and
15 Human Services provides notice and an opportunity
16 to appear and introduce testimony on the destruc-
17 tion of a drug or device, the Secretary of Health and
18 Human Services shall store and, as applicable, dis-
19 pose of the drug or device after the issuance of the
20 notice, except that the owner and consignee shall re-
21 main liable for costs pursuant to subsection (c).”.

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

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

4 (2) after making such redesignations—

5 (A) by striking “(h) The term” and insert-
6 ing “(h)(1) The term”; and

7 (B) by adding at the end the following:

8 “(2) The term ‘counterfeit device’ means a device
9 which, or the container, packaging, or labeling of which,
10 without authorization, bears a trademark, trade name, or
11 other identifying mark, imprint, or symbol, or any likeness
12 thereof, or is manufactured using a design, of a device
13 manufacturer, packer, or distributor other than the person
14 or persons who in fact manufactured, packed, or distrib-
15 uted such device and which thereby falsely purports or is
16 represented to be the product of, or to have been packed
17 or distributed by, such other device manufacturer, packer,
18 or distributor.

19 “(3) For purposes of subparagraph (2)—

20 “(A) the term ‘manufactured’ refers to any of
21 the following activities: manufacture, preparation,
22 propagation, compounding, assembly, or processing;
23 and

1 “(B) the term ‘manufacturer’ means a person
2 who is engaged in any of the activities listed in
3 clause (A).”.

4 **SEC. 1072. DETERMINATION OF BUDGETARY EFFECTS.**

5 The budgetary effects of this subtitle, for the purpose
6 of complying with the Statutory Pay-As-You-Go Act of
7 2010, shall be determined by reference to the latest state-
8 ment titled “Budgetary Effects of PAYGO Legislation”
9 for this subtitle, submitted for printing in the Congres-
10 sional Record by the Chairman of the House Budget Com-
11 mittee, provided that such statement has been submitted
12 prior to the vote on passage.

13 **Subtitle I—Advisory Committee on**
14 **Immunization Practices**

15 **SEC. 1081. EXPEDITED MEETING OF ACIP FOR COVID-19**
16 **VACCINES.**

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

1 564 of the Federal Food, Drug, and Cosmetic Act (21
2 U.S.C. 360bbb-3).

3 (b) DEFINITION.—In this section, the term “Advisory
4 Committee on Immunization Practices” means the Advi-
5 sory Committee on Immunization Practices established by
6 the Secretary of Health and Human Services pursuant to
7 section 222 of the Public Health Service Act (42 U.S.C.
8 217a), acting through the Director of the Centers for Dis-
9 ease Control and Prevention.

10 **Subtitle J—Improvements to**
11 **Transparency of the Pricing of**
12 **Diagnostic Testing for COVID-**
13 **19**

14 **SEC. 1091. IMPROVEMENTS TO TRANSPARENCY OF THE**
15 **PRICING OF DIAGNOSTIC TESTING FOR**
16 **COVID-19.**

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

19 (1) in subsection (b)—

20 (A) in the heading, by inserting “AND RE-
21 LATED ITEMS AND SERVICES” after “DIAG-
22 NOSTIC TESTING FOR COVID-19”;

23 (B) in paragraph (1)—

24 (i) by striking “a diagnostic test for
25 COVID-19” and inserting “a test, item, or

1 service described in section 6001(a) of divi-
2 sion F of the Families First Coronavirus
3 Response Act (Public Law 116–127)”; and

4 (ii) by striking “such test” and insert-
5 ing “such test, item, or service”; and

6 (C) in paragraph (2), by striking “a diag-
7 nostic test for COVID–19” and inserting “a
8 test, item, or service described in section
9 6001(a) of division F of the Families First
10 Coronavirus Response Act (Public Law 116–
11 127)”; and

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

14 “(c) IMPROVEMENTS TO TRANSPARENCY POLICY.—

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

21 “(2) REPRESENTATIVE SAMPLE.—In carrying
22 out paragraph (1), the Secretary shall survey a sam-
23 ple of providers that is representative of the diver-
24 sity of sizes, geographic locations, and care settings
25 (such as hospitals, laboratories, and independent

1 freestanding emergency departments) in which diag-
2 nostic testing for COVID–19 is performed.

3 “(3) CONSUMER COMPLAINTS.—The Secretary
4 shall ensure that consumers have a method to sub-
5 mit complaints to the Department of Health and
6 Human Services that identify providers that—

7 “(A) may be in violation of subsection (b);

8 and

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

11 “(d) PUBLIC REPORT.—Not later than 60 days after
12 the date of the enactment of this subsection, the Secretary
13 of Health and Human Services shall publish on the inter-
14 net website of the Department of Health and Human
15 Services a report on cash prices for items and services
16 published under subsection (b)(1) during the period begin-
17 ning on the date of the enactment of this Act and ending
18 on the date of the enactment of this subsection, which
19 shall include—

20 “(1) the percentage of providers that comply
21 with the requirement under such subsection;

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

1 “(3) any providers identified pursuant to para-
2 graph (2) or (3) of subsection (c) and found to be
3 in violation of such requirement.”.

4 **TITLE II—DOMESTIC MANUFAC-**
5 **TURING AND SUPPLY CHAIN**

6 **Subtitle A—Sustained On-Shore**
7 **Manufacturing Capacity for**
8 **Public Health Emergencies**

9 **SEC. 2001. SUSTAINED ON-SHORE MANUFACTURING CAPAC-**
10 **ITY FOR PUBLIC HEALTH EMERGENCIES.**

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

13 (1) in subsection (a)(6)(B)—

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

16 (B) by inserting after clause (iii), the fol-
17 lowing:

18 “(iv) activities to support domestic
19 manufacturing surge capacity of products
20 or platform technologies, including manu-
21 facturing capacity and capabilities to uti-
22 lize platform technologies to provide for
23 flexible manufacturing initiatives;”;

24 (C) in clause (vi) (as so redesignated), by
25 inserting “manufacture,” after “improvement,”;

1 (2) in subsection (b)—

2 (A) in the first sentence of paragraph (1),
3 by inserting “support for domestic manufac-
4 turing surge capacity,” after “initiatives for in-
5 novation,”; and

6 (B) in paragraph (2)—

7 (i) in subparagraph (B), by striking
8 “and” at the end;

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

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

13 “(C) activities to support manufacturing
14 surge capacities and capabilities to increase the
15 availability of existing medical countermeasures
16 and utilize existing novel platforms to manufac-
17 ture new medical countermeasures to meet
18 manufacturing demands to address threats that
19 pose a significant level of risk to national secu-
20 rity; and”;

21 (3) in subsection (c)—

22 (A) in paragraph (2)—

23 (i) in subparagraph (C), by striking
24 “and” at the end;

1 (ii) in subparagraph (D), by striking
2 the period and inserting “; and”; and

3 (iii) by adding at the end the fol-
4 lowing:

5 “(E) promoting domestic manufacturing
6 surge capacity and capabilities for counter-
7 measure advanced research and development,
8 including facilitating contracts to support flexi-
9 ble or surge manufacturing.”;

10 (B) in paragraph (4)—

11 (i) in subparagraph (B)—

12 (I) in clause (iii), by striking
13 “and” at the end;

14 (II) in clause (iv), by striking the
15 period and inserting “; and”; and

16 (III) by adding at the end the
17 following:

18 “(v) support and maintain domestic
19 manufacturing surge capacity and capabili-
20 ties, including through contracts to sup-
21 port flexible or surge manufacturing, to en-
22 sure that additional production of counter-
23 measures is available in the event that the
24 Secretary determines there is such a need
25 for additional production.”;

1 (ii) in subparagraph (D)—

2 (I) in clause (ii), by striking
3 “and” at the end;

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

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

8 “(iii) research to advance manufac-
9 turing capacities and capabilities for med-
10 ical countermeasures and platform tech-
11 nologies that may be utilized for medical
12 countermeasures; and”;

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

15 (C) in paragraph (7)(C)(i), by striking “up
16 to 100 highly qualified individuals, or up to 50
17 percent of the total number of employees,
18 whichever is less,” and inserting “75 percent of
19 the total number of employees”;

20 (4) in subsection (e)(1)—

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

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

1 “(B) TEMPORARY FLEXIBILITY.—During a
2 public health emergency under section 319, the
3 Secretary shall be provided with an additional
4 60 business days to comply with information re-
5 quests for the disclosure of information under
6 section 552 of title 5, United States Code, re-
7 lated to the activities under this section (unless
8 such activities are otherwise exempt under sub-
9 paragraph (A)).”; and
10 (5) in subsection (f)—

11 (A) in paragraph (1), by striking “Not
12 later than 180 days after the date of enactment
13 of this subsection” and inserting “Not later
14 than 180 days after the date of enactment of
15 the Commitment to Defeat the Virus and Keep
16 America Healthy Act”; and

17 (B) in paragraph (2), by striking “Not
18 later than 1 year after the date of enactment of
19 this subsection” and inserting “Not later than
20 1 year after the date of enactment of the Com-
21 mitment to Defeat the Virus and Keep America
22 Healthy Act”.

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

1 lie Law 116–94), or any other provision of law imposing
2 a restriction on salaries of individuals related to a previous
3 appropriation to the Department of Health and Human
4 Services, shall not apply with respect to salaries paid pur-
5 suant to an agreement under the medical countermeasure
6 innovation partner program under section 319L(c)(4)(E)
7 of the Public Health Service Act (42 U.S.C. 247d–
8 7e(c)(4)(E)).

9 **Subtitle B—Manufacturing API,**
10 **Drugs, and Excipients in America**

11 **SEC. 2011. REPORT TO CONGRESS ON BARRIERS TO DO-**
12 **MESTIC MANUFACTURING OF MEDICAL**
13 **PRODUCTS AND SUPPLIES.**

14 (a) REPORT.—Not later than January 1, 2021, the
15 Secretary of Health and Human Services (referred to in
16 this section as the “Secretary”) shall submit to the Com-
17 mittee on Energy and Commerce of the House of Rep-
18 resentatives and the Committee on Health, Education,
19 Labor, and Pensions of the Senate a report on barriers
20 to domestic manufacturing of active pharmaceutical ingre-
21 dients, drugs, and devices that are manufactured outside
22 of the United States.

23 (b) CONTENTS.—Such report shall—

24 (1) identify factors that limit or otherwise dis-
25 courage the domestic manufacturing of active phar-

1 maceutical ingredients, drugs, and devices that are
2 currently manufactured outside of the United
3 States, including any Federal, State, local, or Tribal
4 laws and regulations that hinder domestic manufac-
5 turing opportunities; and

6 (2) recommend specific strategies to overcome
7 the challenges identified under paragraph (1), in-
8 cluding strategies—

9 (A) to develop effective incentives for do-
10 mestic manufacturing; and

11 (B) to make changes to laws or regulations
12 that hinder domestic manufacturing opportuni-
13 ties.

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

16 (1) the Food and Drug Administration, the
17 Centers for Medicare & Medicaid Services, the De-
18 partment of Defense, the Department of Commerce,
19 the Department of State, the Department of Vet-
20 erans Affairs, the Department of Justice, and any
21 other Federal agencies as appropriate; and

22 (2) relevant stakeholders, including drug, de-
23 vice, and active pharmaceutical ingredient manufac-
24 turers, and other entities, as appropriate.

1 (d) DEFINITION.—In this section, the term “active
2 pharmaceutical ingredient” has the meaning given to such
3 term in section 207.1 of title 21, Code of Federal Regula-
4 tions (and any successor regulations).

5 (e) PUBLICATION.—The Secretary shall make the re-
6 port under subsection (a) available on the public website
7 of the Department of Health and Human Services.

8 **SEC. 2012. ENHANCING INTRA-AGENCY COORDINATION**
9 **AND PUBLIC HEALTH ASSESSMENT WITH RE-**
10 **GARD TO COMPLIANCE ACTIVITIES.**

11 (a) BENEFIT/RISK FRAMEWORK.—

12 (1) IN GENERAL.—Paragraph (2) of section
13 704(b) of the Federal Food, Drug, and Cosmetic Act
14 (21 U.S.C. 374(b)) is amended by adding at the end
15 the following: “The Secretary shall ensure timely
16 and effective coordination among such offices re-
17 garding the reviews of such report and the align-
18 ment of any feedback regarding such report, and
19 any corrective or preventive actions in response to
20 such report, after consideration of the benefits and
21 risks to the public health, patient safety, the drug
22 supply and drug supply chain, and timely patient ac-
23 cess to drugs.”.

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

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

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

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

14 (b) PUBLIC MEETING.—The Secretary of Health and
15 Human Services shall publish in the Federal Register a
16 notice of a public meeting to be held no later than six
17 months after the date of enactment of this Act to discuss
18 and obtain input and recommendations from public stake-
19 holders, including patient advocates, consumers, regulated
20 industry, and health care providers, regarding the con-
21 tents of a benefit/risk framework described in section
22 704(b)(2) of the Federal Food, Drug, and Cosmetic Act,
23 as amended by subsection (a), that supports a safe, stable,
24 redundant drug supply chain.

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

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

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

11 **SEC. 2013. ENCOURAGING INTERNATIONAL HARMONI-**
12 **ZATION.**

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

16 (1) the consistency with which the International
17 Conference on Harmonisation (in this section re-
18 ferred to as “ICH”) guidelines on good manufac-
19 turing practices, including ICH Guidelines Q8–11,
20 are being implemented by drug regulatory authori-
21 ties across countries and international regions;

22 (2) whether domestic active pharmaceutical in-
23 gredient manufacturers (including any such contract
24 manufacturers) are provided sufficient opportunity

1 to participate with regulatory authorities in the de-
2 velopment of guidelines prior to implementation;

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

7 (A) inefficiencies in drug manufacturing;

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

10 (C) the most common areas of divergence
11 between ICH guidelines and regulatory stand-
12 ards and requirements by drug regulatory au-
13 thorities across countries and international re-
14 gions that, if rectified, may reduce the ineffi-
15 ciencies and incompatibilities identified pursu-
16 ant to subparagraphs (A) and (B).

17 (b) INTERNATIONAL TRAINING PROGRAM.—Not later
18 than two years after the date of enactment of this Act,
19 informed by the needs identified in the report issued pur-
20 suant to subsection (a), the Secretary of Health and
21 Human Services, in conjunction with drug regulatory au-
22 thorities across countries and international regions and
23 the ICH, shall develop and implement a training program
24 for drug regulatory authorities across countries and inter-
25 national regions to promote consistent application of and

1 reduce divergence from ICH guidelines on good manufac-
2 turing practices.

3 **SEC. 2014. MUTUAL RECOGNITION AGREEMENTS FOR IN-**
4 **SPECTIONS AND REVIEW ACTIVITIES.**

5 (a) MUTUAL RECOGNITION OF INSPECTIONS.—Pur-
6 suant to section 809 of the Federal Food, Drug, and Cos-
7 metic Act (21 U.S.C. 384e), the Secretary of Health and
8 Human Services (in this section referred to as the “Sec-
9 retary”) shall establish or expand initiatives for mutual
10 sharing of review and inspection findings between drug
11 regulatory authorities across countries and international
12 regions, such as through the Pharmaceutical Cooperation
13 Inspection Scheme, the Mutual Recognition Agreement
14 with the European Union, and the Australia-Canada-
15 Singapore-Switzerland Consortium, to—

16 (1) reduce the potential for duplicative regu-
17 latory evaluation of medical products regulated by
18 the Food and Drug Administration; and

19 (2) more constructively allocate appropriations
20 to the Food and Drug Administration, including
21 those attributable to user fees, to harmonized regu-
22 latory processes.

23 (b) ADDITIONAL COUNTRIES, REGIONS, AND EVAL-
24 UATION.—In carrying out subsection (a), the Secretary
25 may expand the initiatives to include—

1 (1) additional countries and geographic regions
2 with established and competent regulatory frame-
3 works; and

4 (2) additional types of regulatory evaluation, in-
5 cluding with respect to—

6 (A) good manufacturing practice inspec-
7 tions; and

8 (B) approval of changes to the manufac-
9 turing of drugs for which an approval or licen-
10 sure is in effect under section 505 of the Fed-
11 eral Food, Drug, and Cosmetic Act (21 U.S.C.
12 355) or section 351 of the Public Health Serv-
13 ice Act (42 U.S.C. 262).

14 (c) IMPLEMENTATION FRAMEWORK.—

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

21 (2) CONTENTS.—The implementation frame-
22 work under this subsection shall—

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

1 (B) describe additional types of regulatory
2 processes that will become subject to such ini-
3 tiatives;

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

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

10 (d) ANNUAL REPORTING.—

11 (1) IN GENERAL.—Not later than the end of
12 calendar year 2020 and annually thereafter, the Sec-
13 retary shall publish a report on the public website of
14 the Food and Drug Administration on the utilization
15 of agreements described in subsection (c)(1) in the
16 previous fiscal year.

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

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

1 (B) The total number of inspections con-
2 ducted at establishments described in subpara-
3 graph (A).

4 (C) Of the inspections described in sub-
5 paragraph (B), the total number of inspections
6 in each of region of interest.

7 (D) Of the inspections in each region of in-
8 terest reported pursuant to subparagraph (C),
9 the number of inspections in each FDA inspec-
10 tion category.

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

14 (i) the number of inspections which
15 have been conducted pursuant to an agree-
16 ment described in subsection (c)(1); and

17 (ii) the number of inspections which
18 have been conducted by employees or other
19 agents of the Food and Drug Administra-
20 tion.

21 (3) DEFINITIONS.—In this subsection:

22 (A) The term “region of interest” refers to
23 China, India, the European Union, and any
24 other geographic region as determined appro-
25 priate by the Secretary.

1 (B) The term “FDA inspection category”
2 means refers to the following inspection cat-
3 egories:

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

9 (ii) Good manufacturing practice in-
10 spections.

11 (iii) For-cause inspections.

12 **SEC. 2015. ENHANCING TRANSPARENCY OF DRUG FACILITY**
13 **INSPECTION TIMELINES.**

14 Section 902 of the FDA Reauthorization Act of 2017
15 (21 U.S.C. 355 note) is amended to read as follows:

16 **“SEC. 902. ANNUAL REPORT ON INSPECTIONS.**

17 “Not later than March 1 of each year, the Secretary
18 of Health and Human Services shall post on the public
19 website of the Food and Drug Administration information
20 related to inspections of facilities necessary for approval
21 of a drug under subsection (c) or (j) of section 505 of
22 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
23 355), approval of a device under section 515 of such Act
24 (21 U.S.C. 360e), or clearance of a device under section
25 510(k) of such Act (21 U.S.C. 360(k)) that were con-

1 ducted during the previous calendar year. Such informa-
2 tion shall include the following:

3 “(1) The median time following a request from
4 staff of the Food and Drug Administration review-
5 ing an application or report to the beginning of the
6 inspection, and the median time from the beginning
7 of an inspection to the issuance of a report pursuant
8 to section 704(b) of the Federal Food, Drug, and
9 Cosmetic Act (21 U.S.C. 374(b)), including—

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

13 “(B) the median time for drugs described
14 in section 506C(a) of such Act (21 U.S.C.
15 356c(a)) only; and

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

19 “(2) The median time from the issuance of a
20 report pursuant to such section 704(b) to the send-
21 ing of a warning letter, issuance of an import alert,
22 or holding of a regulatory meeting for inspections
23 for which the Secretary concluded that regulatory or
24 enforcement action was indicated, including the me-

1 dian time for each category of drugs listed in sub-
2 paragraphs (A) through (C) of paragraph (1).

3 “(3) The median time from the sending of a
4 warning letter, issuance of an import alert, or hold-
5 ing of a regulatory meeting to resolution of the regu-
6 latory or enforcement action indicated for inspec-
7 tions for which the Secretary concluded that such
8 action was indicated.

9 “(4) The number of times that a facility was
10 issued a report pursuant to such section 704(b) and
11 approval of an application was delayed due to the
12 issuance of a withhold recommendation, including
13 the number of such times for each category of drugs
14 listed in subparagraphs (A) through (C) of para-
15 graph (1).”.

16 **SEC. 2016. ADVANCED MANUFACTURING TECHNOLOGIES**
17 **PROGRAM.**

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

21 **“SEC. 524B. ADVANCED MANUFACTURING TECHNOLOGIES**
22 **PROGRAM.**

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

1 tinue in effect the program to evaluate new drug manufac-
2 turing technologies that are included in an application, or
3 supplement to an application, for a drug under subsection
4 (b) or (j) of section 505 of this Act or for a biological
5 product submitted under subsection (a) or (k) of section
6 351 of the Public Health Service Act.

7 “(b) DESIGNATION.—The Secretary shall designate a
8 method of manufacturing a drug as an advanced manufac-
9 turing technology under this section if the drug manufac-
10 turer demonstrates that such technology is likely to—

11 “(1) prevent or resolve a drug shortage;

12 “(2) maintain an adequate supply of critical
13 medications for national emergencies; or

14 “(3) promote the adoption of innovative ap-
15 proaches to drug product design and manufacturing.

16 “(c) CONSULTATION.—If the Secretary designates a
17 method of manufacturing as an advanced manufacturing
18 technology under this section, the Secretary shall take ac-
19 tions to expedite the development and implementation of
20 such method of manufacture for purposes of approval of
21 the application under subsection (c) or (j) of section 505
22 of this Act or subsection (a) or (k) of section 351 of the
23 Public Health Service Act, which may include, as appro-
24 priate—

1 “(1) holding meetings between the sponsor of
2 the application and appropriate Food and Drug Ad-
3 ministration staff throughout the development of the
4 technology;

5 “(2) providing timely advice to, and interactive
6 communication with, the sponsor regarding the de-
7 velopment of the technology; and

8 “(3) involving senior managers and experienced
9 staff of the Food and Drug Administration, as ap-
10 propriate, in a collaborative, cross-disciplinary review
11 of the method of manufacturing.

12 “(d) EVALUATION OF AN ADVANCED MANUFAC-
13 TURING TECHNOLOGY.—

14 “(1) PACKAGE.—A sponsor who receives des-
15 ignation of an advanced manufacturing technology
16 under this section shall provide the Secretary with a
17 package of scientific evidence supporting the imple-
18 mentation of the advanced manufacturing technology
19 in a particular context-of-use.

20 “(2) EVALUATION.—Within 90 days of receiv-
21 ing the package, the Secretary shall determine
22 whether a designated advanced manufacturing tech-
23 nology is validated for the proposed context of use
24 based on the scientific merit the supporting evidence
25 provided by the sponsor.

1 “(3) EFFECT OF APPROVAL.—Upon approval,
2 the same sponsor may rely upon the advanced man-
3 ufacturing technology for use across multiple manu-
4 facturing product lines within the same context-of-
5 use without having to re-submit data to the Sec-
6 retary validating the underlying technology.

7 “(e) IMPLEMENTATION AND REPORTING.—

8 “(1) PUBLIC MEETING.—The Secretary shall
9 publish in the Federal Register a notice of a public
10 meeting to be held no later than 1 year after the
11 date of enactment of the Commitment to Defeat the
12 Virus and Keep America Healthy Act to discuss and
13 obtain input and recommendations from stake-
14 holders regarding the goals and scope of, and a suit-
15 able framework and procedures and requirements
16 for, the program under this section.

17 “(2) PROGRAM GUIDANCE.—The Secretary
18 shall—

19 “(A) not later than 1 year after the date
20 of enactment of the Commitment to Defeat the
21 Virus and Keep America Healthy Act, issue
22 draft guidance regarding the goals and imple-
23 mentation of the program under this section;
24 and

1 “(B) not later than 2 years after the date
2 of enactment of the Commitment to Defeat the
3 Virus and Keep America Healthy Act, issue
4 final guidance with respect to the implementa-
5 tion of such program.

6 “(3) REPORT.—The Secretary shall make avail-
7 able on the public website of the Food and Drug Ad-
8 ministration an annual report on the progress of the
9 program under this section.”.

10 **Subtitle C—Improving the** 11 **American Drug Supply Chain**

12 **SEC. 2021. STUDY AND REPORTING ON DOMESTIC AND FOR-** 13 **EIGN PRODUCTION.**

14 (a) IN GENERAL.—The Secretary of Health and
15 Human Services shall enter into an agreement with the
16 National Academies of Sciences, Engineering, and Medi-
17 cine (referred to in this section as the “National Acad-
18 emies”) under which, not later than 24 months after the
19 date of enactment of this Act, the National Academies
20 will—

21 (1) study the current and historical production
22 of drugs and key ingredients thereof (including ac-
23 tive pharmaceutical ingredients) in the United
24 States and in foreign countries;

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

5 (3) in a manner that does not compromise na-
6 tional security or disclose trade secrets or other con-
7 fidential commercial information that is subject to
8 section 552(b)(4) of title 5, United States Code, or
9 section 1905 of title 18, United States Code, submit
10 a report to the Congress on—

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

13 (B) the recommendations under paragraph
14 (2).

15 (b) STUDY TOPICS.—The study pursuant to sub-
16 section (a)(1) shall include—

17 (1) evaluation of—

18 (A) the extent to which production of
19 drugs for use in the United States and key in-
20 gredients thereof (including active pharma-
21 ceutical ingredients) takes place in the United
22 States; and

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

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

3 (3) evaluation of historical changes in the coun-
4 tries in which such production takes place;

5 (4) determination of the reasons why such pro-
6 duction takes place in foreign countries, including
7 why such production takes place in particular for-
8 eign countries, including consideration of—

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

13 (B) economic factors, including economic
14 impediments to domestic production and incen-
15 tives for foreign production; and

16 (C) regulatory, intellectual property, inter-
17 national trade, and other legal and policy fac-
18 tors; and

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

22 (c) RECOMMENDATIONS.—The agreement under sub-
23 section (a) shall—

24 (1) provide for inclusion in the recommenda-
25 tions under subsection (a)(2) of measures (which

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

3 (A) to encourage the domestic production
4 of drugs for use in the United States and key
5 ingredients thereof (including active pharma-
6 ceutical ingredients); or

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

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

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

14 (i) access to skilled labor;

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

17 (iii) taxes and other incentives; and

18 (iv) the effects of regulations; and

19 (B) the costs and consequences of imple-
20 menting, or failing to implement, each such rec-
21 ommendation.

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

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

1 Commerce, and, as appropriate, other Federal agen-
2 cies; and

3 (2) consultation with relevant stakeholders,
4 which—

5 (A) may include conducting public meet-
6 ings and other forms of engagement, as appro-
7 priate;

8 (B) shall include consultation with experts
9 in—

10 (i) the manufacturing of drugs;

11 (ii) pharmaceutical industry business
12 and economics;

13 (iii) drug purchasing, pricing, and re-
14 imbursement;

15 (iv) regulatory and intellectual prop-
16 erty issues affecting drug manufacturing;

17 (v) economics;

18 (vi) international trade policy; and

19 (vii) emergency planning; and

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

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

1 **Subtitle D—Essential Medicines**
2 **Strategic Stockpile**

3 **SEC. 2031. PILOT PROGRAM ON ENSURING MEDICATION**
4 **SUPPLY STABILITY.**

5 Part D of title III of the Public Health Service Act
6 (42 U.S.C. 254b et seq.) is amended by adding at the end
7 the following new subpart:

8 **“Subpart XIII—Ensuring Medication Supply Stability**
9 **“SEC. 340J. ENSURING MEDICATION SUPPLY STABILITY.**

10 “(a) AWARD OF CONTRACTS.—Beginning not later
11 than January 1, 2021, the Secretary shall award contracts
12 to eligible entities to each implement and test the effective-
13 ness of acquiring, maintaining, managing, and distrib-
14 uting a stockpile that—

15 “(1) consists of generic drugs at risk of short-
16 age; and

17 “(2) is of sufficient quantity to ensure that cus-
18 tomers in the United States of the respective eligible
19 entity have access to such drugs for at least 6
20 months (as specified by the Secretary based on the
21 historic demand for those drugs).

22 “(b) SELECTION OF DRUGS.—

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

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

1 in a stockpile pursuant to a contract under this
2 section;

3 “(B) maintain an up-to-date list of such
4 drugs; and

5 “(C) make such list publicly available.

6 “(2) CHOICE OF ELIGIBLE ENTITIES.—A con-
7 tract awarded to an eligible entity under this section
8 need not require the stockpile of the eligible entity
9 to include all 50 types of drugs listed pursuant to
10 paragraph (1).

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

17 “(d) DURATION; LIQUIDATION OF INVENTORY.—

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

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

25 “(e) STOCKPILE REQUIREMENTS.—

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

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

8 “(B) to comply with subparagraph (A)—

9 “(i) sell drugs in the stockpile through
10 normal commercial channels and replace
11 those drugs; or

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

16 “(2) MANAGEMENT OF STOCKPILE.—

17 “(A) IN GENERAL.—Each eligible entity
18 with a contract under this section for a stock-
19 pile of generic drugs at risk of shortage shall—

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

1 levels of inventory held by such eligible en-
2 tity over the previous year for such drug;
3 and

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

8 “(B) INVENTORY MANAGEMENT.—Each el-
9 igible entity with a contract under this section
10 for a stockpile of generic drugs at risk of short-
11 age shall manage inventory to ensure that
12 drugs in the stockpile are efficiently cycled to
13 the commercial market and—

14 “(i) may stockpile inventory at the eli-
15 gible entity’s distribution center with speci-
16 fied inventory amounts virtually reserved
17 for the Federal Government with constant
18 cycling to reduce product expiration; or

19 “(ii) may store stockpiled inventory
20 separately in a different location and re-
21 place drugs in the stockpile inventory with
22 the same drug with newer dating.

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

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

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

7 “(ii) shall submit a report to the Sec-
8 retary identifying—

9 “(I) each such drug; and

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

13 “(D) ANNUAL AUDITS.—Not more than
14 annually, the Secretary may request a physical
15 audit count of the inventories of all eligible enti-
16 ties with a contract under this section to vali-
17 date that each such entity is maintaining the
18 appropriate amount of stockpiled inventory.

19 “(3) PERIODIC PRODUCT REVIEW.—

20 “(A) USE OF PROCEEDS.—An eligible enti-
21 ty with a contract under this section for a
22 stockpile of generic drugs at risk of shortage
23 shall use the proceeds of the sale of any drugs
24 in the stockpile to purchase drugs for the stock-
25 pile in accordance with this section.

1 “(B) MARKET INFLATION OR DEFLA-
2 TION.—In the case of market inflation or defla-
3 tion affecting the price of a drug in the stock-
4 pile of an eligible entity maintained pursuant to
5 a contract under this section, the contract shall
6 ensure that the Federal Government does not
7 profit or suffer loss on items of such drug as
8 a result of such inflation or deflation.

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

13 “(A) current inventory levels of stockpiled
14 drugs at a drug level;

15 “(B) indicators of current inventory levels
16 of stockpiled drugs relative to acceptable mini-
17 mums; and

18 “(C) such other matters as the Secretary
19 determines appropriate.

20 “(f) CONTRACT TERMS.—

21 “(1) PAYMENT OF MONTHLY FEES FOR MAN-
22 AGEMENT.—Subject to paragraph (2), the Secretary
23 shall pay to each eligible entity with a contract
24 under this section for a stockpile of generic drugs at

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

3 “(2) PAYMENT CONDITIONED ON STOCKPILE
4 ADEQUACY.—

5 “(A) IN GENERAL.—Except as provided in
6 subparagraph (B), each contract with an eligi-
7 ble entity under this section shall provide that
8 no payment under the contract may be made
9 until the entity demonstrates to the Secretary
10 that the entity has stockpiled such portion of
11 the total quantity of drugs to be stockpiled
12 under the contract as the Secretary determines
13 to be acceptable for payment.

14 “(B) EXCEPTIONS FOR ADVANCE PAY-
15 MENTS.—

16 “(i) IN GENERAL.—A contract under
17 this section may provide that, if the Sec-
18 retary determines (in the Secretary’s dis-
19 cretion) that an advance payment, partial
20 payment for significant milestones, or pay-
21 ment to increase capacity is necessary to
22 ensure success of the terms of the con-
23 tract, the Secretary shall pay, in advance
24 of delivery, an amount not to exceed 10
25 percent of the total contract amount to be

1 paid to the eligible entity by the Secretary
2 pursuant to the contract over the full pe-
3 riod of the contract.

4 “(ii) COST OF CAPITAL.—A contract
5 under this section may provide for pay-
6 ments to compensate the contracting eligi-
7 ble entity for additional capital require-
8 ments related to the additional inventory
9 to be maintained.

10 “(iii) TIMING.—The Secretary shall,
11 to the extent practicable, make any deter-
12 mination under clause (i) to make an ad-
13 vance payment at the same time as the
14 issuance of a solicitation.

15 “(iv) REPAYMENT.—If the Secretary
16 makes an advance payment pursuant to
17 clause (i), the Secretary shall require the
18 eligible entity receiving such advance pay-
19 ment to repay it if there is a failure to per-
20 form by the eligible entity.

21 “(3) TERMINATION.—

22 “(A) IN GENERAL.—Subject to subpara-
23 graph (B), nothing in this section shall be con-
24 strued as affecting the rights of eligible entities
25 under provisions of statute or regulation (in-

1 including the Federal Acquisition Regulation) re-
2 lating to the termination of contracts for the
3 convenience of the Government.

4 “(B) LIQUIDATION OF STOCKPILE.—If a
5 contract under this section is terminated, the
6 eligible entity with the contract shall liquidate
7 the drugs comprising the stockpile funded
8 through the contract and return to the Govern-
9 ment any amounts owed in relation to such
10 drugs, but shall collect the management fees as-
11 sociated with such liquidation.

12 “(g) CONGRESSIONAL OVERSIGHT.—

13 “(1) INDEPENDENT EVALUATION AND RE-
14 PORT.—Not later than 1 year after the date of en-
15 actment of this section and annually thereafter, the
16 Comptroller General of the United States shall con-
17 duct an independent evaluation, and submit to the
18 appropriate congressional committees a report, con-
19 cerning the program under this section.

20 “(2) CONTENTS OF REPORT.—The report under
21 paragraph (1) shall review, assess, and provide rec-
22 ommendations, as appropriate, on the following:

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

1 that does not incorporate perpetual inventory
2 cycling.

3 “(B) Identification of drawdowns from the
4 stockpile, as evidence of market shortage avoid-
5 ance.

6 “(C) The allocation of drugs included in
7 the stockpiles funded pursuant to this section to
8 the customers of the eligible entities with con-
9 tracts under this section.

10 “(D) The degree to which eligible entities
11 with contracts under this section fulfilled their
12 obligations under such contracts.

13 “(h) DEFINITIONS.—In this section:

14 “(1) The term ‘eligible entity’ means an entity
15 that meets each of the following criteria:

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

20 “(B) The entity agrees—

21 “(i) to purchase all drugs to be main-
22 tained in its stockpile funded under this
23 section directly from the manufacturers of
24 the drugs or the exclusive distributors of
25 such manufacturers; or

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

3 “(I) to purchase drugs to be
4 maintained in its stockpile funded
5 under this section from an authorized
6 distributor; and

7 “(II) distribute those drugs only
8 to its member pharmacies.

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

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

14 “(E) The entity agrees to distribute inven-
15 tory from its stockpile funded under this section
16 only to dispensers that are customers of the en-
17 tity.

18 “(2) The term ‘generic drug at risk of shortage’
19 means a drug (as defined in section 201 of the Fed-
20 eral Food, Drug, and Cosmetic Act) that—

21 “(A) is approved pursuant to section
22 505(j) of such Act;

23 “(B) is included in the World Health Or-
24 ganization’s most recent Model List of Essen-
25 tial Medicines;

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

5 “(D) is manufactured by 3 or fewer per-
6 sons that are registered under section 510 of
7 the Federal Food, Drug, and Cosmetic Act for
8 purposes of such manufacture.

9 “(i) AUTHORIZATION OF APPROPRIATIONS.—To
10 carry out this section, there is authorized to be appro-
11 priated \$120,000,000 for fiscal years 2021 through 2023,
12 to remain available until expended.”.

13 **Subtitle E—National Centers of Ex-**
14 **cellence in Continuous Pharma-**
15 **ceutical Manufacturing**

16 **SEC. 2041. NATIONAL CENTERS OF EXCELLENCE IN CON-**
17 **TINUOUS PHARMACEUTICAL MANUFAC-**
18 **TURING.**

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

1 **“SEC. 3016. NATIONAL CENTERS OF EXCELLENCE IN CON-**
2 **TINUOUS PHARMACEUTICAL MANUFAC-**
3 **TURING.**

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

7 “(1) shall solicit and, beginning not later than
8 one year after the date of enactment of the Commit-
9 ment to Defeat the Virus and Keep America Healthy
10 Act, receive requests from institutions of higher edu-
11 cation to be designated as a National Center of Ex-
12 cellence in Continuous Pharmaceutical Manufac-
13 turing (in this section referred to as a ‘National
14 Center of Excellence’) to support the advancement
15 and development of continuous manufacturing; and

16 “(2) shall so designate any institution of higher
17 education that—

18 “(A) requests such designation; and

19 “(B) meets the criteria specified in sub-
20 section (c).

21 “(b) REQUEST FOR DESIGNATION.—A request for
22 designation under subsection (a) shall be made to the Sec-
23 retary at such time, in such manner, and containing such
24 information as the Secretary may require. Any such re-
25 quest shall include a description of how the institution of

1 higher education meets or plans to meet each of the cri-
2 teria specified in subsection (c).

3 “(c) CRITERIA FOR DESIGNATION DESCRIBED.—The
4 criteria specified in this subsection with respect to an in-
5 stitution of higher education are that the institution has,
6 as of the date of the submission of a request under sub-
7 section (a) by such institution—

8 “(1) physical and technical capacity for re-
9 search and development of continuous manufac-
10 turing;

11 “(2) manufacturing knowledge-sharing net-
12 works with other institutions of higher education,
13 large and small pharmaceutical manufacturers, ge-
14 neric and nonprescription manufacturers, contract
15 manufacturers, and other entities;

16 “(3) proven capacity to design and demonstrate
17 new, highly effective technology for use in contin-
18 uous manufacturing;

19 “(4) a track record for creating and transfer-
20 ring knowledge with respect to continuous manufac-
21 turing;

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

1 “(6) experience in participating in and leading
2 a continuous manufacturing technology partnership
3 with other institutions of higher education, large and
4 small pharmaceutical manufacturers, generic and
5 nonprescription manufacturers, contract manufac-
6 turers, and other entities—

7 “(A) to support companies with continuous
8 manufacturing in the United States;

9 “(B) to support Federal agencies with
10 technical assistance, which may include regu-
11 latory and quality metric guidance as applica-
12 ble, for advanced manufacturing and continuous
13 manufacturing;

14 “(C) with respect to continuous manufac-
15 turing, to organize and conduct research and
16 development activities needed to create new and
17 more effective technology, capture and dissemi-
18 nate expertise, create intellectual property, and
19 maintain technological leadership;

20 “(D) to develop best practices for design-
21 ing continuous manufacturing; and

22 “(E) to assess and respond to the work-
23 force needs for continuous manufacturing, in-
24 cluding the development of training programs if
25 needed.

1 “(d) TERMINATION OF DESIGNATION.—The Sec-
2 retary may terminate the designation of any National Cen-
3 ter of Excellence designated under this section if the Sec-
4 retary determines such National Center of Excellence no
5 longer meets the criteria specified in subsection (c). Not
6 later than 60 days before the effective date of such a ter-
7 mination, the Secretary shall provide written notice to the
8 National Center of Excellence, including the rationale for
9 such termination.

10 “(e) CONDITIONS FOR DESIGNATION.—As a condi-
11 tion of designation as a National Center of Excellence
12 under this section, the Secretary shall require that an in-
13 stitution of higher education enter into an agreement with
14 the Secretary under which the institution agrees—

15 “(1) to collaborate directly with the Food and
16 Drug Administration to publish the reports required
17 by subsection (g);

18 “(2) to share data with the Food and Drug Ad-
19 ministration regarding best practices and research
20 generated through the funding under subsection (f);

21 “(3) to develop, along with industry partners
22 (which may include large and small biopharma-
23 ceutical manufacturers, generic and nonprescription
24 manufacturers, and contract manufacturers) and an-
25 other institution or institutions designated under

1 this section, if any, a roadmap for developing a con-
2 tinuous manufacturing workforce;

3 “(4) to develop, along with industry partners
4 and other institutions designated under this section,
5 a roadmap for strengthening existing, and devel-
6 oping new, relationships with other institutions; and

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

12 “(f) FUNDING.—

13 “(1) IN GENERAL.—The Secretary shall award
14 funding, through grants, contracts, or cooperative
15 agreements, to the National Centers of Excellence
16 designated under this section for the purpose of
17 studying and recommending improvements to contin-
18 uous manufacturing, including such improvements
19 as may enable the Centers—

20 “(A) to continue to meet the conditions
21 specified in subsection (e); and

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

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

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

4 “(A) help to further the advancement of
5 continuous manufacturing through the National
6 Center of Excellence; and

7 “(B) be relevant to the mission of the
8 Food and Drug Administration.

9 “(3) AUTHORIZATION OF APPROPRIATIONS.—

10 There is authorized to be appropriated to carry out
11 this subsection \$80,000,000 for the period of fiscal
12 years 2021 through 2025.

13 “(4) RULE OF CONSTRUCTION.—Nothing in
14 this section shall be construed as precluding a Na-
15 tional Center for Excellence designated under this
16 section from receiving funds under any other provi-
17 sion of this Act or any other Federal law.

18 “(g) ANNUAL REVIEW AND REPORTS.—

19 “(1) ANNUAL REPORT.—Beginning not later
20 than one year after the date on which the first des-
21 ignation is made under subsection (a), and annually
22 thereafter, the Secretary shall—

23 “(A) submit to Congress a report describ-
24 ing the activities, partnerships and collabora-
25 tions, Federal policy recommendations, previous

1 and continuing funding, and findings of, and
2 any other applicable information from, the Na-
3 tional Centers of Excellence designated under
4 this section; and

5 “(B) make such report available to the
6 public in an easily accessible electronic format
7 on the website of the Food and Drug Adminis-
8 tration.

9 “(2) REVIEW OF NATIONAL CENTERS OF EX-
10 CELLENCE AND POTENTIAL DESIGNEES.—The Sec-
11 retary shall periodically review the National Centers
12 of Excellence designated under this section to ensure
13 that such National Centers of Excellence continue to
14 meet the criteria for designation under this section.

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

1 “(A) a national framework of principles re-
2 lated to the implementation and regulation of
3 continuous manufacturing;

4 “(B) a plan for the development of Federal
5 regulations and guidance for how advanced
6 manufacturing and continuous manufacturing
7 can be incorporated into the development of
8 pharmaceuticals and regulatory responsibilities
9 of the Food and Drug Administration; and

10 “(C) appropriate feedback solicited from
11 the public, which may include other institutions,
12 large and small biopharmaceutical manufactur-
13 ers, generic and nonprescription manufacturers,
14 and contract manufacturers.

15 “(h) DEFINITIONS.—In this section:

16 “(1) ADVANCED MANUFACTURING.—The term
17 ‘advanced manufacturing’ means an approach for
18 the manufacturing of pharmaceuticals that incor-
19 porates novel technology, or uses an established
20 technique or technology in a new or innovative way
21 (such as continuous manufacturing where the input
22 materials are continuously transformed within the
23 process by two or more unit operations) that en-
24 hances drug quality or improves the manufacturing
25 process.

1 “(2) CONTINUOUS MANUFACTURING.—The
2 term ‘continuous manufacturing’—

3 “(A) means a process where the input ma-
4 terials are continuously fed into and trans-
5 formed within the process, and the processed
6 output materials are continuously removed from
7 the system; and

8 “(B) consists of an integrated process that
9 consists of a series of two or more unit oper-
10 ations.

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

15 “(4) SECRETARY.—The term ‘Secretary’ means
16 the Secretary of Health and Human Services, acting
17 through the Commissioner of Food and Drugs.”.

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

1 **TITLE III—STRATEGIC NA-**
2 **TIONAL STOCKPILE IM-**
3 **PROVEMENTS**

4 **Subtitle A—Stockpiling for**
5 **America’s Future Endeavors**

6 **SEC. 3001. STRATEGIC NATIONAL STOCKPILE.**

7 Section 319F–2(a) of the Public Health Service Act
8 (42 U.S.C. 247d–6b(a)) is amended by adding at the end
9 the following:

10 “(6) ACCEPTANCE OF GIFTS.—

11 “(A) IN GENERAL.—The Secretary may,
12 without further appropriation and without fiscal
13 year limitation, accept, use, and dispose of
14 gifts, bequests, or devises of money, services, or
15 property, both real and personal, for the pur-
16 pose of carrying out this subsection. Any such
17 gift, bequest, or devise of money and proceeds
18 from sales of other property received as a gift,
19 bequest, or devise shall be deposited in the
20 Treasury and shall be available for obligation
21 and expenditure upon order of the Secretary.

22 “(B) LIMITATIONS.—

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

1 retary determines that the use of the prop-
2 erty or services would compromise the in-
3 tegrity or appearance of integrity of—

4 “(I) a program of the Depart-
5 ment of Health and Human Services;
6 or

7 “(II) an individual involved in a
8 program of the Department.

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

16 “(I) a drug that is approved
17 under section 505 of such Act, that
18 meets the requirements for marketing
19 under section 505G of such Act, or
20 that is licensed under section 351 of
21 this Act;

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

1 such Act, that is licensed under sec-
2 tion 351 of this Act, that is cleared
3 under section 510(k) of the Federal
4 Food, Drug, and Cosmetic Act, or for
5 which a report is not required under
6 such section 510(k);

7 “(III) authorized for emergency
8 use in accordance with section 564 or
9 564A of the Federal Food, Drug, and
10 Cosmetic Act or prepositioned for use
11 in accordance with section 564B of
12 such Act;

13 “(IV) authorized for investiga-
14 tional use under section 505, 512, or
15 520 of the Federal Food, Drug, and
16 Cosmetic Act or section 351 of this
17 Act;

18 “(V) determined by the Commis-
19 sioner of Food and Drugs to be ap-
20 propriate for use, without approval, li-
21 censure, authorization, or clearance,
22 to respond to a shortage or potential
23 shortage situation; or

24 “(VI) a respiratory protective de-
25 vice approved and determined to be a

1 priority, as described in section 319F–
2 3(i)(1)(D) of this Act.

3 “(C) REPORT.—

4 “(i) IN GENERAL.—The Secretary
5 shall submit to the Committee on Energy
6 and Commerce of the House of Represent-
7 atives and the Committee on Health, Edu-
8 cation, Labor, and Pensions of the Senate
9 an annual report disclosing—

10 “(I) any gift, bequest, or devise
11 that was accepted under this para-
12 graph during the year covered by the
13 report;

14 “(II) how the gifts, bequests, and
15 devises contribute to the mission of
16 the stockpile; and

17 “(III) the amount of Federal sav-
18 ings that were generated from the ac-
19 ceptance of the gifts, bequests, and
20 devises.

21 “(ii) PUBLICATION.—Each report re-
22 quired under clause (i) shall be made pub-
23 licly available.”.

1 **Subtitle B—Stockpile Inventory**
2 **Modernization**

3 **SEC. 3011. REIMBURSABLE TRANSFERS.**

4 Section 319F–2(a) of the Public Health Service Act
5 (42 U.S.C. 247d–6b(a)), as amended by section 3001, is
6 further amended by adding at the end the following:

7 “(7) TRANSFERS AND REIMBURSEMENTS.—

8 “(A) IN GENERAL.—Without regard to
9 chapter 5 of title 40, United States Code, the
10 Secretary may transfer to any Federal depart-
11 ment or agency, on a reimbursable basis, any
12 drugs, vaccines and other biological products,
13 medical devices, and other supplies in the stock-
14 pile if—

15 “(i) the transferred supplies are less
16 than one year from expiry;

17 “(ii) the stockpile is able to replenish
18 the supplies, as appropriate; and

19 “(iii) the Secretary decides the trans-
20 fer is in the best interest of the United
21 States Government.

22 “(B) USE OF REIMBURSEMENT.—Reim-
23 bursement derived from the transfer of supplies
24 pursuant to subparagraph (A) may, to the ex-
25 tent and in the amounts made available in ad-

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

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

10 “(D) REPORT.—Not later than September
11 30, 2022, the Secretary shall submit to the
12 Committee on Energy and Commerce of the
13 House of Representatives and the Committee
14 on Health, Education, Labor, and Pensions of
15 the Senate a report on each transfer made
16 under this paragraph and the amount received
17 by the Secretary in exchange for that transfer.

18 “(E) SUNSET.—The authority to make
19 transfers under this paragraph shall cease to be
20 effective on September 30, 2023.”.

21 **Subtitle C—Equipment**
22 **Maintenance**

23 **SEC. 3021. EQUIPMENT MAINTENANCE.**

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

1 (1) in subsection (a)(3)—

2 (A) in subparagraph (I), by striking “;
3 and” and inserting a semicolon;

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

7 (C) by inserting the following new subpara-
8 graph at the end:

9 “(K) ensure contents of the stockpile re-
10 main in good working order and, as appro-
11 priate, conduct maintenance services on con-
12 tents of the stockpile; and”; and

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

15 “(ix) EQUIPMENT MAINTENANCE
16 SERVICE.—In carrying out this section, the
17 Secretary may enter into contracts for the
18 procurement of equipment maintenance
19 services.”.

20 **Subtitle D—Medical Supplies for**
21 **Pandemics**

22 **SEC. 3031. SUPPLY CHAIN FLEXIBILITY MANUFACTURING**
23 **PILOT.**

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

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

3 “(L) enhance medical supply chain elas-
4 ticity and establish and maintain domestic re-
5 serves of critical medical supplies (including
6 personal protective equipment, ancillary medical
7 supplies, and other applicable supplies required
8 for the administration of drugs, vaccines and
9 other biological products, and other medical de-
10 vices (including diagnostic tests)) by—

11 “(i) increasing emergency stock of
12 critical medical supplies;

13 “(ii) geographically diversifying do-
14 mestic production of such medical supplies,
15 as appropriate;

16 “(iii) entering into cooperative agree-
17 ments or partnerships with respect to man-
18 ufacturing lines, facilities, and equipment
19 for the domestic production of such med-
20 ical supplies; and

21 “(iv) managing, either directly or
22 through cooperative agreements with man-
23 ufacturers and distributors, domestic re-
24 serves established under this subparagraph

1 by refreshing and replenishing stock of
2 such medical supplies.”.

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

7 “(8) REPORTING.—Not later than September
8 30, 2022, the Secretary shall submit to the Com-
9 mittee on Energy and Commerce of the House of
10 Representatives and the Committee on Health, Edu-
11 cation, Labor, and Pensions of the Senate a report
12 on the details of each cooperative agreement or part-
13 nership entered into under paragraph (3)(L), includ-
14 ing the amount expended by the Secretary on each
15 such cooperative agreement or partnership.

16 “(9) SUNSET.—The authority to enter into co-
17 operative agreements or partnerships pursuant to
18 paragraph (3)(L) shall cease to be effective on Sep-
19 tember 30, 2023.”.

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

23 “(3) SUPPLY CHAIN ELASTICITY.—

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

1 thorized to be appropriated \$500,000,000 for
2 each of fiscal years 2021 through 2023, to re-
3 main available until expended.

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

9 **Subtitle E—State Stockpile** 10 **Readiness**

11 **SEC. 3041. GRANTS FOR STATE STRATEGIC STOCKPILES.**

12 Title III of the Public Health Service Act is amended
13 by inserting after section 319F–4 of such Act (42 U.S.C.
14 247d–6e) the following new section:

15 **“SEC. 319F-5. GRANTS FOR STATE STRATEGIC STOCKPILES.**

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

22 “(b) ALLOWABLE USE OF FUNDS.—

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

1 “(A) acquire commercially available prod-
2 ucts listed pursuant to paragraph (2) for inclu-
3 sion in the State’s strategic stockpile;

4 “(B) store, maintain, and distribute prod-
5 ucts in such stockpile; and

6 “(C) conduct planning in connection with
7 such activities.

8 “(2) LIST.—The Secretary shall develop and
9 publish a list of the products that are eligible, as de-
10 scribed in subsection (a), for inclusion in a State’s
11 strategic stockpile using funds received under this
12 section.

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

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

25 “(d) MATCHING FUNDS.—

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

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

15 “(e) TECHNICAL ASSISTANCE.—The Secretary shall
16 provide technical assistance to States in establishing, ex-
17 panding, and maintaining a stockpile described in sub-
18 section (a).

19 “(f) DEFINITION.—In this section, the term ‘drug’
20 has the meaning given to that term in section 201 of the
21 Federal Food, Drug, and Cosmetic Act.

22 “(g) AUTHORIZATION OF APPROPRIATIONS.—To
23 carry out this section, there is authorized to be appro-
24 priated \$3,500,000,000 for each of fiscal years 2021
25 through 2023, to remain available until expended.

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

3 **Subtitle F—Process Improvements**
4 **and Reports**

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

7 (a) IN GENERAL.—The Comptroller General of the
8 United States shall conduct a study to investigate the fea-
9 sibility of establishing user fees to offset certain Federal
10 costs attributable to the procurement of single-source ma-
11 terials for the Strategic National Stockpile under section
12 319F–2 of the Public Health Service Act (42 U.S.C.
13 247d–6b) and distributions of such materials from the
14 Stockpile. In conducting this study, the Comptroller Gen-
15 eral shall consider, to the extent information is available—

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

18 (2) any Federal costs attributable to such dis-
19 tributions;

20 (3) whether such user fees would provide the
21 Secretary with funding to potentially offset procure-
22 ment costs of such materials for the Strategic Na-
23 tional Stockpile; and

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

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

5 **SEC. 3052. ACTION REPORTING.**

6 (a) IN GENERAL.—The Secretary of Health and
7 Human Services or the Assistant Secretary for Prepared-
8 ness and Response, in consultation with the Administrator
9 of the Federal Emergency Management Agency, shall—

10 (1) not later than 30 days after the date of en-
11 actment of this Act, issue a report to the Committee
12 on Energy and Commerce of the House of Rep-
13 resentatives and the Committee on Health, Edu-
14 cation, Labor, and Pensions of the Senate regarding
15 all State, local, Tribal, and territorial requests for
16 supplies from the Strategic National Stockpile re-
17 lated to COVID–19; and

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

24 (b) REPORTING PERIOD.—

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

4 (A) beginning on January 31, 2020; and

5 (B) ending on the date that is 30 days be-
6 fore the date of submission of the report.

7 (2) UPDATES.—Each update to the report
8 under subsection (a) shall address all requests de-
9 scribed in such subsection made during the period—

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

12 (B) ending on the date that is 30 days be-
13 fore the date of submission of the updated re-
14 port.

15 (c) CONTENTS OF REPORT.—The report under sub-
16 section (a) (and updates thereto) shall include—

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

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

22 (B) the amount of such materials re-
23 quested; and

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

1 (A) whether the request was wholly ful-
2 filled, partially fulfilled, or denied;

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

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

7 **SEC. 3053. IMPROVED, TRANSPARENT PROCESSES.**

8 (a) IN GENERAL.—Not later than January 1, 2021,
9 the Secretary of Health and Human Services shall develop
10 and implement improved, transparent processes for the
11 use and distribution of drugs, vaccines and other biological
12 products, medical devices, and other supplies (including
13 personal protective equipment, ancillary medical supplies,
14 and other applicable supplies required for the administra-
15 tion of drugs, vaccines and other biological products, med-
16 ical devices, and diagnostic tests) in the Strategic National
17 Stockpile under section 319F–2 of the Public Health Serv-
18 ice Act (42 U.S.C. 247d–6b) (in this section referred to
19 as the “Stockpile”).

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

22 (1) the form and manner in which States, local-
23 ities, Tribes, and territories are required to submit
24 requests for supplies from the Stockpile;

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

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

8 (4) clear plans for future, urgent communica-
9 tion between the Secretary and States, localities,
10 Tribes, and territories regarding the outcome of
11 such requests; and

12 (5) any differences in the processes developed
13 under subsection (a) for geographically related emer-
14 gencies, such as weather events, and national emer-
15 gencies, such as pandemics.

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

21 (d) REPORT TO CONGRESS.—Not later than January
22 1, 2021, the Secretary of Health and Human Services
23 shall—

24 (1) submit a report to the Committee on En-
25 ergy and Commerce of the House of Representatives

1 and the Committee on Health, Education, Labor,
2 and Pensions of the Senate regarding the improved,
3 transparent processes developed under this section;

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

9 (3) submit such report in unclassified form to
10 the greatest extent possible, except that the Sec-
11 retary may include a classified appendix if necessary
12 to protect national security.

13 **Subtitle G—Strategic National** 14 **Stockpile Funding**

15 **SEC. 3061. AUTHORIZATION OF APPROPRIATIONS.**

16 Section 319F–2(f)(1) of the Public Health Service
17 Act (42 U.S.C. 247d–6b(f)(1)) is amended by striking
18 “\$610,000,000 for each of fiscal years 2019 through
19 2023” and inserting “\$705,000,000 for each of fiscal
20 years 2021 through 2023”.

1 **TITLE IV—PUBLIC HEALTH IN-**
2 **FRASTRUCTURE IMPROVE-**
3 **MENTS**

4 **Subtitle A—Public Health**
5 **Infrastructure Modernization**

6 **SEC. 4001. PUBLIC HEALTH DATA SYSTEM TRANS-**
7 **FORMATION.**

8 Subtitle C of title XXVIII of the Public Health Serv-
9 ice Act (42 U.S.C. 300hh–31 et seq.) is amended by add-
10 ing at the end the following:

11 **“SEC. 2822. PUBLIC HEALTH DATA SYSTEM TRANS-**
12 **FORMATION.**

13 **“(a) EXPANDING CDC AND PUBLIC HEALTH DE-**
14 **PARTMENT CAPABILITIES.—**

15 **“(1) IN GENERAL.—**The Secretary, acting
16 through the Director of the Centers for Disease
17 Control and Prevention, shall—

18 **“(A)** conduct activities to expand, enhance,
19 and improve public health data systems used by
20 the Centers for Disease Control and Prevention,
21 related to the interoperability and improvement
22 of such systems (including with respect to pre-
23 paredness for, prevention and detection of, and
24 response to public health emergencies); and

1 “(B) award grants or cooperative agree-
2 ments to State, local, Tribal, or territorial pub-
3 lic health departments for the expansion and
4 modernization of public health data systems, to
5 assist public health departments in—

6 “(i) assessing current data infrastruc-
7 ture capabilities and gaps to improve con-
8 sistency in data collection, storage, and
9 analysis, and as appropriate to improve
10 dissemination of public health-related in-
11 formation;

12 “(ii) improving secure public health
13 data collection, transmission, exchange,
14 maintenance, and analysis;

15 “(iii) improving the secure exchange
16 of data between the Centers for Disease
17 Control and Prevention, State, local, Trib-
18 al, and territorial public health depart-
19 ments, public health organizations, and
20 health care providers, including—

21 “(I) between public health offi-
22 cials in multiple jurisdictions within a
23 State; and

24 “(II) by simplifying and sup-
25 porting reporting by health care pro-

1 viders pursuant to State law, includ-
2 ing through the use of health informa-
3 tion technology;

4 “(iv) enhancing the interoperability of
5 public health data systems (including sys-
6 tems created or accessed by public health
7 departments) with health information tech-
8 nology, including with health information
9 technology certified under section
10 3001(c)(5);

11 “(v) supporting and training public
12 health data systems, data science, and
13 informatics personnel;

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

18 “(vii) supporting activities within the
19 applicable jurisdiction related to the expan-
20 sion and modernization of electronic case
21 reporting; and

22 “(viii) developing and disseminating
23 information related to the use and impor-
24 tance of public health data.

1 “(2) DATA STANDARDS.—In carrying out para-
2 graph (1), the Secretary, acting through the Direc-
3 tor of the Centers for Disease Control and Preven-
4 tion, shall, as appropriate and in coordination with
5 the Office of the National Coordinator for Health
6 Information Technology, designate data and tech-
7 nology standards (including standards for interoper-
8 ability) for public health data systems, with def-
9 erence given to standards published by consensus-
10 based standards development organizations with
11 public input and voluntary consensus-based stand-
12 ards bodies.

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

22 “(b) REQUIREMENTS.—

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

1 unless the applicant uses or agrees to use standards
2 endorsed by the National Coordinator for Health In-
3 formation Technology pursuant to section
4 3001(e)(1) or adopted by the Secretary under sec-
5 tion 3004.

6 “(2) WAIVER.—The Secretary may waive the
7 requirement under paragraph (1) with respect to an
8 applicant if the Secretary determines that the activi-
9 ties under subsection (a)(1)(B) cannot otherwise be
10 carried out within the applicable jurisdiction.

11 “(3) APPLICATION.—A State, local, Tribal, or
12 territorial health department applying for a grant or
13 cooperative agreement under this section shall sub-
14 mit an application to the Secretary at such time and
15 in such manner as the Secretary may require. Such
16 application shall include information describing—

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

19 “(B) how the modernization of the public
20 health data systems involved will support or im-
21 pact the public health infrastructure of the
22 health department, including a description of
23 remaining gaps, if any, and the actions needed
24 to address such gaps.

1 “(c) STRATEGY AND IMPLEMENTATION PLAN.—Not
2 later than 180 days after the date of enactment of this
3 section, the Secretary, acting through the Director of the
4 Centers for Disease Control and Prevention, shall submit
5 to the Committee on Health, Education, Labor, and Pen-
6 sions of the Senate and the Committee on Energy and
7 Commerce of the House of Representatives a coordinated
8 strategy and an accompanying implementation plan that
9 identifies and describes the measures the Secretary will
10 utilize to—

11 “(1) update and improve public health data sys-
12 tems used by the Centers for Disease Control and
13 Prevention; and

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

17 “(d) CONSULTATION.—In carrying out this section,
18 the Secretary, acting through the Director of the Centers
19 for Disease Control and Prevention, shall consult with
20 State, local, Tribal, and territorial public health depart-
21 ments, professional medical and public health associations,
22 associations representing hospitals or other health care en-
23 tities, health information technology experts, and other ap-
24 propriate public or private entities.

1 “(e) REPORT TO CONGRESS.—Not later than 1 year
2 after the date of enactment of this section, the Secretary
3 shall submit a report to the Committee on Health, Edu-
4 cation, Labor, and Pensions of the Senate and the Com-
5 mittee on Energy and Commerce of the House of Rep-
6 resentatives that includes—

7 “(1) a description of any barriers to—

8 “(A) public health authorities imple-
9 menting interoperable public health data sys-
10 tems and electronic case reporting;

11 “(B) the exchange of information pursuant
12 to electronic case reporting; or

13 “(C) reporting by health care providers
14 using such public health data systems, as ap-
15 propriate, and pursuant to State law;

16 “(2) an assessment of the potential public
17 health impact of implementing electronic case re-
18 porting and interoperable public health data sys-
19 tems; and

20 “(3) a description of the activities carried out
21 pursuant to this section.

22 “(f) ELECTRONIC CASE REPORTING.—In this sec-
23 tion, the term ‘electronic case reporting’ means the auto-
24 mated identification, generation, and bilateral exchange of
25 reports of health events among electronic health record or

1 health information technology systems and public health
2 authorities.

3 “(g) AUTHORIZATION OF APPROPRIATIONS.—To
4 carry out this section, there is authorized to be appro-
5 priated \$100,000,000 for each of fiscal years 2021
6 through 2025.”.

7 **Subtitle B—Modernizing Infectious** 8 **Disease Data Collection**

9 **SEC. 4011. MODERNIZING INFECTIOUS DISEASE DATA COL-** 10 **LECTION.**

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

14 (1) in subsection (c)—

15 (A) in paragraph (3)(A)(iv), by inserting
16 “(such as commercial, academic, and other hos-
17 pital laboratories)” after “clinical laboratories”;

18 (B) in paragraph (5)—

19 (i) in subparagraph (A)—

20 (I) in the matter preceding clause
21 (i), by striking “and operating” and
22 inserting “, operating, and updating”;

23 (II) in clause (iv), by striking
24 “and” at the end;

1 (III) in clause (v), by striking the
2 period and inserting “; and”; and

3 (IV) by adding at the end the fol-
4 lowing:

5 “(vi) integrate and update applicable
6 existing Centers for Disease Control and
7 Prevention data systems and networks in
8 collaboration with State, local, tribal, and
9 territorial public health officials, including
10 public health surveillance and disease de-
11 tection systems.”; and

12 (ii) in subparagraph (B)—

13 (I) in clause (i), by inserting
14 “and 60 days after the date of enact-
15 ment of the Commitment to Defeat
16 the Virus and Keep America Healthy
17 Act” after “Innovation Act of 2019”;

18 (II) in clause (ii), by inserting
19 “epidemiologists, clinical microbiolo-
20 gists, pathologists and laboratory ex-
21 perts, experts in health information
22 technology, privacy, and data secu-
23 rity” after “forecasting);”; and

24 (III) in clause (iii)—

1 (aa) in subclause (V), by
2 striking “and” at the end;

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

5 (cc) by adding at the end
6 the following:

7 “(VII) strategies to integrate lab-
8 oratory and epidemiology systems and
9 capabilities to conduct rapid and accu-
10 rate laboratory tests;

11 “(VIII) strategies to improve the
12 collection and reporting of appro-
13 priate, aggregated, deidentified demo-
14 graphic data to inform responses to
15 public health emergencies, including
16 identification of at-risk populations
17 and to address health disparities; and

18 “(IX) strategies to improve the
19 electronic exchange of health informa-
20 tion between State and local health
21 departments and health care providers
22 and facilities to improve public health
23 surveillance.”; and

24 (C) in paragraph (6)—

25 (i) in subparagraph (A)—

1 (I) in clause (iii)—

2 (aa) in subclause (III), by
3 striking “and” at the end;

4 (bb) in subclause (IV), by
5 inserting “, including the ability
6 to conduct and report on rapid
7 and accurate laboratory testing
8 during a public health emer-
9 gency” before the semicolon; and

10 (cc) by adding at the end
11 the following:

12 “(V) improve coordination and
13 collaboration, as appropriate, with
14 other Federal departments; and

15 “(VI) implement applicable les-
16 sons learned from recent public health
17 emergencies to address gaps in situa-
18 tional awareness and biosurveillance
19 capabilities, including an evaluation of
20 ways to improve the collection and re-
21 porting of aggregated, deidentified de-
22 mographic data to inform public
23 health preparedness and response”;

24 (II) in clause (iv), by striking
25 “and” at the end;

1 (III) in clause (v), by striking the
2 period and inserting “including a de-
3 scription of how such steps will fur-
4 ther the goal of improving awareness
5 of and timely responses to emerging
6 infectious disease threats; and”;

7 (IV) by adding at the end the fol-
8 lowing:

9 “(vi) identifies and demonstrates
10 measurable steps the Secretary will take to
11 further develop and integrate infectious
12 disease detection, including expanding ca-
13 pabilities to conduct rapid and accurate di-
14 agnostic laboratory testing during a public
15 health emergency, and improve coordina-
16 tion and collaboration with State, local,
17 Tribal, and territorial public health offi-
18 cials, clinical laboratories (including com-
19 mercial, hospital and academic labora-
20 tories), and other entities with expertise in
21 public health surveillance.”; and

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

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

1 “(B) REPORTS.—

2 “(i) IN GENERAL.—Not later than 1
3 month after date of enactment of the Com-
4 mitment to Defeat the Virus and Keep
5 America Healthy Act, and as provided for
6 in clause (ii), the Secretary shall submit to
7 the Committee on Health, Education,
8 Labor, and Pensions of the Senate and the
9 Committee on Energy and Commerce of
10 the House of Representatives, a report on
11 the status of the Department of Health
12 and Human Services’ biosurveillance mod-
13 ernization and assessment progress with
14 respect to emerging infectious disease
15 threats.

16 “(ii) ADDITIONAL REPORTS.—During
17 the 2-year period beginning on the date of
18 enactment of the Commitment to Defeat
19 the Virus and Keep America Healthy Act,
20 the Secretary shall provide additional re-
21 ports under clause (i) every 90 days after
22 the submission of the initial report under
23 such clause. The Secretary shall provide
24 such reports annually thereafter. The Sec-
25 retary may provide such additional reports

1 less frequently, but not less frequently
2 than every 180 days, during an ongoing
3 public health emergency or another signifi-
4 cant infectious disease outbreak.”;

5 (2) in subsection (d)—

6 (A) in paragraph (2)(C), by inserting “, in-
7 cluding any public-private partnerships entered
8 into to improve such capacity” before the semi-
9 colon; and

10 (B) in paragraph (3)—

11 (i) in subparagraph (B), by striking
12 “and” at the end;

13 (ii) in subparagraph (C), by striking
14 the period and inserting “; and”; and

15 (iii) by adding at the end the fol-
16 lowing:

17 “(D) may establish, enhance, or maintain
18 a system or network for the collection of data
19 to provide for early detection of infectious dis-
20 ease outbreaks, near real-time access to rel-
21 evant electronic data and integration of elec-
22 tronic data and information from public health
23 and other appropriate sources, such as labora-
24 tories, hospitals, and epidemiology systems, to
25 enhance the capability to conduct rapid and ac-

1 curate diagnostic laboratory tests to provide for
2 disease detection.”;

3 (3) in subsection (f)(1)(A), by inserting “pa-
4 thologists, clinical microbiologists, laboratory profes-
5 sionals, epidemiologists,” after “forecasting,”; and

6 (4) in subsection (h), by adding at the end the
7 following: “Such evaluation shall include identifica-
8 tion of any gaps in biosurveillance and situational
9 awareness capabilities identified related to recent
10 public health emergencies, any immediate steps
11 taken to address such gaps, and any long-term plans
12 to address such gaps, including steps related to ac-
13 tivities authorized under this section.”.

14 (b) NATIONAL HEALTH SECURITY STRATEGY.—Sec-
15 tion 2802(b)(2) of the Public Health Service Act (42
16 U.S.C. 300hh–1(b)(2)) is amended—

17 (1) in subparagraph (A), by inserting “such as
18 by integrating laboratory and epidemiology systems
19 and capability to conduct rapid and accurate labora-
20 tory tests,” after “detection, identification,”; and

21 (2) in subparagraph (B), by inserting “labora-
22 tory testing,” after “services and supplies,”.

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

- 1 (1) in paragraph (3), by striking “and”;
- 2 (2) in paragraph (4), by striking the period and
3 inserting “; and”; and
- 4 (3) by adding at the end the following:
- 5 “(5) supporting activities of State and local
6 public health departments related to biosurveillance
7 and disease detection, which may include activities
8 related to section 319D, as appropriate.”.

9 **Subtitle C—Diagnostic Testing for**
10 **Public Health Labs**

11 **SEC. 4021. GRANTS FOR PUBLIC HEALTH LABORATORIES**
12 **TO ACQUIRE HIGH-THROUGHPUT DIAG-**
13 **NOSTIC EQUIPMENT.**

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

16 (1) by redesignating subsection (b) as sub-
17 section (c);

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

20 “(b) GRANTS FOR PUBLIC HEALTH LABORATORIES
21 TO ACQUIRE HIGH-THROUGHPUT DIAGNOSTIC EQUIP-
22 MENT.—

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

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

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

5 “(A) be—

6 “(i) a State, local, or Tribal public
7 health laboratory;

8 “(ii) a laboratory within a public
9 health laboratory network coordinated or
10 managed by the Centers for Disease Con-
11 trol and Prevention;

12 “(iii) a laboratory not described in
13 clause (i) or (ii) that the Secretary deter-
14 mines (at the Secretary’s discretion) pro-
15 vides population-based testing for the pre-
16 vention and control of infectious, commu-
17 nicable, genetic, or chronic diseases; or

18 “(iv) a consortium of 2 or more enti-
19 ties described in any of clauses (i) through
20 (iii); and

21 “(B) submit to the Secretary an applica-
22 tion at such time, in such manner, and con-
23 taining such information as the Secretary may
24 reasonably require.

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

4 “(A) to purchase high-throughput diag-
5 nostic equipment and such materials as are nec-
6 essary to administer, store, and process applica-
7 ble tests, including diagnostic and serological
8 tests; and

9 “(B) to hire and train staff to use such
10 equipment.

11 “(4) AMOUNT OF GRANT.—The amount of a
12 grant under paragraph (1) may not exceed
13 \$2,000,000, except in the case of eligible entity de-
14 scribed in paragraph (2)(A)(iv).

15 “(5) HIGH-THROUGHPUT DIAGNOSTIC EQUIP-
16 MENT DEFINED.—In this subsection, the term ‘high-
17 throughput diagnostic equipment’ means legally
18 marketed equipment and supplies capable of per-
19 forming multichannel analysis for use in clinical lab-
20 oratory diagnostic testing.”; and

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

22 (A) by redesignating paragraphs (1), (2),
23 and (3) as subparagraphs (A), (B), and (C), re-
24 spectively, and moving the margin of each such
25 redesignated subparagraph 2 ems to the right;

1 (B) by striking “There are authorized to
2 be appropriated to carry out this section” and
3 inserting the following:

4 “(1) IN GENERAL.—There are authorized to be
5 appropriated to carry out subsection (a)”; and

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

8 “(2) AUTHORIZATION OF APPROPRIATIONS.—

9 “(A) IN GENERAL.—For the purpose of
10 carrying out subsection (b), there is authorized
11 to be appropriated \$250,000,000 for fiscal year
12 2021, to remain available until expended.

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

18 **Subtitle D—Rapid Testing for**
19 **Communities**

20 **SEC. 4031. GRANTS FOR SAME-DAY POINT-OF-CARE CLIN-**
21 **ICAL LABORATORY DIAGNOSTIC TESTING IN**
22 **COMMUNITIES.**

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

1 (1) by redesignating subsection (c), as redesign-
2 nated by section 4021, as subsection (d);

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

5 “(c) GRANTS FOR SAME-DAY POINT-OF-CARE CLIN-
6 ICAL LABORATORY DIAGNOSTIC TESTING IN COMMU-
7 NITIES.—

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

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

15 “(A) be—

16 “(i) a hospital;

17 “(ii) a primary care facility;

18 “(iii) a clinic;

19 “(iv) a physician; or

20 “(v) another type of health care pro-
21 vider as the Secretary may define; and

22 “(B) submit to the Secretary an applica-
23 tion at such time, in such manner, and con-
24 taining such information as the Secretary may
25 reasonably require.

1 “(3) USE OF FUNDS.—Amounts received
2 through a grant under this subsection shall be used
3 to purchase legally marketed rapid diagnostic equip-
4 ment and such materials as are necessary to admin-
5 ister, store, and process same-day clinical laboratory
6 diagnostic testing in a point-of-care setting, includ-
7 ing diagnostic and serological tests.

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

10 “(5) PRIORITY IN MAKING AWARDS.—In award-
11 ing grants under paragraph (1), the Secretary shall
12 give priority to eligible entities providing services
13 to—

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

16 “(B) all other areas.”; and

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

19 “(3) AUTHORIZATION OF APPROPRIATIONS.—

20 “(A) IN GENERAL.—For the purpose of
21 carrying out subsection (c), there is authorized
22 to be appropriated \$500,000,000 for fiscal year
23 2021, to remain available until expended.

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

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

4 **Subtitle E—Public Health**
5 **Workforce Loan Repayment**

6 **SEC. 4041. PUBLIC HEALTH WORKFORCE LOAN REPAY-**
7 **MENT PROGRAM.**

8 Part D of title III of the Public Health Service Act
9 (42 U.S.C. 254b et seq.), as amended by section 2031,
10 is further amended by adding at the end the following new
11 subpart:

12 **“Subpart XIV—Public Health Workforce**

13 **“SEC. 340K. LOAN REPAYMENT PROGRAM.**

14 “(a) ESTABLISHMENT.—The Secretary of Health
15 and Human Services shall establish a program to be
16 known as the Public Health Workforce Loan Repayment
17 Program (referred to in this section as the ‘Program’) to
18 assure an adequate supply of and encourage recruitment
19 of public health professionals to eliminate critical public
20 health workforce shortages in local, State, and Tribal pub-
21 lic health agencies.

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

24 “(1)(A) be accepted for enrollment, or be en-
25 rolled, as a student in an accredited academic edu-

1 cational institution in a State or territory in the
2 final year of a course of study or program leading
3 to a public health or health professions degree or
4 certificate and have accepted employment with a
5 local, State, or Tribal public health agency, or a re-
6 lated training fellowship, as recognized by the Sec-
7 retary, to commence upon graduation; or

8 “(B)(i) have graduated, during the preceding
9 10-year period, from an accredited educational insti-
10 tution in a State or territory and received a public
11 health or health professions degree or certificate;
12 and

13 “(ii) be employed by, or have accepted employ-
14 ment with, a local, State, or Tribal public health
15 agency or a related training fellowship, as recognized
16 by the Secretary;

17 “(2) be a United States citizen;

18 “(3)(A) submit an application to the Secretary
19 to participate in the Program; and

20 “(B) execute a written contract as required in
21 subsection (c); and

22 “(4) not have received, for the same service, a
23 reduction of loan obligations under section 428J,
24 428K, 428L, 455(m), or 460 of the Higher Edu-

1 cation Act of 1965 (20 U.S.C. 1078–10, 1078–11,
2 1078–12, 1087e(m), and 1087j).

3 “(c) CONTRACT.—The written contract referred to in
4 subsection (b)(3)(B) between the Secretary and an indi-
5 vidual shall contain—

6 “(1) an agreement on the part of the Secretary
7 that the Secretary will repay, on behalf of the indi-
8 vidual, loans incurred by the individual in the pur-
9 suit of the relevant degree or certificate in accord-
10 ance with the terms of the contract;

11 “(2) an agreement on the part of the individual
12 that the individual will serve in the full-time employ-
13 ment of a local, State, or Tribal public health agency
14 or a related fellowship program in a position related
15 to the course of study or program for which the con-
16 tract was awarded for a period of time equal to the
17 greater of—

18 “(A) 3 years; or

19 “(B) such longer period of time as deter-
20 mined appropriate by the Secretary and the in-
21 dividual;

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

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

3 “(4) a provision that any financial obligation of
4 the United States arising out of a contract entered
5 into under this section and any obligation of the in-
6 dividual that is conditioned thereon, is contingent on
7 funds being appropriated for loan repayments under
8 this section;

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

12 “(6) such other statements of the rights and li-
13 abilities of the Secretary and of the individual as the
14 Secretary determines appropriate, not inconsistent
15 with this section.

16 “(d) PAYMENTS.—

17 “(1) IN GENERAL.—A loan repayment provided
18 for an individual under a written contract referred
19 to in subsection (b)(3)(B) shall consist of payment,
20 in accordance with paragraph (2), on behalf of the
21 individual of the principal, interest, and related ex-
22 penses on government and commercial loans received
23 by the individual regarding the undergraduate or
24 graduate education of the individual (or both), which

1 loans were made for tuition expenses incurred by the
2 individual.

3 “(2) PAYMENTS FOR YEARS SERVED.—For
4 each year of service that an individual contracts to
5 serve pursuant to subsection (c)(2), the Secretary
6 may pay not more than \$35,000 on behalf of the in-
7 dividual for loans described in paragraph (1). With
8 respect to participants under the Program whose
9 total eligible loans are less than \$105,000, the Sec-
10 retary shall pay an amount that does not exceed $\frac{1}{3}$
11 of the eligible loan balance for each year of such
12 service of such individual.

13 “(3) TAX LIABILITY.—For the purpose of pro-
14 viding reimbursements for tax liability resulting
15 from payments under paragraph (2) on behalf of an
16 individual, the Secretary shall, in addition to such
17 payments, make payments to the individual in an
18 amount not to exceed 39 percent of the total amount
19 of loan repayments made for the taxable year in-
20 volved.

21 “(e) POSTPONING OBLIGATED SERVICE.—With re-
22 spect to an individual receiving a degree or certificate from
23 a health professions or other related school, the date of
24 the initiation of the period of obligated service may be
25 postponed as approved by the Secretary.

1 “(f) BREACH OF CONTRACT.—An individual who fails
 2 to comply with the contract entered into under subsection
 3 (c) shall be subject to the same financial penalties as pro-
 4 vided for under section 338E of the Public Health Service
 5 Act (42 U.S.C. 254o) for breaches of loan repayment con-
 6 tracts under section 338B of such Act (42 U.S.C. section
 7 254l–1).

8 “(g) AUTHORIZATION OF APPROPRIATIONS.—There
 9 is authorized to be appropriated to carry out this section—
 10 “(1) \$100,000,000 for fiscal year 2021; and
 11 “(2) \$75,000,000 for each of fiscal years 2022
 12 through 2026.”.

13 **Subtitle F—Vaccine Awareness and** 14 **Disease Prevention**

15 **SEC. 4051. IMPROVING AWARENESS OF DISEASE PREVEN-** 16 **TION.**

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

20 **“SEC. 313. PUBLIC AWARENESS CAMPAIGN ON THE IMPOR-** 21 **TANCE OF VACCINATIONS.**

22 “(a) IN GENERAL.—The Secretary, acting through
 23 the Director of the Centers for Disease Control and Pre-
 24 vention and in coordination with other offices and agen-
 25 cies, as appropriate, shall award competitive grants or

1 contracts to one or more public or private entities to carry
2 out a national, evidence-based campaign to increase
3 awareness and knowledge of the safety and effectiveness
4 of vaccines for the prevention and control of diseases, com-
5 bat misinformation about vaccines, and disseminate sci-
6 entific and evidence-based vaccine-related information,
7 with the goal of increasing rates of vaccination across all
8 ages, as applicable, particularly in communities with low
9 rates of vaccination, to reduce and eliminate vaccine-pre-
10 ventable diseases.

11 “(b) CONSULTATION.—In carrying out the campaign
12 under this section, the Secretary shall consult with appro-
13 priate public health and medical experts, including the Na-
14 tional Academy of Medicine and medical and public health
15 associations and nonprofit organizations, in the develop-
16 ment, implementation, and evaluation of the evidence-
17 based public awareness campaign.

18 “(c) REQUIREMENTS.—The campaign under this sec-
19 tion shall—

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

22 “(2) include the development of resources for
23 communities with low rates of vaccination, including
24 culturally and linguistically appropriate resources, as
25 applicable;

1 “(3) include the dissemination of vaccine infor-
2 mation and communication resources to public
3 health departments, health care providers, and
4 health care facilities, including such providers and
5 facilities that provide prenatal and pediatric care;

6 “(4) be complementary to, and coordinated
7 with, any other Federal, State, local, or Tribal ef-
8 forts, as appropriate; and

9 “(5) assess the effectiveness of communication
10 strategies to increase rates of vaccination.

11 “(d) ADDITIONAL ACTIVITIES.—The campaign under
12 this section may—

13 “(1) include the use of television, radio, the
14 internet, and other media and telecommunications
15 technologies;

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

17 “(3) be focused to address specific needs of
18 communities and populations with low rates of vac-
19 cination; and

20 “(4) include the dissemination of scientific and
21 evidence-based vaccine-related information, such
22 as—

23 “(A) advancements in evidence-based re-
24 search related to diseases that may be pre-
25 vented by vaccines and vaccine development;

1 “(B) information on vaccinations for indi-
2 viduals and communities, including individuals
3 for whom vaccines are not recommended by the
4 Advisory Committee for Immunization Prac-
5 tices, and the effects of low vaccination rates
6 within a community on such individuals;

7 “(C) information on diseases that may be
8 prevented by vaccines; and

9 “(D) information on vaccine safety and the
10 systems in place to monitor vaccine safety.

11 “(e) EVALUATION.—The Secretary shall—

12 “(1) establish benchmarks and metrics to quan-
13 titatively measure and evaluate the awareness cam-
14 paign under this section;

15 “(2) conduct qualitative assessments regarding
16 the awareness campaign under this section; and

17 “(3) prepare and submit to the Committee on
18 Health, Education, Labor, and Pensions of the Sen-
19 ate and Committee on Energy and Commerce of the
20 House of Representatives an evaluation of the
21 awareness campaign under this section.

22 “(f) SUPPLEMENT NOT SUPPLANT.—Funds appro-
23 priated under this section shall be used to supplement and
24 not supplant other Federal, State, and local public funds
25 provided for activities described in this section.

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

5 (b) GRANTS TO ADDRESS VACCINE-PREVENTABLE
6 DISEASES.—Section 317 of the Public Health Service Act
7 (42 U.S.C. 247b) is amended—

8 (1) in subsection (k)(1)—

9 (A) in subparagraph (C), by striking “;
10 and” and inserting a semicolon;

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

13 (C) by adding at the end the following:

14 “(E) planning, implementation, and eval-
15 uation of activities to address vaccine-prevent-
16 able diseases, including activities to—

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

21 “(ii) pilot innovative approaches to
22 improve vaccination rates in communities
23 and among populations with low rates of
24 vaccination;

1 “(iii) reduce barriers to accessing vac-
2 cines and evidence-based information about
3 the health effects of vaccines;

4 “(iv) partner with community organi-
5 zations and health care providers to de-
6 velop and deliver evidence-based interven-
7 tions, including culturally and linguistically
8 appropriate interventions, to increase vac-
9 cination rates;

10 “(v) improve delivery of evidence-
11 based, vaccine-related information to par-
12 ents and others; and

13 “(vi) improve the ability of State,
14 local, Tribal, and territorial public health
15 departments to engage communities at
16 high risk for outbreaks related to vaccine-
17 preventable diseases, in coordination, as
18 appropriate, with local educational agen-
19 cies, as defined in section 8101 of the Ele-
20 mentary and Secondary Education Act of
21 1965; and

22 “(F) research related to strategies for im-
23 proving awareness of scientific and evidence-
24 based, vaccine-related information, including for
25 communities with low rates of vaccination, in

1 order to understand barriers to vaccination, im-
2 prove vaccination rates, and assess the public
3 health outcomes of such strategies.”; and

4 (2) by adding at the end the following:

5 “(n) VACCINATION DATA.—The Secretary, acting
6 through the Director of the Centers for Disease Control
7 and Prevention, shall expand and enhance, and, as appro-
8 priate, establish and improve, programs and conduct ac-
9 tivities to collect, monitor, and analyze vaccination cov-
10 erage data to assess levels of protection from vaccine-pre-
11 ventable diseases, including by assessing factors contrib-
12 uting to underutilization of vaccines and variations of such
13 factors, and identifying communities at high risk of out-
14 breaks associated with vaccine-preventable diseases.”.

15 (c) SUPPLEMENTAL GRANT FUNDS.—Section
16 330(d)(1) of the Public Health Service Act (42 U.S.C.
17 254b) is amended—

18 (1) in subparagraph (F), by striking “and” at
19 the end;

20 (2) in subparagraph (G), by striking the period
21 and inserting “; and”; and

22 (3) by adding at the end the following:

23 “(H) improving access to recommended
24 immunizations.”.

1 (d) UPDATE OF 2015 NVAC REPORT.—The National
2 Vaccine Advisory Committee established under section
3 2105 of the Public Health Service Act (42 U.S.C. 300aa–
4 5) shall, as appropriate, update the report entitled, “As-
5 sessing the State of Vaccine Confidence in the United
6 States: Recommendations from the National Vaccine Advi-
7 sory Committee”, approved by the National Vaccine Advi-
8 sory Committee on June 10, 2015, with respect to factors
9 affecting childhood vaccination.

10 **Subtitle G—Protecting the Health**
11 **of America’s Older Adults Dur-**
12 **ing COVID–19 & Beyond**

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

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

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

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

3 (A) agencies across the Department of
4 Health and Human Services, including the Ad-
5 ministration for Community Living (including
6 the Administration on Aging), the Centers for
7 Disease Control and Prevention, the Centers for
8 Medicare & Medicaid Services, the Health Re-
9 sources and Services Administration, the Indian
10 Health Service, and the Office of Minority
11 Health in the Office of the Secretary; and

12 (B) other Federal departments, including
13 the Department of Housing and Urban Devel-
14 opment and the Department of Veterans Af-
15 fairs; and

16 (2) collaborate with State and local govern-
17 ments, Indian tribes and Tribal organizations, and
18 nonprofit organizations.

19 (c) ACTIVITIES.—The Center shall perform the fol-
20 lowing activities:

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

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

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

10 (C) Expanding the use of telemedicine, in-
11 cluding the provision of technology to execute
12 televisits that safely and comprehensively ad-
13 dress older adults' health care needs.

14 (D) Supporting family caregivers, includ-
15 ing those with additional responsibilities for
16 homebound individuals.

17 (E) Reducing disparities among under-
18 served populations.

19 (F) Developing cross-sector collaborative
20 efforts.

21 (2) Create and disseminate tools, technical as-
22 sistance, training, and funding to State, local, Trib-
23 al, and territorial governments to adopt best prac-
24 tices developed under subparagraphs (E) and (F) of
25 paragraph (1).

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

6 (4) Facilitate the development of learning net-
7 works of practitioners at the hospital, nursing facil-
8 ity, and community levels to disseminate the best
9 practices developed under paragraph (1) and ensure
10 implementation of such best practices to reduce mor-
11 bidity and mortality of older adults affected by
12 COVID–19.

13 (5) Identify and disseminate approaches that
14 strengthen public health and health care system ca-
15 pacity to serve older Americans with regard to
16 health issues during and beyond the COVID–19
17 pandemic.

18 **SEC. 4062. HEALTHY AGING PROGRAM.**

19 (a) IN GENERAL.—The Secretary, acting through the
20 Director of the Centers for Disease Control and Preven-
21 tion, shall establish a Healthy Aging Program for the pur-
22 pose of promoting the health and well-being of older adults
23 by—

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

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

8 (3) coordinating multisectoral efforts to pro-
9 mote the health and well-being of older adults across
10 governmental and nongovernmental health and re-
11 lated agencies.

12 (b) ACTIVITIES.—For the purpose described in sub-
13 section (a), the Secretary shall design the Healthy Aging
14 Program to carry out the following activities:

15 (1) Regularly assess the health-related needs of
16 older adults and promote policies addressing those
17 needs through evidence-based public health interven-
18 tions to promote overall health and well-being among
19 older adults and reduce health care costs.

20 (2) Identify disparities in health among vulner-
21 able populations of older adults.

22 (3) Identify gaps in existing public health pro-
23 grams and policies that focus on older adults.

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

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

3 (5) Work with multisectoral agencies to improve
4 emergency preparedness plans and activities for vul-
5 nerable older adult populations.

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

10 (7) Identify resources and evidence-based pro-
11 grams available to local and State health depart-
12 ments, including resources and programs that could
13 be coordinated across sectors, to address the health
14 and well-being of older adults.

15 (c) GRANTS TO HEALTH DEPARTMENTS.—The Sec-
16 retary, acting through the Director of the Centers for Dis-
17 ease Control and Prevention, shall award grants or cooper-
18 ative agreements to eligible health departments to carry
19 out any of the following activities:

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

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

1 and supports) to coordinate and promote commu-
2 nity-based prevention services.

3 (3) Ensuring that State and local emergency
4 preparedness plans and activities address the special
5 needs of older adults, particularly the most vulner-
6 able populations.

7 (4) Training State and local public health per-
8 sonnel to implement or adapt evidence-based and in-
9 novative health promotion and disease prevention
10 programs and policies.

11 (5) Improving community conditions and ad-
12 dressing social determinants to promote health and
13 well-being and foster independence among older
14 adults, such as efforts to advance age-friendly com-
15 munities and dementia-friendly communities.

16 (d) TECHNICAL ASSISTANCE.—The Secretary shall
17 (directly or through grants, cooperative agreements, or
18 contracts) provide technical assistance to eligible health
19 departments in carrying out activities described in sub-
20 section (c).

21 (e) EVALUATIONS.—The Secretary shall (directly or
22 through grants, cooperative agreements, or contracts) pro-
23 vide for the evaluation of activities carried out under sub-
24 sections (a), (b), and (c) in order to determine the extent
25 to which such activities have been effective in carrying out

1 the purpose described in subsection (a), including the ef-
2 fects of such activities on addressing health disparities.

3 (f) DEFINITION.—In this section, the term “eligible
4 health department” means a health department of a State,
5 the District of Columbia, the Commonwealth of Puerto
6 Rico, the United States Virgin Islands, Guam, American
7 Samoa, the Commonwealth of the Northern Mariana Is-
8 lands, a Tribe (as defined in section 4 of the Indian Self-
9 Determination and Education Assistance Act (25 U.S.C.
10 5304)), or a large city (as defined by the Director of the
11 Centers for Disease Control and Prevention for purposes
12 of this section).

13 **SEC. 4063. AUTHORIZATION OF APPROPRIATIONS.**

14 There is authorized to be appropriated—

15 (1) \$10,000,000 for the period of fiscal years
16 2021 through 2025 to carry out section 4061, to re-
17 main available until September 30, 2025; and

18 (2) \$20,000,000 for each of fiscal years 2021
19 through 2025 to carry out section 4062, including
20 for grants under section 4062(c), to remain available
21 until September 30, 2025.

1 **Subtitle H—Expanding Capacity**
2 **for Health Outcomes**

3 **SEC. 4071. EXPANDING CAPACITY FOR HEALTH OUTCOMES.**

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

7 **“SEC. 330N. EXPANDING CAPACITY FOR HEALTH OUT-**
8 **COMES.**

9 “(a) DEFINITIONS.—In this section:

10 “(1) ELIGIBLE ENTITY.—The term ‘eligible en-

11 tity’—

12 “(A) means an entity that provides, or

13 supports the provision of, health care services—

14 “(i) in rural areas, frontier areas,

15 health professional shortage areas, or

16 medically underserved areas; or

17 “(ii) to medically underserved popu-

18 lations or Native Americans, including In-

19 dian Tribes, Tribal organizations, or urban

20 Indian organizations; and

21 “(B) may include entities leading, or capa-

22 ble of leading, a technology-enabled collabo-

23 rative learning and capacity building model or

24 engaging in technology-enabled collaborative

25 training of participants in such model.

1 “(2) HEALTH PROFESSIONAL SHORTAGE
2 AREA.—The term ‘health professional shortage area’
3 means a health professional shortage area des-
4 ignated under section 332.

5 “(3) INDIAN TRIBE.—The terms ‘Indian Tribe’
6 and ‘Tribal organization’ have the meanings given
7 the terms ‘Indian tribe’ and ‘tribal organization’ in
8 section 4 of the Indian Self-Determination and Edu-
9 cation Assistance Act.

10 “(4) MEDICALLY UNDERSERVED POPU-
11 LATION.—The term ‘medically underserved popu-
12 lation’ has the meaning given the term in section
13 330(b)(3).

14 “(5) NATIVE AMERICANS.—The term ‘Native
15 Americans’ has the meaning given such term in sec-
16 tion 736 and includes Indian Tribes and Tribal or-
17 ganizations.

18 “(6) TECHNOLOGY-ENABLED COLLABORATIVE
19 LEARNING AND CAPACITY BUILDING MODEL.—The
20 term ‘technology-enabled collaborative learning and
21 capacity building model’ means a distance health
22 education model that connects health care profes-
23 sionals, and particularly specialists, with multiple
24 other health care professionals through simultaneous
25 interactive videoconferencing for the purpose of fa-

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

3 “(7) URBAN INDIAN ORGANIZATION.—The
4 ‘urban Indian organization’ has the meaning given
5 the term ‘Urban Indian organization’ in section 4 of
6 the Indian Health Care Improvement Act.

7 “(b) PROGRAM ESTABLISHED.—The Secretary shall,
8 as appropriate, award grants to evaluate, develop, and, as
9 appropriate, expand the use of technology-enabled collabo-
10 rative learning and capacity building models, to improve
11 retention of health care providers and increase access to
12 health care services, such as those to address chronic dis-
13 eases and conditions, infectious diseases, mental health,
14 substance use disorders, prenatal and maternal health, pe-
15 diatric care, pain management, palliative care, and other
16 specialty care in rural areas, frontier areas, health profes-
17 sional shortage areas, or medically underserved areas and
18 for medically underserved populations or Native Ameri-
19 cans, including Indian Tribes and Tribal organizations.

20 “(c) USE OF FUNDS.—

21 “(1) IN GENERAL.—Grants awarded under sub-
22 section (b) shall be used for—

23 “(A) the development and acquisition of
24 instructional programming, and the training of
25 health care providers and other professionals

1 that provide or assist in the provision of serv-
2 ices through models described in subsection (b),
3 such as training on best practices for data col-
4 lection and leading or participating in such
5 technology-enabled activities consistent with
6 technology-enabled collaborative learning and
7 capacity building models;

8 “(B) information collection and evaluation
9 activities to study the impact of such models on
10 patient outcomes and health care providers, and
11 to identify best practices for the expansion and
12 use of such models; or

13 “(C) other activities consistent with achiev-
14 ing the objectives of the grants awarded under
15 this section, as determined by the Secretary.

16 “(2) OTHER USES.—In addition to any of the
17 uses under paragraph (1), grants awarded under
18 subsection (b) may be used for—

19 “(A) equipment to support the use and ex-
20 pansion of technology-enabled collaborative
21 learning and capacity building models, including
22 for hardware and software that enables distance
23 learning, health care provider support, and the
24 secure exchange of electronic health informa-
25 tion; or

1 “(B) support for health care providers and
2 other professionals that provide or assist in the
3 provision of services through such models.

4 “(d) LENGTH OF GRANTS.—Grants awarded under
5 subsection (b) shall be for a period of up to 5 years.

6 “(e) GRANT REQUIREMENTS.—The Secretary may
7 require entities awarded a grant under this section to col-
8 lect information on the effect of the use of technology-
9 enabled collaborative learning and capacity building mod-
10 els, such as on health outcomes, access to health care serv-
11 ices, quality of care, and provider retention in areas and
12 populations described in subsection (b). The Secretary
13 may award a grant or contract to assist in the coordina-
14 tion of such models, including to assess outcomes associ-
15 ated with the use of such models in grants awarded under
16 subsection (b), including for the purpose described in sub-
17 section (c)(1)(B).

18 “(f) APPLICATION.—An eligible entity that seeks to
19 receive a grant under subsection (b) shall submit to the
20 Secretary an application, at such time, in such manner,
21 and containing such information as the Secretary may re-
22 quire. Such application shall include plans to assess the
23 effect of technology-enabled collaborative learning and ca-
24 pacity building models on patient outcomes and health
25 care providers.

1 “(g) ACCESS TO BROADBAND.—In administering
2 grants under this section, the Secretary may coordinate
3 with other agencies to ensure that funding opportunities
4 are available to support access to reliable, high-speed
5 internet for grantees.

6 “(h) TECHNICAL ASSISTANCE.—The Secretary shall
7 provide (either directly through the Department of Health
8 and Human Services or by contract) technical assistance
9 to eligible entities, including recipients of grants under
10 subsection (b), on the development, use, and evaluation
11 of technology-enabled collaborative learning and capacity
12 building models in order to expand access to health care
13 services provided by such entities, including for medically
14 underserved areas and to medically underserved popu-
15 lations or Native Americans, including Indian Tribes and
16 Tribal organizations.

17 “(i) RESEARCH AND EVALUATION.—The Secretary,
18 in consultation with stakeholders with appropriate exper-
19 tise in such models, shall develop a strategic plan to re-
20 search and evaluate the evidence for such models. The
21 Secretary shall use such plan to inform the activities car-
22 ried out under this section.

23 “(j) REPORT BY SECRETARY.—Not later than 4
24 years after the date of enactment of this section, the Sec-
25 retary shall prepare and submit to the Committee on

1 Health, Education, Labor, and Pensions of the Senate and
2 the Committee on Energy and Commerce of the House
3 of Representatives, and post on the internet website of the
4 Department of Health and Human Services, a report in-
5 cluding, at minimum—

6 “(1) a description of any new and continuing
7 grants awarded to entities under subsection (b) and
8 the specific purpose and amounts of such grants;

9 “(2) an overview of—

10 “(A) the evaluations conducted under sub-
11 section (b);

12 “(B) technical assistance provided under
13 subsection (h); and

14 “(C) activities conducted by entities award-
15 ed grants under subsection (b); and

16 “(3) a description of any significant findings or
17 developments related to patient outcomes or health
18 care providers and best practices for eligible entities
19 expanding, using, or evaluating technology-enabled
20 collaborative learning and capacity building models,
21 including through the activities described in sub-
22 section (h).

23 “(k) AUTHORIZATION OF APPROPRIATIONS.—There
24 is authorized to be appropriated to carry out this section,
25 \$20,000,000 for each of fiscal years 2021 through 2025.”.

1 **Subtitle I—Community Readiness**

2 **SEC. 4081. GRANTS FOR RESEARCH ON, OR ESTABLISHING,**
3 **WASTEWATER SURVEILLANCE AND OTHER**
4 **EARLY WARNING SYSTEMS.**

5 Subtitle C of title XXVIII of the Public Health Serv-
6 vice Act (42 U.S.C. 300hh–31 et seq.) is amended by add-
7 ing at the end the following:

8 **“SEC. 2823. GRANTS FOR RESEARCH ON, OR ESTABLISHING,**
9 **WASTEWATER SURVEILLANCE AND OTHER**
10 **EARLY WARNING SYSTEMS.**

11 “(a) IN GENERAL.—The Secretary, in consultation
12 with the Administrator of the Environmental Protection
13 Agency, may award grants to eligible entities to conduct
14 research on, or to establish, a wastewater surveillance or
15 other early warning system through—

16 “(1) wastewater testing;

17 “(2) temperature tracking to monitor axillary
18 body temperature; and

19 “(3) other methods deemed permissible by the
20 Secretary and Administrator.

21 “(b) PERMISSIBLE USES OF FUNDS.—A grant recipi-
22 ent under this section may use grant funds to support the
23 activities described in subsection (a), including by—

1 “(1) paying for data-centric services that can
2 detect infectious diseases before positive cases or
3 hospitalizations;

4 “(2) entering into contracts with private compa-
5 nies to implement early warning detection methods;
6 or

7 “(3) funding research to study early warning
8 detection methods.

9 “(c) PRIORITY.—In selecting grant recipients under
10 this section, the Secretary shall give priority to eligible en-
11 tities proposing to conduct research on, or to establish,
12 wastewater surveillance or other early warning system in
13 one or more areas that—

14 “(1) are (or include one or more areas that are)
15 a hot spot; or

16 “(2) a higher percentage of vulnerable popu-
17 lations than the national average.

18 “(d) FEDERAL PRIVACY REQUIREMENTS.—Nothing
19 in this section shall be construed to supersede any Federal
20 privacy or confidentiality requirement, including the regu-
21 lations promulgated under section 264(c) of the Health
22 Insurance Portability and Accountability Act of 1996 and
23 section 543 of this Act.

24 “(e) DEFINITIONS.—In this section:

1 “(1) The term ‘Administrator’ means the Ad-
2 ministrator of the Environmental Protection Agency.

3 “(2) The term ‘eligible entity’ means—

4 “(A) a State government;

5 “(B) a local government;

6 “(C) a Tribal government;

7 “(D) an entity that conducts health re-
8 search; and

9 “(E) an academic institution.

10 “(3) The term ‘emergency period’ has the
11 meaning given to that term in section 1135(g)(1)(B)
12 of the Social Security Act.

13 “(4) The term ‘hot spot’ means a geographic
14 area where the rate of infection with a particular
15 pathogen exceeds the national average.

16 “(5) The term ‘local government’ means a
17 county, municipality, town, township, village, parish,
18 borough, or other unit of general local government.

19 “(6) The term ‘Secretary’ means the Secretary
20 of Health and Human Services.

21 “(7) The term ‘State’ means each of the several
22 States, the District of Columbia, the Commonwealth
23 of Puerto Rico, American Samoa, Guam, the Com-
24 monwealth of the Northern Mariana Islands, the

1 Virgin Islands, and the Trust Territory of the Pa-
2 cific Islands.

3 “(8) The term ‘vulnerable population’ means
4 people at increased risk of severe illness.

5 “(f) AUTHORIZATION OF APPROPRIATIONS.—To
6 carry out this section, there are authorized to be appro-
7 priated \$18,000,000 for each of fiscal years 2021 through
8 2025.”.

9 **TITLE V—ADDRESSING COVID-19**
10 **HEALTH DISPARITIES**
11 **Subtitle A—Tribal Health Data**
12 **Improvement**

13 **SEC. 5001. COLLECTION AND AVAILABILITY OF HEALTH**
14 **DATA WITH RESPECT TO INDIAN TRIBES.**

15 (a) DATA COLLECTION.—Section 3101(a)(1) of the
16 Public Health Service Act (42 U.S.C. 300kk(a)(1)) is
17 amended—

18 (1) by striking “, by not later than 2 years
19 after the date of enactment of this title,”; and

20 (2) in subparagraph (B), by inserting “Tribal,”
21 after “State,”.

22 (b) DATA REPORTING AND DISSEMINATION.—Sec-
23 tion 3101(c) of the Public Health Service Act (42 U.S.C.
24 300kk(c)) is amended—

1 (1) by amending subparagraph (F) of para-
2 graph (1) to read as follows:

3 “(F) the Indian Health Service, Indian
4 Tribes, Tribal organizations, and epidemiology
5 centers authorized under the Indian Health
6 Care Improvement Act;”; and

7 (2) in paragraph (3), by inserting “Indian
8 Tribes, Tribal organizations, and epidemiology cen-
9 ters,” after “Federal agencies,”.

10 (c) PROTECTION AND SHARING OF DATA.—Section
11 3101(e) of the Public Health Service Act (42 U.S.C.
12 300kk(e)) is amended by adding at the end the following
13 new paragraphs:

14 “(3) DATA SHARING STRATEGY.—With respect
15 to data access for Tribal epidemiology centers and
16 Tribes, the Secretary shall create a data sharing
17 strategy that takes into consideration recommenda-
18 tions by the Secretary’s Tribal Advisory Committee
19 for—

20 “(A) ensuring that Tribal epidemiology
21 centers and Indian Tribes have access to the
22 data sources necessary to accomplish their pub-
23 lic health responsibilities; and

24 “(B) protecting the privacy and security of
25 such data.

1 “(4) TRIBAL PUBLIC HEALTH AUTHORITY.—

2 “(A) AVAILABILITY.—Beginning not later
3 than 180 days after the date of the enactment
4 of the Commitment to Defeat the Virus and
5 Keep America Healthy Act, the Secretary shall
6 make available to the entities listed in subpara-
7 graph (B) all data that is collected pursuant to
8 this title with respect to health care and public
9 health surveillance programs and activities, in-
10 cluding such programs and activities that are
11 federally supported or conducted, so long as—

12 “(i) such entities request the data
13 pursuant to statute; and

14 “(ii) the data is requested for use—

15 “(I) consistent with Federal law
16 and obligations; and

17 “(II) to satisfy a particular pur-
18 pose or carry out a specific function
19 consistent with the purpose for which
20 the data was collected.

21 “(B) ENTITIES.—The entities listed in this
22 subparagraph are—

23 “(i) the Indian Health Service;

24 “(ii) Indian Tribes and Tribal organi-
25 zations; and

1 “(iii) epidemiology centers.”.

2 (d) TECHNICAL UPDATES.—Section 3101 of the
3 Public Health Service Act (42 U.S.C. 300kk) is amend-
4 ed—

5 (1) by striking subsections (g) and (h); and

6 (2) by redesignating subsection (i) as subsection
7 (h).

8 (e) DEFINITIONS.—After executing the amendments
9 made by subsection (d), section 3101 of the Public Health
10 Service Act (42 U.S.C. 300kk) is amended by inserting
11 after subsection (f) the following new subsection:

12 “(g) DEFINITIONS.—In this section:

13 “(1) The term ‘epidemiology center’ means an
14 epidemiology center established under section 214 of
15 the Indian Health Care Improvement Act, including
16 such Tribal epidemiology centers serving Indian
17 Tribes regionally and any Tribal epidemiology center
18 serving Urban Indian organizations nationally.

19 “(2) The term ‘Indian Tribe’ has the meaning
20 given to the term ‘Indian tribe’ in section 4 of the
21 Indian Self-Determination and Education Assistance
22 Act.

23 “(3) The term ‘Tribal organization’ has the
24 meaning given to the term ‘tribal organization’ in

1 section 4 of the of the Indian Self-Determination
2 and Education Assistance Act.

3 “(4) The term ‘Urban Indian organization’ has
4 the meaning given to that term in section 4 of the
5 Indian Health Care Improvement Act.”.

6 (f) TECHNICAL CORRECTION.—Section 3101(b) of
7 the Public Health Service Act (42 U.S.C. 300kk(b)) is
8 amended by striking “DATA ANALYSIS.—” and all that
9 follows through “For each federally” and inserting “DATA
10 ANALYSIS.—For each federally”.

11 **SEC. 5002. IMPROVING HEALTH STATISTICS REPORTING**
12 **WITH RESPECT TO INDIAN TRIBES.**

13 (a) TECHNICAL AID TO STATES AND LOCALITIES.—
14 Section 306(d) of the Public Health Service Act (42
15 U.S.C. 242k(d)) is amended by inserting “, Indian Tribes,
16 Tribal organizations, and epidemiology centers” after “ju-
17 risdictions”.

18 (b) COOPERATIVE HEALTH STATISTICS SYSTEM.—
19 Section 306(e)(3) of the Public Health Service Act (42
20 U.S.C. 242k(e)(3)) is amended by inserting “, Indian
21 Tribes, Tribal organizations, and epidemiology centers”
22 after “health agencies”.

23 (c) FEDERAL-STATE-TRIBAL COOPERATION.—Sec-
24 tion 306(f) of the Public Health Service Act (42 U.S.C.
25 242k(f)) is amended—

1 (1) by inserting “the Indian Health Service,”
2 before “the Departments of Commerce”;

3 (2) by inserting a comma after “the Depart-
4 ments of Commerce and Labor”;

5 (3) by inserting “, Indian Tribes, Tribal organi-
6 zations, and epidemiology centers” after “State and
7 local health departments and agencies”; and

8 (4) by striking “he shall” and inserting “the
9 Secretary shall”.

10 (d) REGISTRATION AREA RECORDS.—Section
11 306(h)(1) of the Public Health Service Act (42 U.S.C.
12 242k(h)(1)) is amended—

13 (1) by striking “in his discretion” and inserting
14 “in the discretion of the Secretary”; and

15 (2) by striking “Hispanics, Asian Americans,
16 and Pacific Islanders” and inserting “American In-
17 dians and Alaska Natives, Hispanics, Asian Ameri-
18 cans, and Native Hawaiian and other Pacific Island-
19 ers”.

20 (e) NATIONAL COMMITTEE ON VITAL AND HEALTH
21 STATISTICS.—Section 306(k) of the Public Health Service
22 Act (42 U.S.C. 242k(k)) is amended—

23 (1) in paragraph (3), by striking “, not later
24 than 60 days after the date of the enactment of the

1 Health Insurance Portability and Accountability Act
2 of 1996,” each place it appears; and

3 (2) in paragraph (7), by striking “Not later
4 than 1 year after the date of the enactment of the
5 Health Insurance Portability and Accountability Act
6 of 1996, and annually thereafter, the Committee
7 shall” and inserting “The Committee shall, on an bi-
8 ennial basis,”.

9 (f) GRANTS FOR ASSEMBLY AND ANALYSIS OF DATA
10 ON ETHNIC AND RACIAL POPULATIONS.—Section
11 306(m)(4) of the Public Health Service Act (42 U.S.C.
12 242k(m)(4)) is amended—

13 (1) in subparagraph (A)—

14 (A) by striking “Subject to subparagraph
15 (B), the” and inserting “The”; and

16 (B) by striking “and major Hispanic sub-
17 population groups and American Indians” and
18 inserting “, major Hispanic subgroups, and
19 American Indians and Alaska Natives”; and

20 (2) by amending subparagraph (B) to read as
21 follows:

22 “(B) In carrying out subparagraph (A), with respect
23 to American Indians and Alaska Natives, the Secretary
24 shall—

1 “(i) consult with Indian Tribes, Tribal organi-
2 zations, the Tribal Technical Advisory Group of the
3 Centers for Medicare & Medicaid Services main-
4 tained under section 5006(e) of the American Recov-
5 ery and Reinvestment Act of 2009, and the Tribal
6 Advisory Committee established by the Centers for
7 Disease Control and Prevention, in coordination with
8 epidemiology centers, to develop guidelines for State
9 and local health agencies to improve the quality and
10 accuracy of data with respect to the birth and death
11 records of American Indians and Alaska Natives;

12 “(ii) confer with Urban Indian organizations to
13 develop guidelines for State and local health agencies
14 to improve the quality and accuracy of data with re-
15 spect to the birth and death records of American In-
16 dians and Alaska Natives;

17 “(iii) enter into cooperative agreements with In-
18 dian Tribes, Tribal organizations, Urban Indian or-
19 ganizations, and epidemiology centers to address
20 misclassification and undersampling of American In-
21 dians and Alaska Natives with respect to—

22 “(I) birth and death records; and

23 “(II) health care and public health surveil-
24 lance systems, including, but not limited to,
25 data with respect to chronic and infectious dis-

1 eases, unintentional injuries, environmental
2 health, child and adolescent health, maternal
3 health and mortality, foodborne and waterborne
4 illness, reproductive health, and any other
5 notifiable disease or condition;

6 “(iv) encourage States to enter into data shar-
7 ing agreements with Indian Tribes, Tribal organiza-
8 tions, and epidemiology centers to improve the qual-
9 ity and accuracy of public health data; and

10 “(v) not later than 180 days after the date of
11 enactment of the Commitment to Defeat the Virus
12 and Keep America Healthy Act, and biennially
13 thereafter, issue a report on the following:

14 “(I) Which States have data sharing agree-
15 ments with Indian Tribes, Tribal organizations,
16 Urban Indian organizations, and Tribal epide-
17 miology centers to improve the quality and ac-
18 curacy of health data.

19 “(II) What the Centers for Disease Control
20 and Prevention is doing to encourage States to
21 enter into data sharing agreements with Indian
22 Tribes, Tribal organizations, Urban Indian or-
23 ganizations, and Tribal epidemiology centers to
24 improve the quality and accuracy of health
25 data.

1 “(III) Best practices and guidance for
2 States, Indian Tribes, Tribal organizations,
3 Urban Indian organizations, and Tribal epide-
4 miology centers that wish to enter into data
5 sharing agreements.

6 “(IV) Best practices and guidance for
7 local, State, Tribal, and Federal uniform stand-
8 ards for the collection of data on race and eth-
9 nicity.”.

10 (g) DEFINITIONS.—Section 306 of the Public Health
11 Service Act (42 U.S.C. 242k) is amended—

12 (1) by redesignating subsection (n) as sub-
13 section (o); and

14 (2) by inserting after subsection (m) the fol-
15 lowing:

16 “(n) In this section:

17 “(1) The term ‘epidemiology center’ means an
18 epidemiology center established under section 214 of
19 the Indian Health Care Improvement Act, including
20 such Tribal epidemiology centers serving Indian
21 Tribes regionally and any Tribal epidemiology center
22 serving Urban Indian organizations nationally.

23 “(2) The term ‘Indian Tribe’ has the meaning
24 given to the term ‘Indian tribe’ in section 4 of the

1 Indian Self-Determination and Education Assistance
2 Act.

3 “(3) The term ‘Tribal organization’ has the
4 meaning given to the term ‘tribal organization’ in
5 section 4 of the Indian Self-Determination and Edu-
6 cation Assistance Act.

7 “(4) The term ‘Urban Indian organization’ has
8 the meaning given to that term in section 4 of the
9 Indian Health Care Improvement Act.”.

10 (h) AUTHORIZATION OF APPROPRIATIONS.—Section
11 306(o) of the Public Health Service Act, as redesignated
12 by subsection (g), is amended to read as follows:

13 “(o)(1) To carry out this section, there is authorized
14 to be appropriated \$185,000,000 for each of the fiscal
15 years 2021 through 2025.

16 “(2) Of the amount authorized to be appropriated to
17 carry out this section for a fiscal year, the Secretary shall
18 not use more than 10 percent for the combined costs of—

19 “(A) administration of this section; and

20 “(B) carrying out subsection (m)(2).”.

1 **Subtitle B—Tribal Medical**
2 **Supplies Stockpile Access**

3 **SEC. 5011. PROVISION OF ITEMS TO INDIAN PROGRAMS**
4 **AND FACILITIES.**

5 (a) STRATEGIC NATIONAL STOCKPILE.—Section
6 319F–2(a)(3)(G) of the Public Health Service Act (42
7 U.S.C. 247d–6b(a)(3)(G)) is amended by inserting “, and,
8 in the case that the Secretary deploys the stockpile under
9 this subparagraph, ensure that appropriate drugs, vac-
10 cines and other biological products, medical devices, and
11 other supplies are deployed by the Secretary directly to
12 health programs or facilities operated by the Indian
13 Health Service, an Indian tribe, a tribal organization (as
14 those terms are defined in section 4 of the Indian Self-
15 Determination and Education Assistance Act (25 U.S.C.
16 5304)), or an inter-tribal consortium (as defined in section
17 501 of the Indian Self-Determination and Education As-
18 sistance Act (25 U.S.C. 5381)) or through an urban In-
19 dian organization (as defined in section 4 of the Indian
20 Health Care Improvement Act), while avoiding duplicative
21 distributions to such programs or facilities” before the
22 semicolon.

23 (b) DISTRIBUTION OF QUALIFIED PANDEMIC OR EPI-
24 DEMIC PRODUCTS TO IHS FACILITIES.—Title III of the
25 Public Health Service Act (42 U.S.C. 241 et seq.), as

1 health program, serving a high proportion of individuals
2 from racial and ethnic minority groups (as defined in sec-
3 tion 1707(g)).

4 “(c) **SCIENTIFICALLY BASED.**—Integrated health
5 care funded through this section shall be scientifically
6 based, taking into consideration the results of the most
7 recent peer-reviewed research available.

8 “(d) **AUTHORIZATION OF APPROPRIATIONS.**—To
9 carry out this section, there is authorized to be appro-
10 priated \$20,000,000 for each of the first 5 fiscal years
11 following the date of enactment of the Commitment to De-
12 feat the Virus and Keep America Healthy Act.”.

13 **SEC. 5032. ADDRESSING RACIAL AND ETHNIC MINORITY**
14 **MENTAL HEALTH DISPARITIES RESEARCH**
15 **GAPS.**

16 Not later than 6 months after the date of the enact-
17 ment of this Act, the Director of the National Institutes
18 of Health shall enter into an arrangement with the Na-
19 tional Academies of Sciences, Engineering, and Medicine
20 (or, if the National Academies of Sciences, Engineering,
21 and Medicine decline to enter into such an arrangement,
22 the Patient-Centered Outcomes Research Institute, the
23 Agency for Healthcare Research and Quality, or another
24 appropriate entity)—

1 (1) to conduct a study with respect to mental
2 health disparities in racial and ethnic minority
3 groups (as defined in section 1707(g) of the Public
4 Health Service Act (42 U.S.C. 300u-6(g))); and

5 (2) to submit to the Congress a report on the
6 results of such study, including—

7 (A) a compilation of information on the dy-
8 namics of mental disorders in such racial and
9 ethnic minority groups; and

10 (B) a compilation of information on the
11 impact of exposure to community violence, ad-
12 verse childhood experiences, structural racism,
13 and other psychological traumas on mental dis-
14 orders in such racial and minority groups.

15 **SEC. 5033. HEALTH PROFESSIONS COMPETENCIES TO AD-**
16 **DRESS RACIAL AND ETHNIC MINORITY MEN-**
17 **TAL HEALTH DISPARITIES.**

18 (a) IN GENERAL.—The Secretary of Health and
19 Human Services shall award grants to qualified national
20 organizations for the purposes of—

21 (1) developing, and disseminating to health pro-
22 fessional educational programs best practices or core
23 competencies addressing mental health disparities
24 among racial and ethnic minority groups for use in
25 the training of students in the professions of social

1 work, psychology, psychiatry, marriage and family
2 therapy, mental health counseling, and substance
3 misuse counseling; and

4 (2) certifying community health workers and
5 peer wellness specialists with respect to such best
6 practices and core competencies and integrating and
7 expanding the use of such workers and specialists
8 into health care to address mental health disparities
9 among racial and ethnic minority groups.

10 (b) BEST PRACTICES; CORE COMPETENCIES.—Orga-
11 nizations receiving funds under subsection (a) may use the
12 funds to engage in the following activities related to the
13 development and dissemination of best practices or core
14 competencies described in subsection (a)(1):

15 (1) Formation of committees or working groups
16 comprised of experts from accredited health profes-
17 sions schools to identify best practices and core com-
18 petencies relating to mental health disparities among
19 racial and ethnic minority groups.

20 (2) Planning of workshops in national fora to
21 allow for public input into the educational needs as-
22 sociated with mental health disparities among racial
23 and ethnic minority groups.

24 (3) Dissemination and promotion of the use of
25 best practices or core competencies in undergraduate

1 and graduate health professions training programs
2 nationwide.

3 (4) Establishing external stakeholder advisory
4 boards to provide meaningful input into policy and
5 program development and best practices to reduce
6 mental health disparities among racial and ethnic
7 minority groups.

8 (c) DEFINITIONS.—In this section:

9 (1) QUALIFIED NATIONAL ORGANIZATION.—The
10 term “qualified national organization” means a na-
11 tional organization that focuses on the education of
12 students in one or more of the professions of social
13 work, psychology, psychiatry, marriage and family
14 therapy, mental health counseling, and substance
15 misuse counseling.

16 (2) RACIAL AND ETHNIC MINORITY GROUP.—
17 The term “racial and ethnic minority group” has the
18 meaning given to such term in section 1707(g) of
19 the Public Health Service Act (42 U.S.C. 300u–
20 6(g)).

21 **SEC. 5034. RACIAL AND ETHNIC MINORITY BEHAVIORAL**
22 **AND MENTAL HEALTH OUTREACH AND EDU-**
23 **CATION STRATEGY.**

24 Part D of title V of the Public Health Service Act
25 (42 U.S.C. 290dd et seq.), as amended by section 5031,

1 is further amended by adding at the end the following new
2 section:

3 **“SEC. 555. BEHAVIORAL AND MENTAL HEALTH OUTREACH**
4 **AND EDUCATION STRATEGY.**

5 “(a) IN GENERAL.—The Secretary shall, in consulta-
6 tion with advocacy and behavioral and mental health orga-
7 nizations serving racial and ethnic minority groups, de-
8 velop and implement an outreach and education strategy
9 to promote behavioral and mental health and reduce stig-
10 ma associated with mental health conditions and sub-
11 stance abuse among racial and ethnic minority groups.
12 Such strategy shall—

13 “(1) be designed to—

14 “(A) meet the diverse cultural and lan-
15 guage needs of the various racial and ethnic mi-
16 nority groups; and

17 “(B) be developmentally and age-appro-
18 priate;

19 “(2) increase awareness of symptoms of mental
20 illnesses common among such groups, taking into
21 account differences within at-risk subgroups;

22 “(3) provide information on evidence-based, cul-
23 turally and linguistically appropriate and adapted
24 interventions and treatments;

1 “(4) ensure full participation of, and engage,
2 both consumers and community members in the de-
3 velopment and implementation of materials; and

4 “(5) seek to broaden the perspective among
5 both individuals in these groups and stakeholders
6 serving these groups to use a comprehensive public
7 health approach to promoting behavioral health that
8 addresses a holistic view of health by focusing on the
9 intersection between behavioral and physical health.

10 “(b) REPORTS.—Beginning not later than 1 year
11 after the date of the enactment of this section and annu-
12 ally thereafter, the Secretary shall submit to Congress,
13 and make publicly available, a report on the extent to
14 which the strategy developed and implemented under sub-
15 section (a) increased behavioral and mental health out-
16 comes associated with mental health conditions and sub-
17 stance abuse among racial and ethnic minority groups.

18 “(c) DEFINITION.—In this section, the term ‘racial
19 and ethnic minority group’ has the meaning given to that
20 term in section 1707(g).

21 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
22 is authorized to be appropriated to carry out this section
23 \$10,000,000 for each of fiscal years 2021 through 2025.”.

1 **SEC. 5035. ADDITIONAL FUNDS FOR NATIONAL INSTITUTES**
2 **OF HEALTH.**

3 (a) IN GENERAL.—In addition to amounts otherwise
4 authorized to be appropriated to the National Institutes
5 of Health, there is authorized to be appropriated to such
6 Institutes \$100,000,000 for each of fiscal years 2021
7 through 2025 to build relations with communities and con-
8 duct or support clinical research, including clinical re-
9 search on racial or ethnic disparities in physical and men-
10 tal health.

11 (b) DEFINITION.—In this section, the term “clinical
12 research” has the meaning given to such term in section
13 409 of the Public Health Service Act (42 U.S.C. 284d).

14 **SEC. 5036. ADDITIONAL FUNDS FOR NATIONAL INSTITUTE**
15 **ON MINORITY HEALTH AND HEALTH DISPARI-**
16 **TIES.**

17 In addition to amounts otherwise authorized to be ap-
18 propriated to the National Institute on Minority Health
19 and Health Disparities, there is authorized to be appro-
20 priated to such Institute \$650,000,000 for each of fiscal
21 years 2021 through 2025.

22 **PART 2—OTHER PROVISIONS**

23 **SEC. 5037. REAUTHORIZATION OF MINORITY FELLOWSHIP**
24 **PROGRAM.**

25 Section 597(c) of the Public Health Service Act (42
26 U.S.C. 2971l(c)) is amended by striking “\$12,669,000 for

1 each of fiscal years 2018 through 2022” and inserting
2 “\$25,000,000 for each of fiscal years 2021 through
3 2025”.

4 **SEC. 5038. STUDY ON THE EFFECTS OF SMARTPHONE AND**
5 **SOCIAL MEDIA USE ON ADOLESCENTS.**

6 (a) IN GENERAL.—Not later than 1 year after the
7 date of enactment of this Act, the Secretary of Health and
8 Human Services shall conduct or support research on—

9 (1) smartphone and social media use by adoles-
10 cents; and

11 (2) the effects of such use on—

12 (A) emotional, behavioral, and physical
13 health and development; and

14 (B) disparities in minority and under-
15 served populations.

16 (b) REPORT.—Not later than 5 years after the date
17 of the enactment of this Act, the Secretary shall submit
18 to the Congress, and make publicly available, a report on
19 the findings of research described in this section.

20 **SEC. 5039. TECHNICAL CORRECTION.**

21 Title V of the Public Health Service Act (42 U.S.C.
22 290aa et seq.) is amended—

23 (1) by redesignating the second section 550 of
24 such Act (42 U.S.C. 290ee–10) (relating to Sobriety

1 Treatment And Recovery Teams) as section 553;
2 and

3 (2) by moving such section 553, as so redesign-
4 nated, so as to appear after section 552 of such Act
5 (42 U.S.C. 290ee-7).

6 **Subtitle E—Maternal Health**
7 **Quality Improvement**

8 **SEC. 5041. INNOVATION FOR MATERNAL HEALTH.**

9 Part D of title III of the Public Health Service Act
10 (42 U.S.C. 254b et seq.), as amended by section 4071,
11 is further amended—

12 (1) in the section designation of section 330M
13 of such Act (42 U.S.C. 254c-19) by inserting a pe-
14 riod after “330M”; and

15 (2) by inserting after section 330N of such Act,
16 as inserted by section 4071, the following:

17 **“SEC. 3300. INNOVATION FOR MATERNAL HEALTH.**

18 “(a) IN GENERAL.—The Secretary, in consultation
19 with experts representing a variety of clinical specialties,
20 State, Tribal, or local public health officials, researchers,
21 epidemiologists, statisticians, and community organiza-
22 tions, shall establish or continue a program to award com-
23 petitive grants to eligible entities for the purposes of—

24 “(1) identifying, developing, or disseminating
25 best practices to improve maternal health care qual-

1 ity and outcomes, eliminate preventable maternal
2 mortality and severe maternal morbidity, and im-
3 prove infant health outcomes, which may include—

4 “(A) information on evidence-based prac-
5 tices to improve the quality and safety of ma-
6 ternal health care in hospitals and other health
7 care settings of a State or health care system,
8 including by addressing topics commonly associ-
9 ated with health complications or risks related
10 to prenatal care, labor care, birthing, and
11 postpartum care;

12 “(B) best practices for improving maternal
13 health care based on data findings and reviews
14 conducted by a State maternal mortality review
15 committee that address topics of relevance to
16 common complications or health risks related to
17 prenatal care, labor care, birthing, and
18 postpartum care; and

19 “(C) information on addressing deter-
20 minants of health that impact maternal health
21 outcomes for women before, during, and after
22 pregnancy;

23 “(2) collaborating with State maternal mor-
24 tality review committees to identify issues for the de-
25 velopment and implementation of evidence-based

1 practices to improve maternal health outcomes and
2 reduce preventable maternal mortality and severe
3 maternal morbidity;

4 “(3) providing technical assistance and sup-
5 porting the implementation of best practices identi-
6 fied pursuant to paragraph (1) to entities providing
7 health care services to pregnant and postpartum
8 women; and

9 “(4) identifying, developing, and evaluating new
10 models of care that improve maternal and infant
11 health outcomes, which may include the integration
12 of community-based services and clinical care.

13 “(b) ELIGIBLE ENTITIES.—To be eligible for a grant
14 under subsection (a), an entity shall—

15 “(1) submit to the Secretary an application at
16 such time, in such manner, and containing such in-
17 formation as the Secretary may require; and

18 “(2) demonstrate in such application that the
19 entity is capable of carrying out data-driven mater-
20 nal safety and quality improvement initiatives in the
21 areas of obstetrics and gynecology or maternal
22 health.

23 “(c) AUTHORIZATION OF APPROPRIATIONS.—To
24 carry out this section, there are authorized to be appro-

1 priated \$5,000,000 for each of fiscal years 2021 through
2 2025.”.

3 **SEC. 5042. TRAINING FOR HEALTH CARE PROVIDERS.**

4 Title VII of the Public Health Service Act is amended
5 by striking section 763 (42 U.S.C. 294p) and inserting
6 the following:

7 **“SEC. 763. TRAINING FOR HEALTH CARE PROVIDERS.**

8 “(a) GRANT PROGRAM.—The Secretary shall estab-
9 lish a program to award grants to accredited schools of
10 allopathic medicine, osteopathic medicine, and nursing,
11 and other health professional training programs for the
12 training of health care professionals to reduce and prevent
13 discrimination (including training related to implicit and
14 explicit biases) in the provision of health care services re-
15 lated to prenatal care, labor care, birthing, and
16 postpartum care.

17 “(b) ELIGIBILITY.—To be eligible for a grant under
18 subsection (a), an entity described in such subsection shall
19 submit to the Secretary an application at such time, in
20 such manner, and containing such information as the Sec-
21 retary may require.

22 “(c) REPORTING REQUIREMENT.—Each entity
23 awarded a grant under this section shall periodically sub-
24 mit to the Secretary a report on the status of activities

1 conducted using the grant, including a description of the
2 impact of such training on patient outcomes, as applicable.

3 “(d) BEST PRACTICES.—The Secretary may identify
4 and disseminate best practices for the training of health
5 care professionals to reduce and prevent discrimination
6 (including training related to implicit and explicit biases)
7 in the provision of health care services related to prenatal
8 care, labor care, birthing, and postpartum care.

9 “(e) AUTHORIZATION OF APPROPRIATIONS.—To
10 carry out this section, there are authorized to be appro-
11 priated \$5,000,000 for each of fiscal years 2021 through
12 2025.”.

13 **SEC. 5043. STUDY ON TRAINING TO REDUCE AND PREVENT**
14 **DISCRIMINATION.**

15 Not later than 2 years after date of enactment of this
16 Act, the Secretary of Health and Human Services shall,
17 through a contract with an independent research organiza-
18 tion, conduct a study and make recommendations for ac-
19 credited schools of allopathic medicine, osteopathic medi-
20 cine, and nursing, and other health professional training
21 programs, on best practices related to training to reduce
22 and prevent discrimination, including training related to
23 implicit and explicit biases, in the provision of health care
24 services related to prenatal care, labor care, birthing, and
25 postpartum care.

1 **SEC. 5044. PERINATAL QUALITY COLLABORATIVES.**

2 Section 317K(a)(2) of the Public Health Service Act
3 (42 U.S.C. 247b–12(a)(2)) is amended by adding at the
4 end the following:

5 “(E)(i) The Secretary, acting through the
6 Director of the Centers for Disease Control and
7 Prevention and in coordination with other of-
8 fices and agencies, as appropriate, shall estab-
9 lish or continue a competitive grant program
10 for the establishment or support of perinatal
11 quality collaboratives to improve perinatal care
12 and perinatal health outcomes for pregnant and
13 postpartum women and their infants. A State,
14 Indian Tribe, or Tribal organization may use
15 funds received through such grant to—

16 “(I) support the use of evidence-based
17 or evidence-informed practices to improve
18 outcomes for maternal and infant health;

19 “(II) work with clinical teams; ex-
20 perts; State, local, and, as appropriate,
21 Tribal public health officials; and stake-
22 holders, including patients and families, to
23 identify, develop, or disseminate best prac-
24 tices to improve perinatal care and out-
25 comes; and

1 “(III) employ strategies that provide
2 opportunities for health care professionals
3 and clinical teams to collaborate across
4 health care settings and disciplines, includ-
5 ing primary care and mental health, as ap-
6 propriate, to improve maternal and infant
7 health outcomes, which may include the
8 use of data to provide timely feedback
9 across hospital and clinical teams to in-
10 form responses, and to provide support
11 and training to hospital and clinical teams
12 for quality improvement, as appropriate.

13 “(ii) To be eligible for a grant under
14 clause (i), an entity shall submit to the Sec-
15 retary an application in such form and manner
16 and containing such information as the Sec-
17 retary may require.”.

18 **SEC. 5045. INTEGRATED SERVICES FOR PREGNANT AND**
19 **POSTPARTUM WOMEN.**

20 (a) GRANTS.—Title III of the Public Health Service
21 Act is amended by inserting after section 3300 of such
22 Act, as added by section 5041, the following:

1 **“SEC. 330P. INTEGRATED SERVICES FOR PREGNANT AND**
2 **POSTPARTUM WOMEN.**

3 “(a) IN GENERAL.—The Secretary may award grants
4 to States, Indian Tribes, and Tribal organizations for the
5 purpose of establishing or operating evidence-based or in-
6 novative, evidence-informed programs to deliver integrated
7 health care services to pregnant and postpartum women
8 to optimize the health of women and their infants, includ-
9 ing to reduce adverse maternal health outcomes, preg-
10 nancy-related deaths, and related health disparities (in-
11 cluding such disparities associated with racial and ethnic
12 minority populations), and, as appropriate, by addressing
13 issues researched under subsection (b)(2) of section 317K.

14 “(b) INTEGRATED SERVICES FOR PREGNANT AND
15 POSTPARTUM WOMEN.—

16 “(1) ELIGIBILITY.—To be eligible to receive a
17 grant under subsection (a), a State, Indian Tribe, or
18 Tribal organization shall work with relevant stake-
19 holders that coordinate care (including coordinating
20 resources and referrals for health care and social
21 services) to develop and carry out the program, in-
22 cluding—

23 “(A) State, Tribal, and local agencies re-
24 sponsible for Medicaid, public health, social
25 services, mental health, and substance use dis-
26 order treatment and services;

1 “(B) health care providers who serve preg-
2 nant and postpartum women; and

3 “(C) community-based health organiza-
4 tions and health workers, including providers of
5 home visiting services and individuals rep-
6 resenting communities with disproportionately
7 high rates of maternal mortality and severe ma-
8 ternal morbidity, and including individuals rep-
9 resenting racial and ethnic minority popu-
10 lations.

11 “(2) TERMS.—

12 “(A) PERIOD.—A grant awarded under
13 subsection (a) shall be made for a period of 5
14 years. Any supplemental award made to a
15 grantee under subsection (a) may be made for
16 a period of less than 5 years.

17 “(B) PREFERENCE.—In awarding grants
18 under subsection (a), the Secretary shall—

19 “(i) give preference to States, Indian
20 Tribes, and Tribal organizations that have
21 the highest rates of maternal mortality and
22 severe maternal morbidity relative to other
23 such States, Indian Tribes, or Tribal orga-
24 nizations, respectively; and

1 “(ii) shall consider health disparities
2 related to maternal mortality and severe
3 maternal morbidity, including such dispari-
4 ties associated with racial and ethnic mi-
5 nority populations.

6 “(C) PRIORITY.—In awarding grants
7 under subsection (a), the Secretary shall give
8 priority to applications from up to 15 entities
9 described in subparagraph (B)(i).

10 “(D) EVALUATION.—The Secretary shall
11 require grantees to evaluate the outcomes of the
12 programs supported under the grant.

13 “(c) DEFINITIONS.—In this section, the terms ‘In-
14 dian Tribe’ and ‘Tribal organization’ have the meanings
15 given the terms ‘Indian tribe’ and ‘tribal organization’, re-
16 spectively, in section 4 of the Indian Self-Determination
17 and Education Assistance Act.

18 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
19 are authorized to be appropriated to carry out this section
20 \$10,000,000 for each of fiscal years 2021 through 2025.”.

21 (b) REPORT ON GRANT OUTCOMES AND DISSEMINA-
22 TION OF BEST PRACTICES.—

23 (1) REPORT.—Not later than February 1,
24 2026, the Secretary of Health and Human Services
25 shall submit to the Committee on Health, Edu-

1 cation, Labor, and Pensions of the Senate and the
2 Committee on Energy and Commerce of the House
3 of Representatives a report that describes—

4 (A) the outcomes of the activities sup-
5 ported by the grants awarded under the amend-
6 ment made by this section on maternal and
7 child health;

8 (B) best practices and models of care used
9 by recipients of grants under such amendment;
10 and

11 (C) obstacles identified by recipients of
12 grants under such amendment, and strategies
13 used by such recipients to deliver care, improve
14 maternal and child health, and reduce health
15 disparities.

16 (2) DISSEMINATION OF BEST PRACTICES.—Not
17 later than August 1, 2026, the Secretary of Health
18 and Human Services shall disseminate information
19 on best practices and models of care used by recipi-
20 ents of grants under the amendment made by this
21 section (including best practices and models of care
22 relating to the reduction of health disparities, includ-
23 ing such disparities associated with racial and ethnic
24 minority populations, in rates of maternal mortality
25 and severe maternal morbidity) to relevant stake-

1 holders, which may include health providers, medical
2 schools, nursing schools, relevant State, Tribal, and
3 local agencies, and the general public.

4 **SEC. 5046. IMPROVING RURAL MATERNAL AND OBSTETRIC**
5 **CARE DATA.**

6 (a) **MATERNAL MORTALITY AND MORBIDITY ACTIVI-**
7 **TIES.**—Section 301(e) of the Public Health Service Act
8 (42 U.S.C. 241(e)) is amended by inserting “, preventable
9 maternal mortality and severe maternal morbidity,” after
10 “delivery”.

11 (b) **OFFICE OF WOMEN’S HEALTH.**—Section
12 310A(b)(1) of the Public Health Service Act (42 U.S.C.
13 242s(b)(1)) is amended by striking “and sociocultural con-
14 texts,” and inserting “sociocultural (including among
15 American Indians, Native Hawaiians, and Alaska Na-
16 tives), and geographical contexts”.

17 (c) **SAFE MOTHERHOOD.**—Section 317K of the Pub-
18 lic Health Service Act (42 U.S.C. 247b–12) is amended—

19 (1) in subsection (a)(2)(A), by inserting “, in-
20 cluding improving collection of data on race, eth-
21 nicity, and other demographic information” before
22 the period; and

23 (2) in subsection (b)(2)—

24 (A) in subparagraph (L), by striking
25 “and” at the end;

1 (B) by redesignating subparagraph (M) as
2 subparagraph (N); and

3 (C) by inserting after subparagraph (L)
4 the following:

5 “(M) an examination of the relationship
6 between maternal health and obstetric services
7 in rural areas and outcomes in delivery and
8 postpartum care; and”.

9 (d) OFFICE OF RESEARCH ON WOMEN’S HEALTH.—
10 Section 486 of the Public Health Service Act (42 U.S.C.
11 287d) is amended—

12 (1) in subsection (b), by amending paragraph
13 (3) to read as follows:

14 “(3) carry out paragraphs (1) and (2) with re-
15 spect to—

16 “(A) the aging process in women, with pri-
17 ority given to menopause; and

18 “(B) pregnancy, with priority given to
19 deaths related to preventable maternal mor-
20 tality and severe maternal morbidity;”; and

21 (2) in subsection (d)(4)(A)(iv), by inserting “,
22 including preventable maternal morbidity and severe
23 maternal morbidity” before the semicolon.

1 **SEC. 5047. RURAL OBSTETRIC NETWORK GRANTS.**

2 The Public Health Service Act is amended by insert-
3 ing after section 330A–1 (42 U.S.C. 254c–1a) the fol-
4 lowing:

5 **“SEC. 330A–2. RURAL OBSTETRIC NETWORK GRANTS.**

6 “(a) PROGRAM ESTABLISHED.—The Secretary shall
7 award grants or cooperative agreements to eligible entities
8 to establish collaborative improvement and innovation net-
9 works (referred to in this section as ‘rural obstetric net-
10 works’) to improve maternal and infant health outcomes
11 and reduce preventable maternal mortality and severe ma-
12 ternal morbidity by improving maternity care and access
13 to care in rural areas, frontier areas, maternity care health
14 professional target areas, or jurisdictions of Indian Tribes
15 and Tribal organizations.

16 “(b) USE OF FUNDS.—Grants or cooperative agree-
17 ments awarded pursuant to this section shall be used for
18 the establishment or continuation of collaborative improve-
19 ment and innovation networks to improve maternal health
20 in rural areas by improving infant health and maternal
21 outcomes and reducing preventable maternal mortality
22 and severe maternal morbidity. Rural obstetric networks
23 established in accordance with this section may—

24 “(1) develop a network to improve coordination
25 and increase access to maternal health care and as-
26 sist pregnant women in the areas described in sub-

1 section (a) with accessing and utilizing maternal and
2 obstetric care, including health care services related
3 to prenatal care, labor care, birthing, and
4 postpartum care to improve outcomes in birth and
5 maternal mortality and morbidity;

6 “(2) identify and implement evidence-based and
7 sustainable delivery models for maternal and obstet-
8 ric care (including health care services related to
9 prenatal care, labor care, birthing, and postpartum
10 care for women in the areas described in subsection
11 (a)), including home visiting programs and culturally
12 appropriate care models that reduce health dispari-
13 ties;

14 “(3) develop a model for maternal health care
15 collaboration between health care settings to improve
16 access to care in areas described in subsection (a),
17 which may include the use of telehealth;

18 “(4) provide training for professionals in health
19 care settings that do not have specialty maternity
20 care;

21 “(5) collaborate with academic institutions that
22 can provide regional expertise and help identify bar-
23 riers to providing maternal health care, including
24 strategies for addressing such barriers; and

1 “(6) assess and address disparities in infant
2 and maternal health outcomes, including among ra-
3 cial and ethnic minority populations and underserved
4 populations in areas described in subsection (a).

5 “(c) DEFINITIONS.—In this section:

6 “(1) ELIGIBLE ENTITIES.—The term ‘eligible
7 entities’ means entities providing maternal health
8 care services in rural areas, frontier areas, or medi-
9 cally underserved areas, or to medically underserved
10 populations or Indian Tribes or Tribal organizations.

11 “(2) FRONTIER AREA.—The term ‘frontier
12 area’ means a frontier county, as defined in section
13 1886(d)(3)(E)(iii)(III) of the Social Security Act.

14 “(3) INDIAN TRIBES; TRIBAL ORGANIZATION.—
15 The terms ‘Indian Tribe’ and ‘Tribal organization’
16 have the meanings given the terms ‘Indian tribe’ and
17 ‘tribal organization’, respectively, in section 4 of the
18 Indian Self-Determination and Education Assistance
19 Act.

20 “(4) MATERNITY CARE HEALTH PROFESSIONAL
21 TARGET AREA.—The term ‘maternity care health
22 professional target area’ has the meaning described
23 in section 332(k)(2).

1 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
2 are authorized to be appropriated to carry out this section
3 \$3,000,000 for each of fiscal years 2021 through 2025.”.

4 **SEC. 5048. TELEHEALTH NETWORK AND TELEHEALTH RE-**
5 **SOURCE CENTERS GRANT PROGRAMS.**

6 Section 330I of the Public Health Service Act (42
7 U.S.C. 254c–14) is amended—

8 (1) in subsection (f)(3), by adding at the end
9 the following:

10 “(M) Providers of maternal care, including
11 prenatal, labor care, birthing, and postpartum
12 care services and entities operating obstetric
13 care units.”; and

14 (2) in subsection (h)(1)(B), by inserting “labor
15 care, birthing care, postpartum care,” before “or
16 prenatal”.

17 **SEC. 5049. RURAL MATERNAL AND OBSTETRIC CARE**
18 **TRAINING DEMONSTRATION.**

19 Subpart 1 of part E of title VII of the Public Health
20 Service Act (42 U.S.C. 294n et seq.) is amended by adding
21 at the end the following:

22 **“SEC. 764. RURAL MATERNAL AND OBSTETRIC CARE TRAIN-**
23 **ING DEMONSTRATION.**

24 “(a) IN GENERAL.—The Secretary shall award
25 grants to accredited schools of allopathic medicine, osteo-

1 pathic medicine, and nursing, and other appropriate
2 health professional training programs, to establish a train-
3 ing demonstration program to support—

4 “(1) training for physicians, medical residents,
5 fellows, nurse practitioners, physician assistants,
6 nurses, certified nurse midwives, relevant home vis-
7 iting workforce professionals and paraprofessionals,
8 or other professionals who meet relevant State train-
9 ing and licensing requirements, as applicable, to pro-
10 vide maternal health care services in rural commu-
11 nity-based settings; and

12 “(2) developing recommendations for such
13 training programs.

14 “(b) APPLICATION.—To be eligible to receive a grant
15 under subsection (a), an entity shall submit to the Sec-
16 retary an application at such time, in such manner, and
17 containing such information as the Secretary may require.

18 “(c) ACTIVITIES.—

19 “(1) TRAINING FOR HEALTH CARE PROFES-
20 SIONALS.—A recipient of a grant under subsection
21 (a)—

22 “(A) shall use the grant funds to plan, de-
23 velop, and operate a training program to pro-
24 vide maternal health care in rural areas; and

1 “(B) may use the grant funds to provide
2 additional support for the administration of the
3 program or to meet the costs of projects to es-
4 tablish, maintain, or improve faculty develop-
5 ment, or departments, divisions, or other units
6 necessary to implement such training.

7 “(2) TRAINING PROGRAM REQUIREMENTS.—
8 The recipient of a grant under subsection (a) shall
9 ensure that training programs carried out under the
10 grant are evidence-based and address improving ma-
11 ternal health care in rural areas, and such programs
12 may include training on topics such as—

13 “(A) maternal mental health, including
14 perinatal depression and anxiety;

15 “(B) substance use disorders;

16 “(C) social determinants of health that af-
17 fect individuals living in rural areas; and

18 “(D) implicit and explicit bias.

19 “(d) EVALUATION AND REPORT.—

20 “(1) EVALUATION.—

21 “(A) IN GENERAL.—The Secretary shall
22 evaluate the outcomes of the demonstration
23 program under this section.

24 “(B) DATA SUBMISSION.—Recipients of a
25 grant under subsection (a) shall submit to the

1 Secretary performance metrics and other re-
2 lated data in order to evaluate the program for
3 the report described in paragraph (2).

4 “(2) REPORT TO CONGRESS.—Not later than
5 January 1, 2025, the Secretary shall submit to the
6 Committee on Health, Education, Labor, and Pen-
7 sions of the Senate and the Committee on Energy
8 and Commerce of the House of Representatives a re-
9 port that includes—

10 “(A) an analysis of the effects of the dem-
11 onstration program under this section on the
12 quality, quantity, and distribution of maternal
13 health care services, including health care serv-
14 ices related to prenatal care, labor care, birth-
15 ing, and postpartum care, and the demo-
16 graphics of the recipients of those services;

17 “(B) an analysis of maternal and infant
18 health outcomes (including quality of care, mor-
19 bidity, and mortality) before and after imple-
20 mentation of the program in the communities
21 served by entities participating in the dem-
22 onstration program; and

23 “(C) recommendations on whether the
24 demonstration program should be continued.

1 “(e) AUTHORIZATION OF APPROPRIATIONS.—There
2 are authorized to be appropriated to carry out this section
3 \$5,000,000 for each of fiscal years 2021 through 2025.”.

4 **TITLE VI—ADDRESSING THE IM-**
5 **PACTS OF COVID-19 ON MEN-**
6 **TAL HEALTH**

7 **Subtitle A—Creating Resources To**
8 **Improve Situations of Inherent**
9 **Severity**

10 **SEC. 6001. SET-ASIDE FOR EVIDENCE-BASED CRISIS CARE**
11 **SERVICES.**

12 Section 1920 of the Public Health Service Act (42
13 U.S.C. 300x-9) is amended—

14 (1) in subsection (a), by striking
15 “\$532,571,000 for each of fiscal years 2018 through
16 2022” and inserting “\$532,571,000 for each of fis-
17 cal years 2018 through 2020, and \$758,000,000 for
18 each of fiscal years 2021 through 2022”; and

19 (2) by adding at the end the following:

20 “(d) CRISIS CARE.—

21 “(1) IN GENERAL.—Except as provided in para-
22 graph (3), a State shall expend at least 5 percent of
23 the amount the State receives pursuant to section
24 1911 for each fiscal year to support evidenced-based
25 programs that address the crisis care needs of indi-

1 viduals with serious mental disorders, and children
2 with serious mental and emotional disturbances.

3 “(2) CORE ELEMENTS.—At the discretion of
4 the single State agency responsible for the adminis-
5 tration of the program of the State under a grant
6 under section 1911, funds expended pursuant to
7 paragraph (1) may be used to fund some or all of
8 the core crisis care service components, delivered ac-
9 cording to evidence-based principles, including the
10 following:

11 “(A) Crisis call centers.

12 “(B) 24/7 mobile crisis services.

13 “(C) Crisis stabilization programs offering
14 acute care or subacute care in a hospital or ap-
15 propriately licensed facility, as determined by
16 the Substance Abuse and Mental Health Serv-
17 ices Administration, with referrals to inpatient
18 or outpatient care.

19 “(3) STATE FLEXIBILITY.—In lieu of expending
20 5 percent of the amount the State receives pursuant
21 to section 1911 for a fiscal year to support evidence-
22 based programs as required by paragraph (1), a
23 State may elect to expend not less than 10 percent
24 of such amount to support such programs by the
25 end of two consecutive fiscal years.”.

1 **Subtitle B—Emergency Mental**
2 **Health and Substance Use**
3 **Training and Technical Assist-**
4 **ance Center**

5 **SEC. 6011. EMERGENCY MENTAL HEALTH AND SUBSTANCE**
6 **USE TRAINING AND TECHNICAL ASSISTANCE**
7 **CENTER.**

8 Subpart 3 of part B of title V of the Public Health
9 Service Act (42 U.S.C. 290bb–31 et seq.) is amended by
10 inserting after section 520A (42 U.S.C. 290bb–32) the fol-
11 lowing:

12 **“SEC. 520B. EMERGENCY MENTAL HEALTH AND SUB-**
13 **STANCE USE TRAINING AND TECHNICAL AS-**
14 **SISTANCE CENTER.**

15 “(a) ESTABLISHMENT.—The Secretary, acting
16 through the Assistant Secretary, shall establish or operate
17 a center to be known as the Emergency Mental Health
18 and Substance Use Training and Technical Assistance
19 Center (referred to in this section as the ‘Center’) to pro-
20 vide technical assistance and support—

21 “(1) to public or nonprofit entities seeking to
22 establish or expand access to mental health and sub-
23 stance use prevention, treatment, and recovery sup-
24 port services, and increase awareness of such serv-
25 ices; and

1 “(2) to public health professionals, health care
2 professionals and support staff, essential workers (as
3 defined by a State, Tribe, locality, or territory), and
4 members of the public to address the trauma, stress,
5 and mental health needs associated with an emer-
6 gency period.

7 “(b) ASSISTANCE AND SUPPORT.—The assistance
8 and support provided under subsection (a) shall include
9 assistance and support with respect to—

10 “(1) training on identifying signs of trauma,
11 stress, and mental health needs;

12 “(2) providing accessible resources to assist in-
13 dividuals and families experiencing trauma, stress,
14 or other mental health needs during and after an
15 emergency period;

16 “(3) providing resources for substance use dis-
17 order prevention, treatment, and recovery designed
18 to assist individuals and families during and after an
19 emergency period;

20 “(4) the provision of language access services,
21 including translation services, interpretation, or
22 other such services for individuals with limited
23 English speaking proficiency or individuals with dis-
24 abilities; and

1 “(5) evaluation and improvement, as necessary,
2 of the effectiveness of such services provided by pub-
3 lic or nonprofit entities.

4 “(c) BEST PRACTICES.—The Center shall periodi-
5 cally issue best practices for use by organizations seeking
6 to provide mental health services or substance use disorder
7 prevention, treatment, or recovery services, including best
8 practices for the following special populations:

9 “(1) Incarcerated individuals.

10 “(2) Children.

11 “(3) Pregnant women.

12 “(4) Underserved populations.

13 “(5) Communities of color.

14 “(6) Health care providers and essential work-
15 ers.

16 “(d) EMERGENCY PERIOD.—In this section, the term
17 ‘emergency period’ has the meaning given such term in
18 section 1135(g)(1)(A) of the Social Security Act.

19 “(e) AUTHORIZATION OF APPROPRIATIONS.—There
20 is authorized to be appropriated to carry out this section
21 \$20,000,000 for each of fiscal years 2021 and 2022.”.

1 **Subtitle C—Suicide Prevention**
2 **Grants**

3 **SEC. 6021. SYNDROMIC SURVEILLANCE OF SELF-HARM BE-**
4 **HAVIORS PROGRAM.**

5 Title III of the Public Health Service Act is amended
6 by inserting after section 317U of such Act (42 U.S.C.
7 247b–23) the following:

8 **“SEC. 317V. SYNDROMIC SURVEILLANCE OF SELF-HARM BE-**
9 **HAVIORS PROGRAM.**

10 “(a) IN GENERAL.—The Secretary shall award
11 grants to State, local, Tribal, and territorial public health
12 departments for the expansion of surveillance of self-harm.

13 “(b) DATA SHARING BY GRANTEES.—As a condition
14 of receipt of such grant under subsection (a), each grantee
15 shall agree to share with the Centers for Disease Control
16 and Prevention in real time, to the extent feasible and as
17 specified in the grant agreement, data on suicides and self-
18 harm for purposes of—

19 “(1) tracking and monitoring self-harm to in-
20 form response activities to suicide clusters;

21 “(2) informing prevention programming for
22 identified at-risk populations; and

23 “(3) conducting or supporting research.

24 “(c) DISAGGREGATION OF DATA.—The Secretary
25 shall provide for the data collected through surveillance

1 of self-harm under subsection (b) to be disaggregated by
2 the following categories:

3 “(1) Nonfatal self-harm data of any intent.

4 “(2) Data on suicidal ideation.

5 “(3) Data on self-harm where there is no evi-
6 dence, whether implicit or explicit, of suicidal intent.

7 “(4) Data on self-harm where there is evidence,
8 whether implicit or explicit, of suicidal intent.

9 “(5) Data on self-harm where suicidal intent is
10 unclear based on the available evidence.

11 “(d) PRIORITY.—In making awards under subsection
12 (a), the Secretary shall give priority to eligible entities that
13 are—

14 “(1) located in a State with an age-adjusted
15 rate of nonfatal suicidal behavior that is above the
16 national rate of nonfatal suicidal behavior, as deter-
17 mined by the Director of the Centers for Disease
18 Control and Prevention;

19 “(2) serving an Indian Tribe (as defined in sec-
20 tion 4 of the Indian Self-Determination and Edu-
21 cation Assistance Act) with an age-adjusted rate of
22 nonfatal suicidal behavior that is above the national
23 rate of nonfatal suicidal behavior, as determined
24 through appropriate mechanisms determined by the
25 Secretary in consultation with Indian Tribes; or

1 “(3) located in a State with a high rate of cov-
2 erage of statewide (or Tribal) emergency department
3 visits, as determined by the Director of the Centers
4 for Disease Control and Prevention.

5 “(e) GEOGRAPHIC DISTRIBUTION.—In making
6 grants under this section, the Secretary shall make an ef-
7 fort to ensure geographic distribution, taking into account
8 the unique needs of rural communities, including—

9 “(1) communities with an incidence of individ-
10 uals with serious mental illness, demonstrated suici-
11 dal ideation or behavior, or suicide rates that are
12 above the national average, as determined by the As-
13 sistant Secretary for Mental Health and Substance
14 Use;

15 “(2) communities with a shortage of prevention
16 and treatment services, as determined by the Assist-
17 ant Secretary for Mental Health and Substance Use
18 and the Administrator of the Health Resources and
19 Services Administration; and

20 “(3) other appropriate community-level factors
21 and social determinants of health such as income,
22 employment, and education.

23 “(f) PERIOD OF PARTICIPATION.—To be selected as
24 a grant recipient under this section, a State, local, Tribal,
25 or territorial public health department shall agree to par-

1 ticipate in the program for a period of not less than 4
2 years.

3 “(g) TECHNICAL ASSISTANCE.—The Secretary shall
4 provide technical assistance and training to grantees for
5 collecting and sharing the data under subsection (b).

6 “(h) DATA SHARING BY HHS.—Subject to sub-
7 section (b), the Secretary shall, with respect to data on
8 self-harm that is collected pursuant to this section, share
9 and integrate such data through—

10 “(1) the National Syndromic Surveillance Pro-
11 gram’s Early Notification of Community Epidemics
12 (ESSENCE) platform (or any successor platform);

13 “(2) the National Violent Death Reporting Sys-
14 tem, as appropriate; or

15 “(3) another appropriate surveillance program,
16 including such a program that collects data on sui-
17 cides and self-harm among special populations, such
18 as members of the military and veterans.

19 “(i) RULE OF CONSTRUCTION REGARDING APPLICA-
20 BILITY OF PRIVACY PROTECTIONS.—Nothing in this sec-
21 tion shall be construed to limit or alter the application
22 of Federal or State law relating to the privacy of informa-
23 tion to data or information that is collected or created
24 under this section.

25 “(j) REPORT.—

1 “(1) SUBMISSION.—Not later than 3 years
2 after the date of enactment of this Act, the Sec-
3 retary shall evaluate the suicide and self-harm
4 syndromic surveillance systems at the Federal,
5 State, and local levels and submit a report to Con-
6 gress on the data collected under subsections (b) and
7 (c) in a manner that prevents the disclosure of indi-
8 vidually identifiable information, at a minimum, con-
9 sistent with all applicable privacy laws and regula-
10 tions.

11 “(2) CONTENTS.—In addition to the data col-
12 lected under subsections (b) and (c), the report
13 under paragraph (1) shall include—

14 “(A) challenges and gaps in data collection
15 and reporting;

16 “(B) recommendations to address such
17 gaps and challenges; and

18 “(C) a description of any public health re-
19 sponses initiated at the Federal, State, or local
20 level in response to the data collected.

21 “(k) AUTHORIZATION OF APPROPRIATIONS.—To
22 carry out this section, there are authorized to be appro-
23 priated \$20,000,000 for each of fiscal years 2021 through
24 2025.”.

1 **SEC. 6022. GRANTS TO PROVIDE SELF-HARM AND SUICIDE**
2 **PREVENTION SERVICES.**

3 Part B of title V of the Public Health Service Act
4 (42 U.S.C. 290aa et seq.) is amended by adding at the
5 end the following:

6 **“SEC. 520N. GRANTS TO PROVIDE SELF-HARM AND SUICIDE**
7 **PREVENTION SERVICES.**

8 “(a) IN GENERAL.—The Secretary of Health and
9 Human Services shall award grants to hospital emergency
10 departments to provide self-harm and suicide prevention
11 services.

12 “(b) ACTIVITIES SUPPORTED.—

13 “(1) IN GENERAL.—A hospital emergency de-
14 partment awarded a grant under subsection (a) shall
15 use amounts under the grant to implement a pro-
16 gram or protocol to better prevent suicide attempts
17 among hospital patients after discharge, which may
18 include—

19 “(A) screening patients for self-harm and
20 suicide in accordance with the standards of
21 practice described in subsection (e)(1) and
22 standards of care established by appropriate
23 medical and advocacy organizations;

24 “(B) providing patients short-term self-
25 harm and suicide prevention services in accord-

1 ance with the results of the screenings de-
2 scribed in subparagraph (A); and

3 “(C) referring patients, as appropriate, to
4 a health care facility or provider for purposes of
5 receiving long-term self-harm and suicide pre-
6 vention services, and providing any additional
7 follow up services and care identified as appro-
8 priate as a result of the screenings and short-
9 term self-harm and suicide prevention services
10 described in subparagraphs (A) and (B).

11 “(2) USE OF FUNDS TO HIRE AND TRAIN
12 STAFF.—Amounts awarded under subsection (a)
13 may be used to hire clinical social workers, mental
14 and behavioral health care professionals, and sup-
15 port staff as appropriate, and to train existing staff
16 and newly hired staff to carry out the activities de-
17 scribed in paragraph (1).

18 “(c) GRANT TERMS.—A grant awarded under sub-
19 section (a)—

20 “(1) shall be for a period of 3 years; and

21 “(2) may be renewed subject to the require-
22 ments of this section.

23 “(d) APPLICATIONS.—A hospital emergency depart-
24 ment seeking a grant under subsection (a) shall submit
25 an application to the Secretary at such time, in such man-

1 ner, and accompanied by such information as the Sec-
2 retary may require.

3 “(e) STANDARDS OF PRACTICE.—

4 “(1) IN GENERAL.—Not later than 180 days
5 after the date of the enactment of this section, the
6 Secretary shall develop standards of practice for
7 screening patients for self-harm and suicide for pur-
8 poses of carrying out subsection (b)(1)(C).

9 “(2) CONSULTATION.—The Secretary shall de-
10 velop the standards of practice described in para-
11 graph (1) in consultation with individuals and enti-
12 ties with expertise in self-harm and suicide preven-
13 tion, including public, private, and non-profit enti-
14 ties.

15 “(f) REPORTING.—

16 “(1) REPORTS TO THE SECRETARY.—

17 “(A) IN GENERAL.—A hospital emergency
18 department awarded a grant under subsection
19 (a) shall, at least quarterly for the duration of
20 the grant, submit to the Secretary a report
21 evaluating the activities supported by the grant.

22 “(B) MATTERS TO BE INCLUDED.—The
23 report required under subparagraph (A) shall
24 include—

1 “(i) the number of patients receiv-
2 ing—

3 “(I) screenings carried out at the
4 hospital emergency department;

5 “(II) short-term self-harm and
6 suicide prevention services at the hos-
7 pital emergency department; and

8 “(III) referrals to health care fa-
9 cilities for the purposes of receiving
10 long-term self-harm and suicide pre-
11 vention;

12 “(ii) information on the adherence of
13 the hospital emergency department to the
14 standards of practice described in sub-
15 section (f)(1); and

16 “(iii) other information as the Sec-
17 retary determines appropriate to evaluate
18 the use of grant funds.

19 “(2) REPORTS TO CONGRESS.—Not later than
20 2 years after the date of the enactment of the Com-
21 mitment to Defeat the Virus and Keep America
22 Healthy Act, and biennially thereafter, the Secretary
23 shall submit to the Committee on Health, Edu-
24 cation, Labor, and Pensions of the Senate and the
25 Committee on Energy and Commerce of the House

1 of Representatives a report on the grant program
2 under this section, including—

3 “(A) a summary of reports received by the
4 Secretary under paragraph (1); and

5 “(B) an evaluation of the program by the
6 Secretary.

7 “(g) AUTHORIZATION OF APPROPRIATIONS.—To
8 carry out this section, there are authorized to be appro-
9 priated \$30,000,000 for each of fiscal years 2021 through
10 2025.”.

11 **Subtitle D—Effective Suicide**
12 **Screening in the Emergency De-**
13 **partment**

14 **SEC. 6031. PROGRAM TO IMPROVE THE CARE PROVIDED TO**
15 **PATIENTS IN THE EMERGENCY DEPARTMENT**
16 **WHO ARE AT RISK OF SUICIDE.**

17 Part P of title III of the Public Health Service Act
18 (42 U.S.C. 280g et seq.) is amended by adding at the end
19 the following new section:

20 **“SEC. 399V-7. PROGRAM TO IMPROVE THE CARE PROVIDED**
21 **TO PATIENTS IN THE EMERGENCY DEPART-**
22 **MENT WHO ARE AT RISK OF SUICIDE.**

23 “(a) IN GENERAL.—The Secretary shall establish a
24 program (in this section referred to as the ‘Program’) to
25 improve the identification, assessment, and treatment of

1 patients in emergency departments who are at risk for sui-
2 cide, including by—

3 “(1) developing policies and procedures for
4 identifying and assessing individuals who are at risk
5 of suicide; and

6 “(2) enhancing the coordination of care for
7 such individuals after discharge.

8 “(b) GRANT ESTABLISHMENT AND PARTICIPA-
9 TION.—

10 “(1) IN GENERAL.—In carrying out the Pro-
11 gram, the Secretary shall award grants on a com-
12 petitive basis to not more than 40 eligible health
13 care sites described in paragraph (2).

14 “(2) ELIGIBILITY.—To be eligible for a grant
15 under this section, a health care site shall—

16 “(A) submit an application to the Sec-
17 retary at such time, in such manner, and con-
18 taining such information as the Secretary may
19 specify;

20 “(B) be a hospital (as defined in section
21 1861(e) of the Social Security Act);

22 “(C) have an emergency department; and

23 “(D) deploy onsite health care or social
24 service professionals to help connect and inte-

1 grate patients who are at risk of suicide with
2 treatment and mental health support services.

3 “(3) PREFERENCE.—In awarding grants under
4 this section, the Secretary may give preference to eli-
5 gible health care sites described in paragraph (2)
6 that meet at least one of the following criteria:

7 “(A) The eligible health care site is a crit-
8 ical access hospital (as defined in section
9 1861(mm)(1) of the Social Security Act).

10 “(B) The eligible health care site is a sole
11 community hospital (as defined in section
12 1886(d)(5)(D)(iii) of the Social Security Act).

13 “(C) The eligible health care site is oper-
14 ated by the Indian Health Service, by an Indian
15 tribe or tribal organization (as such terms are
16 defined in section 4 of the Indian Self-Deter-
17 mination and Education Assistance Act), or by
18 an urban Indian organization (as defined in
19 section 4 of the Indian Health Care Improve-
20 ment Act).

21 “(D) The eligible health care site is located
22 in a geographic area with a suicide rate that is
23 higher than the national rate, as determined by
24 the Secretary based on the most recent data

1 from the Centers for Disease Control and Pre-
2 vention.

3 “(c) PERIOD OF GRANT.—A grant awarded to an eli-
4 gible health care site under this section shall be for a pe-
5 riod of at least 2 years.

6 “(d) GRANT USES.—

7 “(1) REQUIRED USES.—A grant awarded under
8 this section to an eligible health care site shall be
9 used for the following purposes:

10 “(A) To train emergency department
11 health care professionals to identify, assess, and
12 treat patients who are at risk of suicide.

13 “(B) To establish and implement policies
14 and procedures for emergency departments to
15 improve the identification, assessment and
16 treatment of individuals who are at risk of sui-
17 cide.

18 “(C) To establish and implement policies
19 and procedures with respect to care coordina-
20 tion, integrated care models, or referral to evi-
21 dence-based treatment to be used upon the dis-
22 charge from the emergency department of pa-
23 tients who are at risk of suicide.

24 “(2) ADDITIONAL PERMISSIBLE USES.—In ad-
25 dition to the required uses listed in paragraph (1),

1 a grant awarded under this section to an eligible
2 health care site may be used for any of the following
3 purposes:

4 “(A) To hire emergency department psy-
5 chiatrists, psychologists, nurse practitioners,
6 counselors, therapists, or other licensed health
7 care and behavioral health professionals special-
8 izing in the treatment of individuals at risk of
9 suicide.

10 “(B) To develop and implement best prac-
11 tices for the follow-up care and long-term treat-
12 ment of individuals who are at risk of suicide.

13 “(C) To increase the availability of and ac-
14 cess to evidence-based treatment for individuals
15 who are at risk of suicide, including through
16 telehealth services and strategies to reduce the
17 boarding of these patients in emergency depart-
18 ments.

19 “(D) To offer consultation with and refer-
20 ral to other supportive services that provide evi-
21 dence-based treatment and recovery for individ-
22 uals who are at risk of suicide.

23 “(e) REPORTING REQUIREMENTS.—

24 “(1) REPORTS BY GRANTEES.—Each eligible
25 health care site receiving a grant under this section

1 shall submit to the Secretary an annual report for
2 each year for which the grant is received on the
3 progress of the program funded through the grant.

4 Each such report shall include information on—

5 “(A) the number of individuals screened in
6 the site’s emergency department for being at
7 risk of suicide;

8 “(B) the number of individuals identified
9 in the site’s emergency department as being—

10 “(i) survivors of an attempted suicide;

11 or

12 “(ii) are at risk of suicide;

13 “(C) the number of individuals who are
14 identified in the site’s emergency department as
15 being at risk of suicide by a health care or be-
16 havioral health professional hired pursuant to
17 subsection (d)(2)(A);

18 “(D) the number of individuals referred by
19 the site’s emergency department to other treat-
20 ment facilities, the types of such other facilities,
21 and the number of such individuals admitted to
22 such other facilities pursuant to such referrals;

23 “(E) the effectiveness of programs and ac-
24 tivities funded through the grant in preventing
25 suicides and suicide attempts; and

1 “(F) any other relevant additional data re-
2 garding the programs and activities funded
3 through the grant.

4 “(2) REPORT BY SECRETARY.—Not later than
5 one year after the end of fiscal year 2025, the Sec-
6 retary shall submit to Congress a report that in-
7 cludes—

8 “(A) findings on the Program;

9 “(B) overall patient outcomes achieved
10 through the Program;

11 “(C) an evaluation of the effectiveness of
12 having a trained health care or behavioral
13 health professional onsite to identify, assess,
14 and treat patients who are at risk of suicide;
15 and

16 “(D) a compilation of policies, procedures,
17 and best practices established, developed, or im-
18 plemented by grantees under this section.

19 “(f) AUTHORIZATION OF APPROPRIATIONS.—There
20 is authorized to be appropriated to carry out this section
21 \$20,000,000 for the period of fiscal years 2021 through
22 2025.”.

1 **Subtitle E—Suicide Prevention**
2 **Lifeline Improvement**

3 **SEC. 6041. SUICIDE PREVENTION LIFELINE.**

4 (a) PLAN.—Section 520E-3 of the Public Health
5 Service Act (42 U.S.C. 290bb-36c) is amended—

6 (1) by redesignating subsection (c) as sub-
7 section (e); and

8 (2) by inserting after subsection (b) the fol-
9 lowing:

10 “(c) PLAN.—

11 “(1) IN GENERAL.—For purposes of maintain-
12 ing the suicide prevention hotline under subsection
13 (b)(2), the Secretary shall develop and implement a
14 plan to ensure the provision of high-quality service.

15 “(2) CONTENTS.—The plan required by para-
16 graph (1) shall include the following:

17 “(A) Quality assurance provisions, includ-
18 ing—

19 “(i) clearly defined and measurable
20 performance indicators and objectives to
21 improve the responsiveness and perform-
22 ance of the hotline, including at backup
23 call centers; and

1 “(ii) quantifiable timeframes to track
2 the progress of the hotline in meeting such
3 performance indicators and objectives.

4 “(B) Standards that crisis centers and
5 backup centers must meet—

6 “(i) to participate in the network
7 under subsection (b)(1); and

8 “(ii) to ensure that each telephone
9 call, online chat message, and other com-
10 munication received by the hotline, includ-
11 ing at backup call centers, is answered in
12 a timely manner by a person, consistent
13 with the guidance established by the Amer-
14 ican Association of Suicidology or other
15 guidance determined by the Secretary to be
16 appropriate.

17 “(C) Guidelines for crisis centers and
18 backup centers to implement evidence-based
19 practices including with respect to followup and
20 referral to other health and social services re-
21 sources.

22 “(D) Guidelines to ensure that resources
23 are available and distributed to individuals
24 using the hotline who are not personally in a
25 time of crisis but know of someone who is.

1 “(E) Guidelines to carry out periodic test-
2 ing of the hotline, including at crisis centers
3 and backup centers, during each fiscal year to
4 identify and correct any problems in a timely
5 manner.

6 “(F) Guidelines to operate in consultation
7 with the State department of health, local gov-
8 ernments, Indian tribes, and tribal organiza-
9 tions.

10 “(3) INITIAL PLAN; UPDATES.—The Secretary
11 shall—

12 “(A) not later than 6 months after the
13 date of enactment of the Commitment to Defeat
14 the Virus and Keep America Healthy Act, com-
15 plete development of the initial version of the
16 plan required by paragraph (1), begin imple-
17 mentation of such plan, and make such plan
18 publicly available; and

19 “(B) periodically thereafter, update such
20 plan and make the updated plan publicly avail-
21 able.”.

22 (b) TRANSMISSION OF DATA TO CDC.—Section
23 520E–3 of the Public Health Service Act (42 U.S.C.
24 290bb–36c) is amended by inserting after subsection (c)

1 of such section, as added by subsection (a) of this section,
2 the following:

3 “(d) TRANSMISSION OF DATA TO CDC.—The Sec-
4 retary shall formalize and strengthen agreements between
5 the National Suicide Prevention Lifeline program and the
6 Centers for Disease Control and Prevention to transmit
7 any necessary epidemiological data from the program to
8 the Centers, including local call center data, to assist the
9 Centers in suicide prevention efforts.”.

10 (c) AUTHORIZATION OF APPROPRIATIONS.—Sub-
11 section (e) of section 520E–3 of the Public Health Service
12 Act (42 U.S.C. 290bb–36e) is amended to read as follows:

13 “(e) AUTHORIZATION OF APPROPRIATIONS.—

14 “(1) IN GENERAL.—To carry out this section,
15 there are authorized to be appropriated \$50,000,000
16 for each of fiscal years 2021 through 2023.

17 “(2) ALLOCATION.—Of the amount authorized
18 to be appropriated by paragraph (1) for each of fis-
19 cal years 2021 through 2023, at least 80 percent
20 shall be made available to crisis centers.”.

21 **SEC. 6042. PILOT PROGRAM ON INNOVATIVE TECH-**
22 **NOLOGIES.**

23 (a) PILOT PROGRAM.—

24 (1) IN GENERAL.—The Secretary of Health and
25 Human Services, acting through the Assistant Sec-

1 retary for Mental Health and Substance Use, shall
2 carry out a pilot program to research, analyze, and
3 employ various technologies and platforms of com-
4 munication (including social media platforms,
5 texting platforms, and email platforms) for suicide
6 prevention in addition to the telephone and online
7 chat service provided by the Suicide Prevention Life-
8 line.

9 (2) AUTHORIZATION OF APPROPRIATIONS.—To
10 carry out paragraph (1), there is authorized to be
11 appropriated \$5,000,000 for the period of fiscal
12 years 2021 and 2022.

13 (b) REPORT.—Not later than 24 months after the
14 date on which the pilot program under subsection (a) com-
15 mences, the Secretary of Health and Human Services, act-
16 ing through the Assistant Secretary for Mental Health
17 and Substance Use, shall submit to the Congress a report
18 on the pilot program. With respect to each platform of
19 communication employed pursuant to the pilot program,
20 the report shall include—

21 (1) a full description of the program;

22 (2) the number of individuals served by the pro-
23 gram;

24 (3) the average wait time for each individual to
25 receive a response;

1 (4) the cost of the program, including the cost
2 per individual served; and

3 (5) any other information the Secretary deter-
4 mines appropriate.

5 **SEC. 6043. HHS STUDY AND REPORT.**

6 Not later than 24 months after the Secretary of
7 Health and Human Services begins implementation of the
8 plan required by section 520E–3(c) of the Public Health
9 Service Act, as added by section 6041(a)(2) of this sub-
10 title, the Secretary shall—

11 (1) complete a study on—

12 (A) the implementation of such plan, in-
13 cluding the progress towards meeting the objec-
14 tives identified pursuant to paragraph (2)(A)(i)
15 of such section 520E–3(c) by the timeframes
16 identified pursuant to paragraph (2)(A)(ii) of
17 such section 520E–3(c); and

18 (B) in consultation with the Director of
19 the Centers for Disease Control and Prevention,
20 options to expand data gathering from calls to
21 the Suicide Prevention Lifeline in order to bet-
22 ter track aspects of usage such as repeat calls,
23 consistent with applicable Federal and State
24 privacy laws; and

1 (2) submit a report to the Congress on the re-
2 sults of such study, including recommendations on
3 whether additional legislation or appropriations are
4 needed.

5 **SEC. 6044. GAO STUDY AND REPORT.**

6 (a) IN GENERAL.—Not later than 24 months after
7 the Secretary of Health and Human Services begins imple-
8 mentation of the plan required by section 520E–3(e) of
9 the Public Health Service Act, as added by section
10 6041(a)(2) of this subtitle, the Comptroller General of the
11 United States shall—

12 (1) complete a study on the Suicide Prevention
13 Lifeline; and

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

16 (b) ISSUES TO BE STUDIED.—The study required by
17 subsection (a) shall address—

18 (1) the feasibility of geolocating callers to direct
19 calls to the nearest crisis center;

20 (2) operation shortcomings of the Suicide Pre-
21 vention Lifeline;

22 (3) geographic coverage of each crisis call cen-
23 ter;

24 (4) the call answer rate of each crisis call cen-
25 ter;

1 (5) the call wait time of each crisis call center;

2 (6) the hours of operation of each crisis call
3 center;

4 (7) funding avenues of each crisis call center;

5 (8) the implementation of the plan under sec-
6 tion 520E-3(c) of the Public Health Service Act, as
7 added by section 6041(a) of this subtitle, including
8 the progress towards meeting the objectives identi-
9 fied pursuant to paragraph (2)(A)(i) of such section
10 520E-3(c) by the timeframes identified pursuant to
11 paragraph (2)(A)(ii) of such section 520E-3(c); and

12 (9) service to individuals requesting a foreign
13 language speaker, including—

14 (A) the number of calls or chats the Life-
15 line receives from individuals speaking a foreign
16 language;

17 (B) the capacity of the Lifeline to handle
18 these calls or chats; and

19 (C) the number of crisis centers with the
20 capacity to serve foreign language speakers, in
21 house.

22 (c) RECOMMENDATIONS.—The report required by
23 subsection (a) shall include recommendations for improv-
24 ing the Suicide Prevention Lifeline, including rec-
25 ommendations for legislative and administrative actions.

1 **SEC. 6045. DEFINITION.**

2 In this subtitle, the term “Suicide Prevention Life-
3 line” means the suicide prevention hotline maintained pur-
4 suant to section 520E–3 of the Public Health Service Act
5 (42 U.S.C. 290bb–36c).

6 **Subtitle F—Campaign To Prevent**
7 **Suicide**

8 **SEC. 6051. NATIONAL SUICIDE PREVENTION LIFELINE.**

9 Section 520E–3(b)(2) of the Public Health Service
10 Act (42 U.S.C. 290bb–36c(b)(2)) is amended by inserting
11 after “suicide prevention hotline” the following: “, which,
12 beginning not later than one year after the date of the
13 enactment of the Commitment to Defeat the Virus and
14 Keep America Healthy Act, shall be a 3-digit nationwide
15 toll-free telephone number,”.

16 **SEC. 6052. NATIONAL SUICIDE PREVENTION MEDIA CAM-**
17 **PAIGN.**

18 (a) NATIONAL SUICIDE PREVENTION MEDIA CAM-
19 PAIGN.—

20 (1) IN GENERAL.—Not later than the date that
21 is three years after the date of the enactment of this
22 Act, the Secretary of Health and Human Services
23 (referred to in this section as the “Secretary”), in
24 coordination with the Assistant Secretary for Mental
25 Health and Substance Use (referred to in this sec-
26 tion as the “Assistant Secretary”) and the Director

1 of the Centers for Disease Control and Prevention
2 (referred to in this section as the “Director”), shall
3 conduct a national suicide prevention media cam-
4 paign (referred to in this section as the “national
5 media campaign”), in accordance with the require-
6 ments of this section, for purposes of—

7 (A) preventing suicide in the United
8 States;

9 (B) educating families, friends, and com-
10 munities on how to address suicide and suicidal
11 thoughts, including when to encourage individ-
12 uals with suicidal risk to seek help; and

13 (C) increasing awareness of suicide preven-
14 tion resources of the Centers for Disease Con-
15 trol and Prevention and the Substance Abuse
16 and Mental Health Services Administration (in-
17 cluding the suicide prevention hotline main-
18 tained under section 520E–3 of the Public
19 Health Service Act (42 U.S.C. 290bb–36c)),
20 any suicide prevention mobile application of the
21 Centers for Disease Control and Prevention or
22 the Substance Abuse Mental Health Services
23 Administration, and other support resources de-
24 termined appropriate by the Secretary.

1 (2) ADDITIONAL CONSULTATION.—In addition
2 to coordinating with the Assistant Secretary and the
3 Director under this section, the Secretary shall con-
4 sult with, as appropriate, State, local, Tribal, and
5 territorial health departments, primary health care
6 providers, hospitals with emergency departments,
7 mental and behavioral health services providers, cri-
8 sis response services providers, first responders, sui-
9 cide prevention and mental health professionals, pa-
10 tient advocacy groups, survivors of suicide attempts,
11 and representatives of television and social media
12 platforms in planning the national media campaign
13 to be conducted under paragraph (1).

14 (b) TARGET AUDIENCES.—

15 (1) TAILORING ADVERTISEMENTS AND OTHER
16 COMMUNICATIONS.—In conducting the national
17 media campaign under subsection (a)(1), the Sec-
18 retary may tailor culturally competent advertise-
19 ments and other communications of the campaign
20 across all available media for a target audience
21 (such as a particular geographic location or demo-
22 graphic) across the lifespan.

23 (2) TARGETING CERTAIN LOCAL AREAS.—The
24 Secretary shall, to the maximum extent practicable,
25 use amounts made available under subsection (f) for

1 media that targets individuals in local areas with
2 higher suicide rates.

3 (c) USE OF FUNDS.—

4 (1) REQUIRED USES.—

5 (A) IN GENERAL.—The Secretary shall, to
6 the extent reasonably feasible with the funds
7 made available under subsection (f), carry out
8 the following, with respect to the national media
9 campaign:

10 (i) The purchase of advertising time
11 and space, including the strategic planning
12 for, and accounting of, any such purchase.

13 (ii) Creative services and talent costs.

14 (iii) Advertising production costs.

15 (iv) Testing and evaluation of adver-
16 tising.

17 (v) Evaluation of the effectiveness of
18 the national media campaign.

19 (vi) Operational and management ex-
20 penses.

21 (vii) The creation of an educational
22 toolkit for television and social media plat-
23 forms to use in discussing suicide and rais-
24 ing awareness about how to prevent sui-
25 cide.

1 (B) SPECIFIC REQUIREMENTS.—

2 (i) TESTING AND EVALUATION OF AD-
3 VERTISING.—In testing and evaluating ad-
4 vertising under subparagraph (A)(iv), the
5 Secretary shall test all advertisements
6 after use in the national media campaign
7 to evaluate the extent to which such adver-
8 tisements have been effective in carrying
9 out the purposes of the national media
10 campaign.

11 (ii) EVALUATION OF EFFECTIVENESS
12 OF NATIONAL MEDIA CAMPAIGN.—In eval-
13 uating the effectiveness of the national
14 media campaign under subparagraph
15 (A)(v), the Secretary shall take into ac-
16 count—

17 (I) the number of unique calls
18 that are made to the suicide preven-
19 tion hotline maintained under section
20 520E–3 of the Public Health Service
21 Act (42 U.S.C. 290bb–36c) and as-
22 sess whether there are any State and
23 regional variations with respect to the
24 capacity to answer such calls;

1 (II) the number of unique en-
2 counters with suicide prevention and
3 support resources of the Centers for
4 Disease Control and Prevention and
5 the Substance Abuse and Mental
6 Health Services Administration and
7 assess engagement with such suicide
8 prevention and support resources;

9 (III) whether the national media
10 campaign has contributed to increased
11 awareness that suicidal individuals
12 should be engaged, rather than ig-
13 nored; and

14 (IV) such other measures of eval-
15 uation as the Secretary determines
16 are appropriate.

17 (2) OPTIONAL USES.—The Secretary may use
18 amounts made available under subsection (f) for the
19 following, with respect to the national media cam-
20 paign:

21 (A) Partnerships with professional and
22 civic groups, community-based organizations,
23 including faith-based organizations, and Gov-
24 ernment or Tribal organizations that the Sec-
25 retary determines have experience in suicide

1 prevention, including the Substance Abuse and
2 Mental Health Services Administration and the
3 Centers for Disease Control and Prevention.

4 (B) Entertainment industry outreach,
5 interactive outreach, media projects and activi-
6 ties, public information, news media outreach,
7 outreach through television programs, and cor-
8 porate sponsorship and participation.

9 (d) PROHIBITIONS.—None of the amounts made
10 available under subsection (f) may be obligated or ex-
11 pended for any of the following:

12 (1) To supplant current suicide prevention cam-
13 paigns.

14 (2) For partisan political purposes, or to ex-
15 press advocacy in support of or to defeat any clearly
16 identified candidate, clearly identified ballot initia-
17 tive, or clearly identified legislative or regulatory
18 proposal.

19 (e) REPORT TO CONGRESS.—Not later than 18
20 months after implementation of the national media cam-
21 paign has begun, the Secretary, in coordination with the
22 Assistant Secretary and the Director, shall, with respect
23 to the first year of the national media campaign, submit
24 to Congress a report that describes—

1 (1) the strategy of the national media campaign
2 and whether specific objectives of such campaign
3 were accomplished, including whether such campaign
4 impacted the number of calls made to lifeline crisis
5 centers and the capacity of such centers to manage
6 such calls;

7 (2) steps taken to ensure that the national
8 media campaign operates in an effective and effi-
9 cient manner consistent with the overall strategy
10 and focus of the national media campaign;

11 (3) plans to purchase advertising time and
12 space;

13 (4) policies and practices implemented to ensure
14 that Federal funds are used responsibly to purchase
15 advertising time and space and eliminate the poten-
16 tial for waste, fraud, and abuse; and

17 (5) all contracts entered into with a corpora-
18 tion, a partnership, or an individual working on be-
19 half of the national media campaign.

20 (f) AUTHORIZATION OF APPROPRIATIONS.—For pur-
21 poses of carrying out this section, there is authorized to
22 be appropriated \$10,000,000 for each of fiscal years 2021
23 through 2025.

1 **Subtitle G—Helping Emergency**
2 **Responders Overcome**

3 **SEC. 6061. DATA SYSTEM TO CAPTURE NATIONAL PUBLIC**
4 **SAFETY OFFICER SUICIDE INCIDENCE.**

5 The Public Health Service Act is amended by insert-
6 ing before section 318 of such Act (42 U.S.C. 247c) the
7 following:

8 **“SEC. 317W. DATA SYSTEM TO CAPTURE NATIONAL PUBLIC**
9 **SAFETY OFFICER SUICIDE INCIDENCE.**

10 “(a) IN GENERAL.—The Secretary, in coordination
11 with the Director of the Centers for Disease Control and
12 Prevention and other agencies as the Secretary determines
13 appropriate, shall—

14 “(1) develop and maintain a data system, to be
15 known as the Public Safety Officer Suicide Report-
16 ing System, for the purposes of—

17 “(A) collecting data on the suicide inci-
18 dence among public safety officers; and

19 “(B) facilitating the study of successful
20 interventions to reduce suicide among public
21 safety officers; and

22 “(2) integrate such system into the National
23 Violent Death Reporting System, so long as the Sec-
24 retary determines such integration to be consistent
25 with the purposes described in paragraph (1).

1 “(b) DATA COLLECTION.—In collecting data for the
2 Public Safety Officer Suicide Reporting System, the Sec-
3 retary shall, at a minimum, collect the following informa-
4 tion:

5 “(1) The total number of suicides in the United
6 States among all public safety officers in a given cal-
7 endar year.

8 “(2) Suicide rates for public safety officers in
9 a given calendar year, disaggregated by—

10 “(A) age and gender of the public safety
11 officer;

12 “(B) State;

13 “(C) occupation; including both the indi-
14 vidual’s role in their public safety agency and
15 their primary occupation in the case of volun-
16 teer public safety officers;

17 “(D) where available, the status of the
18 public safety officer as volunteer, paid-on-call,
19 or career; and

20 “(E) status of the public safety officer as
21 active or retired.

22 “(c) CONSULTATION DURING DEVELOPMENT.—In
23 developing the Public Safety Officer Suicide Reporting
24 System, the Secretary shall consult with non-Federal ex-
25 perts to determine the best means to collect data regard-

1 ing suicide incidence in a safe, sensitive, anonymous, and
2 effective manner. Such non-Federal experts shall include,
3 as appropriate, the following:

4 “(1) Public health experts with experience in
5 developing and maintaining suicide registries.

6 “(2) Organizations that track suicide among
7 public safety officers.

8 “(3) Mental health experts with experience in
9 studying suicide and other profession-related trau-
10 matic stress.

11 “(4) Clinicians with experience in diagnosing
12 and treating mental health issues.

13 “(5) Active and retired volunteer, paid-on-call,
14 and career public safety officers.

15 “(6) Relevant national police, and fire and
16 emergency medical services, organizations.

17 “(d) DATA PRIVACY AND SECURITY.—In developing
18 and maintaining the Public Safety Officer Suicide Report-
19 ing System, the Secretary shall ensure that all applicable
20 Federal privacy and security protections are followed to
21 ensure that—

22 “(1) the confidentiality and anonymity of sui-
23 cide victims and their families are protected, includ-
24 ing so as to ensure that data cannot be used to deny
25 benefits; and

1 “(2) data is sufficiently secure to prevent unau-
2 thorized access.

3 “(e) REPORTING.—

4 “(1) ANNUAL REPORT.—Not later than 2 years
5 after the date of enactment of the Commitment to
6 Defeat the Virus and Keep America Healthy Act,
7 and biannually thereafter, the Secretary shall submit
8 a report to the Congress on the suicide incidence
9 among public safety officers. Each such report
10 shall—

11 “(A) include the number and rate of such
12 suicide incidence, disaggregated by age, gender,
13 and State of employment;

14 “(B) identify characteristics and contrib-
15 uting circumstances for suicide among public
16 safety officers;

17 “(C) disaggregate rates of suicide by—

18 “(i) occupation;

19 “(ii) status as volunteer, paid-on-call,
20 or career; and

21 “(iii) status as active or retired;

22 “(D) include recommendations for further
23 study regarding the suicide incidence among
24 public safety officers;

1 “(E) specify in detail, if found, any obsta-
2 cles in collecting suicide rates for volunteers
3 and include recommended improvements to
4 overcome such obstacles;

5 “(F) identify options for interventions to
6 reduce suicide among public safety officers; and

7 “(G) describe procedures to ensure the
8 confidentiality and anonymity of suicide victims
9 and their families, as described in subsection
10 (d)(1).

11 “(2) PUBLIC AVAILABILITY.—Upon the submis-
12 sion of each report to the Congress under paragraph
13 (1), the Secretary shall make the full report publicly
14 available on the website of the Centers for Disease
15 Control and Prevention.

16 “(f) DEFINITION.—In this section, the term ‘public
17 safety officer’ means—

18 “(1) a public safety officer as defined in section
19 1204 of the Omnibus Crime Control and Safe
20 Streets Act of 1968; or

21 “(2) a public safety telecommunicator as de-
22 scribed in detailed occupation 43–5031 in the Stand-
23 ard Occupational Classification Manual of the Office
24 of Management and Budget (2018).

1 “(g) PROHIBITED USE OF INFORMATION.—Notwith-
2 standing any other provision of law, if an individual is
3 identified as deceased based on information contained in
4 the Public Safety Officer Suicide Reporting System, such
5 information may not be used to deny or rescind life insur-
6 ance payments or other benefits to a survivor of the de-
7 ceased individual.”.

8 **SEC. 6062. PEER-SUPPORT BEHAVIORAL HEALTH AND**
9 **WELLNESS PROGRAMS WITHIN FIRE DEPART-**
10 **MENTS AND EMERGENCY MEDICAL SERVICE**
11 **AGENCIES.**

12 (a) IN GENERAL.—Part B of title III of the Public
13 Health Service Act (42 U.S.C. 243 et seq.) is amended
14 by adding at the end the following:

15 **“SEC. 320B. PEER-SUPPORT BEHAVIORAL HEALTH AND**
16 **WELLNESS PROGRAMS WITHIN FIRE DEPART-**
17 **MENTS AND EMERGENCY MEDICAL SERVICE**
18 **AGENCIES.**

19 “(a) IN GENERAL.—The Secretary shall award
20 grants to eligible entities for the purpose of establishing
21 or enhancing peer-support behavioral health and wellness
22 programs within fire departments and emergency medical
23 services agencies.

1 “(b) PROGRAM DESCRIPTION.—A peer-support be-
2 havioral health and wellness program funded under this
3 section shall—

4 “(1) use career and volunteer members of fire
5 departments or emergency medical services agencies
6 to serve as peer counselors;

7 “(2) provide training to members of career, vol-
8 unteer, and combination fire departments or emer-
9 gency medical service agencies to serve as such peer
10 counselors;

11 “(3) purchase materials to be used exclusively
12 to provide such training; and

13 “(4) disseminate such information and mate-
14 rials as are necessary to conduct the program.

15 “(c) DEFINITION.—In this section:

16 “(1) The term ‘eligible entity’ means a non-
17 profit organization with expertise and experience
18 with respect to the health and life safety of members
19 of fire and emergency medical services agencies.

20 “(2) The term ‘member’—

21 “(A) with respect to an emergency medical
22 services agency, means an employee, regardless
23 of rank or whether the employee receives com-
24 pensation (as defined in section 1204(7) of the

1 Omnibus Crime Control and Safe Streets Act of
2 1968); and

3 “(B) with respect to a fire department,
4 means any employee, regardless of rank or
5 whether the employee receives compensation, of
6 a Federal, State, Tribal, or local fire depart-
7 ment who is responsible for responding to calls
8 for emergency service.”.

9 (b) TECHNICAL CORRECTION.—Effective as if in-
10 cluded in the enactment of the Children’s Health Act of
11 2000 (Public Law 106–310), the amendment instruction
12 in section 1603 of such Act is amended by striking “Part
13 B of the Public Health Service Act” and inserting “Part
14 B of title III of the Public Health Service Act”.

15 **SEC. 6063. HEALTH CARE PROVIDER BEHAVIORAL HEALTH**
16 **AND WELLNESS PROGRAMS.**

17 Part B of title III of the Public Health Service Act
18 (42 U.S.C. 243 et seq.), as amended by section 6062, is
19 further amended by adding at the end the following:

20 **“SEC. 320C. HEALTH CARE PROVIDER BEHAVIORAL**
21 **HEALTH AND WELLNESS PROGRAMS.**

22 “(a) IN GENERAL.—The Secretary shall award
23 grants to eligible entities for the purpose of establishing
24 or enhancing behavioral health and wellness programs for
25 health care providers.

1 “(b) PROGRAM DESCRIPTION.—A behavioral health
2 and wellness program funded under this section shall—

3 “(1) provide confidential support services for
4 health care providers to help handle stressful or
5 traumatic patient-related events, including coun-
6 seling services and wellness seminars;

7 “(2) provide training to health care providers to
8 serve as peer counselors to other health care pro-
9 viders;

10 “(3) purchase materials to be used exclusively
11 to provide such training; and

12 “(4) disseminate such information and mate-
13 rials as are necessary to conduct such training and
14 provide such peer counseling.

15 “(c) DEFINITIONS.—In this section, the term ‘eligible
16 entity’ means a hospital, including a critical access hos-
17 pital (as defined in section 1861(mm)(1) of the Social Se-
18 curity Act) or a disproportionate share hospital (as defined
19 under section 1923(a)(1)(A) of such Act), a federally
20 qualified health center (as defined in section
21 1905(1)(2)(B) of such Act), or any other health care facil-
22 ity.”.

1 **SEC. 6064. DEVELOPMENT OF RESOURCES FOR EDUCATING**
2 **MENTAL HEALTH PROFESSIONALS ABOUT**
3 **TREATING FIRE FIGHTERS AND EMERGENCY**
4 **MEDICAL SERVICES PERSONNEL.**

5 (a) IN GENERAL.—The Administrator of the United
6 States Fire Administration, in consultation with the Sec-
7 retary of Health and Human Services, shall develop and
8 make publicly available resources that may be used by the
9 Federal Government and other entities to educate mental
10 health professionals about—

11 (1) the culture of Federal, State, Tribal, and
12 local career, volunteer, and combination fire depart-
13 ments and emergency medical services agencies;

14 (2) the different stressors experienced by fire-
15 fighters and emergency medical services personnel,
16 supervisory firefighters and emergency medical serv-
17 ices personnel, and chief officers of fire departments
18 and emergency medical services agencies;

19 (3) challenges encountered by retired fire-
20 fighters and emergency medical services personnel;
21 and

22 (4) evidence-based therapies for mental health
23 issues common to firefighters and emergency med-
24 ical services personnel within such departments and
25 agencies.

1 (b) CONSULTATION.—In developing resources under
2 subsection (a), the Administrator of the United States
3 Fire Administration and the Secretary of Health and
4 Human Services shall consult with national fire and emer-
5 gency medical services organizations.

6 (c) DEFINITIONS.—In this section:

7 (1) The term “firefighter” means any employee,
8 regardless of rank or whether the employee receives
9 compensation, of a Federal, State, Tribal, or local
10 fire department who is responsible for responding to
11 calls for emergency service.

12 (2) The term “emergency medical services per-
13 sonnel” means any employee, regardless of rank or
14 whether the employee receives compensation, as de-
15 fined in section 1204(7) of the Omnibus Crime Con-
16 trol and Safe Streets Act of 1968 (34 U.S.C.
17 10284(7)).

18 (3) The term “chief officer” means any indi-
19 vidual who is responsible for the overall operation of
20 a fire department or an emergency medical services
21 agency, irrespective of whether such individual also
22 serves as a firefighter or emergency medical services
23 personnel.

1 **SEC. 6065. BEST PRACTICES AND OTHER RESOURCES FOR**
2 **ADDRESSING POSTTRAUMATIC STRESS DIS-**
3 **ORDER IN PUBLIC SAFETY OFFICERS.**

4 (a) DEVELOPMENT; UPDATES.—The Secretary of
5 Health and Human Services shall—

6 (1) develop and assemble evidence-based best
7 practices and other resources to identify, prevent,
8 and treat posttraumatic stress disorder and co-oc-
9 ccurring disorders in public safety officers; and

10 (2) reassess and update, as the Secretary deter-
11 mines necessary, such best practices and resources,
12 including based upon the options for interventions to
13 reduce suicide among public safety officers identified
14 in the annual reports required by section
15 317W(e)(1)(F) of the Public Health Service Act, as
16 added by section 6061 of this subtitle.

17 (b) CONSULTATION.—In developing, assembling, and
18 updating the best practices and resources under sub-
19 section (a), the Secretary of Health and Human Services
20 shall consult with, at a minimum, the following:

21 (1) Public health experts.

22 (2) Mental health experts with experience in
23 studying suicide and other profession-related trau-
24 matic stress.

25 (3) Clinicians with experience in diagnosing and
26 treating mental health issues.

1 (4) Relevant national police, fire, and emer-
2 gency medical services organizations.

3 (c) AVAILABILITY.—The Secretary of Health and
4 Human Services shall make the best practices and re-
5 sources under subsection (a) available to Federal, State,
6 and local fire, law enforcement, and emergency medical
7 services agencies.

8 (d) FEDERAL TRAINING AND DEVELOPMENT PRO-
9 GRAMS.—The Secretary of Health and Human Services
10 shall work with Federal departments and agencies, includ-
11 ing the United States Fire Administration, to incorporate
12 education and training on the best practices and resources
13 under subsection (a) into Federal training and develop-
14 ment programs for public safety officers.

15 (e) DEFINITION.—In this section, the term “public
16 safety officer” means—

17 (1) a public safety officer as defined in section
18 1204 of the Omnibus Crime Control and Safe
19 Streets Act of 1968 (34 U.S.C. 10284); or

20 (2) a public safety telecommunicator as de-
21 scribed in detailed occupation 43–5031 in the Stand-
22 ard Occupational Classification Manual of the Office
23 of Management and Budget (2018).

1 **Subtitle H—Behavioral Health**
2 **Intervention Guidelines**

3 **SEC. 6071. BEST PRACTICES FOR BEHAVIORAL INTERVEN-**
4 **TION TEAMS.**

5 The Public Health Service Act is amended by insert-
6 ing after section 520G of such Act (42 U.S.C. 290bb–38)
7 the following new section:

8 **“SEC. 520H. BEST PRACTICES FOR BEHAVIORAL INTERVEN-**
9 **TION TEAMS.**

10 “(a) IN GENERAL.—The Secretary, acting through
11 the Assistant Secretary, shall develop and periodically up-
12 date—

13 “(1) best practices to assist elementary schools,
14 secondary schools, and institutions of higher edu-
15 cation in establishing and using behavioral interven-
16 tion teams; and

17 “(2) a list of evidence-based threat assessment
18 training providers to assist personnel in elementary
19 schools, secondary schools, and institutions of higher
20 education in implementing such best practices, in-
21 cluding with respect to training behavioral interven-
22 tion teams.

23 “(b) ELEMENTS.—The best practices under sub-
24 section (a)(1) shall include guidance on the following:

1 “(1) How behavioral intervention teams can op-
2 erate effectively from an evidence-based, objective
3 perspective while protecting the constitutional and
4 civil rights of individuals, including any individual of
5 concern.

6 “(2) The use of behavioral intervention teams
7 to identify individuals of concern, implement inter-
8 ventions, and manage risk through the framework of
9 the school’s or institution’s rules or code of conduct,
10 as applicable.

11 “(3) How behavioral intervention teams can,
12 when assessing an individual of concern—

13 “(A) seek training on evidence-based,
14 threat-assessment rubrics;

15 “(B) ensure that such teams—

16 “(i) have adequately trained, diverse
17 stakeholders with varied expertise; and

18 “(ii) use cross validation by a wide-
19 range of individual perspectives on the
20 team; and

21 “(C) use violence risk assessment.

22 “(4) How behavioral intervention teams can
23 avoid—

24 “(A) attempting to predict future behavior
25 by the concept of pre-crime;

1 “(B) inappropriately using a mental health
2 assessment;

3 “(C) inappropriately limiting or restricting
4 law enforcement’s jurisdiction over criminal
5 matters;

6 “(D) attempting to substitute the behav-
7 ioral intervention process in place of a criminal
8 process, or impede a criminal process, when an
9 individual of concern’s behavior has potential
10 criminal implications;

11 “(E) endangering an individual’s privacy
12 by failing to ensure that all applicable Federal
13 and State privacy laws are fully complied with;
14 or

15 “(F) creating school-to-prison pipelines.

16 “(c) CONSULTATION.—In carrying out subsection
17 (a)(1), the Secretary shall consult with—

18 “(1) the Secretary of Education;

19 “(2) the Director of the National Threat As-
20 sessment Center of the Department of Homeland
21 Security;

22 “(3) the Attorney General of the United States;
23 and

24 “(4) as appropriate, relevant stakeholders in-
25 cluding—

1 “(A) teachers and other educators, prin-
2 cipals, school administrators, school board
3 members, school psychologists, mental health
4 professionals, and parents of elementary school
5 and secondary school students;

6 “(B) local law enforcement agencies and
7 campus law enforcement administrators;

8 “(C) mental health mobile crisis providers;

9 “(D) child and adolescent psychiatrists;
10 and

11 “(E) other education and mental health
12 professionals.

13 “(d) PUBLICATION.—Not later than 2 years after the
14 date of enactment of this section, the Secretary shall pub-
15 lish the best practices under subsection (a)(1) and the list
16 under subsection (a)(2) on a publicly accessible website
17 of the Department of Health and Human Services.

18 “(e) TECHNICAL ASSISTANCE.—The Secretary shall
19 provide technical assistance to institutions of higher edu-
20 cation, elementary schools, and secondary schools to assist
21 such institutions and schools in implementing the best
22 practices under subsection (a).

23 “(f) DEFINITIONS.—In this section:

24 “(1) The term ‘behavioral intervention team’
25 means a team of qualified individuals who—

1 “(A) are responsible for identifying and as-
2 sessing individuals of concern; and

3 “(B) develop and facilitate implementation
4 of evidence-based interventions to mitigate the
5 threat of harm to self or others posed by indi-
6 viduals of concern and address the mental and
7 behavioral health needs of individuals of con-
8 cern to reduce such threat.

9 “(2) The terms ‘elementary school’, ‘parent’,
10 and ‘secondary school’ have the meanings given to
11 such terms in section 8101 of the Elementary and
12 Secondary Education Act of 1965 (20 U.S.C. 7801).

13 “(3) The term ‘individual of concern’ means an
14 individual whose behavior indicates a potential
15 threat to self or others.

16 “(4) The term ‘institution of higher education’
17 has the meaning given to such term in section 102
18 of the Higher Education Act of 1965 (20 U.S.C.
19 1002).

20 “(5) The term ‘mental health assessment’
21 means an evaluation, primarily focused on diagnosis,
22 determining the need for involuntary commitment,
23 medication management, and on-going treatment
24 recommendations.

1 “(6) The term ‘pre-crime’ means law-enforce-
2 ment efforts and strategies to deter crime by pre-
3 dicting when and where criminal activity will occur.

4 “(7) The term ‘violence risk assessment’ refers
5 to a broad determination of the potential risk of vio-
6 lence based on evidence-based literature.”.

7 **Subtitle I—Suicide Training and**
8 **Awareness Nationally Delivered**
9 **for Universal Prevention**

10 **SEC. 6081. STUDENT SUICIDE AWARENESS AND PREVEN-**
11 **TION TRAINING.**

12 (a) IN GENERAL.—Title V of the Public Health Serv-
13 ice Act is amended by inserting after section 520A of such
14 Act (42 U.S.C. 290bb–32) the following:

15 **“SEC. 520B. STUDENT SUICIDE AWARENESS AND PREVEN-**
16 **TION TRAINING POLICIES.**

17 “(a) IN GENERAL.—As a condition on receipt of
18 funds under section 520A, each State educational agency,
19 local educational agency, and Tribal educational agency
20 that receives such funds, directly or through a State or
21 Indian Tribe, for activities to be performed within sec-
22 ondary schools, including the Project AWARE State Edu-
23 cation Agency Grant Program, shall—

1 “(1) establish and implement a school-based
2 student suicide awareness and prevention training
3 policy;

4 “(2) consult with stakeholders (including prin-
5 cipals, teachers, parents, local Tribal officials, and
6 other school leaders) in the development of the pol-
7 icy under subsection (a)(1); and

8 “(3) collect and report information in accord-
9 ance with subsection (c).

10 “(b) SCHOOL-BASED STUDENT SUICIDE AWARENESS
11 AND PREVENTION TRAINING POLICY.—A school-based
12 student suicide awareness and prevention training policy
13 implemented pursuant to subsection (a)—

14 “(1) shall be evidence-based;

15 “(2) shall be culturally and linguistically appro-
16 priate;

17 “(3) shall provide evidence-based training to
18 students in grades 6 through 12, in coordination
19 with school-based mental health service providers as
20 defined in section 4102(6) of the Elementary and
21 Secondary Education Act of 1965, if applicable, re-
22 garding—

23 “(A) suicide education and awareness, in-
24 cluding warning signs of self-harm or suicidal
25 ideation;

1 “(B) methods that students can use to
2 seek help for themselves and others; and

3 “(C) student resources for suicide aware-
4 ness and prevention;

5 “(4) shall provide for retraining of such stu-
6 dents every school year;

7 “(5) may last for such period as the State edu-
8 cational agency, local educational agency, or Tribal
9 educational agency involved determines to be appro-
10 priate;

11 “(6) may be implemented through any delivery
12 method, including in-person trainings, digital
13 trainings, or train-the-trainer models; and

14 “(7) may include discussion of comorbidities or
15 risk factors for suicidal ideation or self-harm, includ-
16 ing substance misuse, sexual or physical abuse, men-
17 tal illness, or other evidence-based comorbidities and
18 risk factors.

19 “(c) COLLECTION OF INFORMATION AND REPORT-
20 ING.—Each State educational agency, local educational
21 agency, and Tribal educational agency that receives funds
22 under section 520A shall, with respect to each school
23 served by the agency, collect and report to the Secretary
24 the following information:

1 “(1) The number of student trainings con-
2 ducted.

3 “(2) The number of students trained,
4 disaggregated by age and grade level.

5 “(3) The number of help-seeking reports made
6 by students after implementation of such policy.

7 “(d) EVIDENCE-BASED PROGRAM LISTING.—The
8 Secretary of Health and Human Services shall coordinate
9 with the Secretary of Education to make publicly available
10 the policies established by State educational agencies, local
11 educational agencies, and Tribal educational agencies pur-
12 suant to this section and the training that is available to
13 students and teams pursuant to such policies, including
14 identification of whether such training is available to
15 trainees at no cost.

16 “(e) IMPLEMENTATION TIMELINE.—A State edu-
17 cational agency, local educational agency, or Tribal edu-
18 cational agency shall establish and begin implementation
19 of the policies required by subsection (a)(1) not later than
20 the beginning of the third fiscal year following the date
21 of enactment of this section for which the agency receives
22 funds under section 520A.

23 “(f) DEFINITIONS.—In this section and section
24 520B–1:

1 “(1) The term ‘evidence-based’ has the meaning
2 given to such term in section 8101 of the Elemen-
3 tary and Secondary Education Act of 1965.

4 “(2) The term ‘local educational agency’ has
5 the meaning given to such term in section 8101 of
6 the Elementary and Secondary Education Act of
7 1965.

8 “(3) The term ‘State educational agency’ has
9 the meaning given to such term in section 8101 of
10 the Elementary and Secondary Education Act of
11 1965.

12 “(4) The term ‘Tribal educational agency’ has
13 the meaning given to the term ‘tribal educational
14 agency’ in section 6132 of the Elementary and Sec-
15 ondary Education Act of 1965.

16 **“SEC. 520B-1. BEST PRACTICES FOR STUDENT SUICIDE**
17 **AWARENESS AND PREVENTION TRAINING.**

18 “The Secretary of Health and Human Services, in
19 consultation with the Secretary of Education and the Bu-
20 reau of Indian Education, shall—

21 “(1) publish best practices for school-based stu-
22 dent suicide awareness and prevention training, pur-
23 suant to section 520B, that are based on—

24 “(A) evidence-based practices; and

1 “(B) input from relevant Federal agencies,
2 national organizations, Indian Tribes and Trib-
3 al organizations, and related stakeholders;

4 “(2) publish guidance, based on the best prac-
5 tices under paragraph (1), to provide State edu-
6 cational agencies, local educational agencies, and
7 Tribal educational agencies with information on stu-
8 dent suicide awareness and prevention best prac-
9 tices;

10 “(3) disseminate such best practices to State
11 educational agencies, local educational agencies, and
12 Tribal educational agencies; and

13 “(4) provide technical assistance to State edu-
14 cational agencies, local educational agencies, and
15 Tribal educational agencies.”.

16 **SEC. 6082. EFFECTIVE DATE.**

17 The amendments made by this subtitle shall only
18 apply with respect to applications for assistance under sec-
19 tion 520A of the Public Health Service Act (42 U.S.C.
20 290bb–32) that are submitted after the date of enactment
21 of this Act.

1 **TITLE VII—ADDRESSING THE IM-**
2 **PACTS OF COVID-19 ON SUB-**
3 **STANCE USE DISORDERS**

4 **Subtitle A—Easy Medication Ac-**
5 **cess and Treatment for Opioid**
6 **Addiction**

7 **SEC. 7001. DISPENSATION OF NARCOTIC DRUGS FOR THE**
8 **PURPOSE OF RELIEVING ACUTE WITH-**
9 **DRAWAL SYMPTOMS FROM OPIOID USE DIS-**
10 **ORDER.**

11 Not later than 180 days after the date of enactment
12 of this Act, the Attorney General shall revise section
13 1306.07(b) of title 21, Code of Federal Regulations, so
14 that practitioners, in accordance with applicable State,
15 Federal, or local laws relating to controlled substances, are
16 allowed to dispense not more than a three-day supply of
17 narcotic drugs to one person or for one person's use at
18 one time for the purpose of initiating maintenance treat-
19 ment or detoxification treatment (or both).

20 **Subtitle B—Access to Remote**
21 **Behavioral Health Treatment**

22 **SEC. 7011. REGISTRATION OF QUALIFIED COMMUNITY**
23 **MENTAL HEALTH CENTERS.**

24 (a) DEFINITIONS.—Section 102 of the Controlled
25 Substances Act (21 U.S.C. 802) is amended—

1 (1) by striking paragraph (54)(A)(i) and insert-
2 ing the following:

3 “(i) while the patient is being treated by,
4 and physically located in—

5 “(I) a hospital or clinic registered
6 under section 303(f); or

7 “(II) a qualified community mental
8 health center registered under section
9 303(l); and”;

10 (2) by redesignating paragraph (58) as para-
11 graph (59);

12 (3) by redesignating the second paragraph (57)
13 (as added by section 401(a) of the First Step Act
14 of 2018 (Public Law 115–391)) as paragraph (58);
15 and

16 (4) by adding at the end the following:

17 “(60) The term ‘qualified community mental health
18 center’ means a facility that—

19 “(A)(i) meets the criteria specified in section
20 1913(e) of the Public Health Service Act to be con-
21 sidered a community mental health center; or

22 “(ii) meets the criteria specified pursuant to
23 section 223 of the Protecting Access to Medicare Act
24 of 2014 to be considered a certified community be-
25 havioral health clinic; and

1 “(B) is licensed, operated, authorized, certified,
2 or otherwise recognized by a State government.”.

3 (b) REGISTRATION.—Section 303 of the Controlled
4 Substances Act (21 U.S.C. 823) is amended by adding at
5 the end the following:

6 “(1) QUALIFIED COMMUNITY MENTAL HEALTH CEN-
7 TERS.—

8 “(1) REGISTRATION.—The Attorney General
9 shall register qualified community mental health
10 centers to administer controlled substances through
11 the practice of telemedicine.

12 “(2) DENIAL OF APPLICATIONS.—The Attorney
13 General may deny an application for registration
14 under paragraph (1) if the Attorney General deter-
15 mines that the registration would be inconsistent
16 with the public interest after considering—

17 “(A) any recommendation by the licensing
18 board or professional disciplinary authority of
19 the State in which the applicant is located;

20 “(B) the experience of the applicant in
21 treating patients;

22 “(C) any conviction of an employee of the
23 applicant under Federal or State law relating to
24 treatment of patients;

1 “(D) the compliance of the applicant with
2 applicable Federal, State, or local laws relating
3 to treatment of patients; and

4 “(E) any other conduct by the applicant
5 that may threaten the public’s health and safe-
6 ty.”.

7 (c) REPORT TO CONGRESS.—Not later than 60 days
8 after the date of enactment of this Act, the Attorney Gen-
9 eral of the United States shall submit to the Congress a
10 plan for implementation of the amendments made by sub-
11 sections (a) and (b).

12 (d) DELAYED APPLICABILITY.—The amendments
13 made by subsections (a) and (b) apply beginning on the
14 date that is 120 days after the date of enactment of this
15 Act.

16 **Subtitle C—PDMP Pilot Program**

17 **SEC. 7021. PILOT PROGRAM FOR INTEGRATING SUBSTANCE** 18 **USE DISORDER AND BEHAVIORAL HEALTH** 19 **TREATMENT LOCATOR TOOL INTO STATE** 20 **PRESCRIPTION DRUG MONITORING PRO-** 21 **GRAMS.**

22 (a) IN GENERAL.—The Secretary of Health and
23 Human Services, in consultation with the Assistant Sec-
24 retary for Mental Health and Substance Use, shall estab-
25 lish and implement a pilot program in which the Secretary

1 awards grants to, or enters into cooperative agreements
2 with, not more than 5 eligible States to test the feasibility
3 and outcomes of integrating a substance use disorder and
4 behavioral health treatment locator tool into the State's
5 prescription drug monitoring program.

6 (b) GRANT ESTABLISHMENT AND PARTICIPATION.—

7 (1) IN GENERAL.—In carrying out the pilot
8 program under this section, the Secretary shall, on
9 a competitive basis, award grants to, or enter into
10 cooperative agreements with, not more than 5 eligi-
11 ble States.

12 (2) ELIGIBILITY.—To be eligible for a grant
13 under this section, a State shall demonstrate to the
14 Secretary's satisfaction that the State is making
15 progress in integrating the State's PDMP with elec-
16 tronic health records and health information tech-
17 nology infrastructure.

18 (3) PREFERENCE.—In awarding grants under
19 this section, the Secretary shall give preference to el-
20 igible States described in paragraph (2) whose rates
21 of death due to drug overdose per population of
22 100,000 are in the top quartile according to the
23 most recent data of the Centers for Disease Control
24 and Prevention.

1 (c) PERIOD OF GRANT.—A grant awarded to an eligi-
2 ble entity under this section shall be for a period of 2
3 years.

4 (d) GRANT USES.—

5 (1) REQUIRED USES.—A grant awarded under
6 this section to an eligible State shall be used for
7 both of the following purposes:

8 (A) To integrate a substance use disorder
9 and behavioral health treatment locator tool
10 into the PDMP.

11 (B) To develop and disseminate guidance
12 for health care providers on how to consult and
13 share information obtained through the sub-
14 stance use disorder and behavioral health treat-
15 ment locator tool when a patient’s PDMP infor-
16 mation indicates possible misuse of a controlled
17 substance.

18 (2) ADDITIONAL PERMISSIBLE USES.—A grant
19 awarded under this section to an eligible State may
20 be used for any of the following additional purposes:

21 (A) To integrate a substance use disorder
22 and behavioral health treatment locator tool
23 into the PDMP that incorporates direct referral
24 capabilities that enable the health care pro-
25 vider—

1 (i) to refer a patient to treatment or
2 for an assessment; and

3 (ii) consistent with the protection of
4 information by Federal and State privacy
5 laws and security rules, receive feedback
6 about the patient's engagement with such
7 treatment or assessment.

8 (B) To integrate a substance use disorder
9 and behavioral health treatment locator tool
10 into the PDMP that provides information re-
11 garding the current capacity of inpatient or
12 outpatient treatment resources of a health care
13 provider.

14 (e) REPORTING REQUIREMENTS.—

15 (1) REPORTS BY STATES.—Each eligible State
16 that participates in the pilot program under this sec-
17 tion shall submit to the Secretary an annual report
18 for each year of the pilot program that includes in-
19 formation on—

20 (A) the number of health care providers
21 and health facilities with access to the sub-
22 stance use disorder and behavioral health treat-
23 ment locator tool;

1 (B) the number of individuals referred to
2 treatment with the assistance of the locator
3 tool;

4 (C) aggregate, de-identified patient data
5 related to the type of treatment located by the
6 locator tool, how often patients followed
7 through on seeking such treatment, and the av-
8 erage duration of such treatment, to the extent
9 collected by the State;

10 (D) feedback from providers with access to
11 the locator tool on usability and any impact on
12 outcomes;

13 (E) recommendations to improve the
14 usability and efficacy of a substance use dis-
15 order and behavioral health treatment locator
16 tool within the PDMP; and

17 (F) additional information and reporting
18 metrics as determined by the Secretary.

19 (2) REPORT BY SECRETARY.—Not less than
20 180 days after the conclusion of the pilot program
21 under this section, the Secretary shall submit to the
22 Congress a report on the findings of the program,
23 including—

24 (A) outcomes reported by the participating
25 States;

1 (B) findings on the suitability of including
2 a substance use disorder and behavioral health
3 treatment locator tool within State PDMPs;
4 and

5 (C) recommendations on best practices for
6 integrating a substance use disorder and behav-
7 ioral health treatment locator tool within State
8 PDMPs.

9 (f) DEFINITIONS.—In this section:

10 (1) The term “prescription drug monitoring
11 program” or “PDMP” has the meaning given to the
12 term “PDMP” in section 3990 of the Public Health
13 Service Act (42 U.S.C. 280g–3).

14 (2) The term “Secretary” means the Secretary
15 of Health and Human Services.

16 (g) AUTHORIZATION OF APPROPRIATIONS.—To carry
17 out this section, there are authorized to be appropriated
18 \$2,500,000 for each of fiscal years 2021 and 2022.

1 **Subtitle D—Family Support**
2 **Services for Addiction**

3 **SEC. 7031. FAMILY SUPPORT SERVICES FOR INDIVIDUALS**
4 **STRUGGLING WITH SUBSTANCE USE DIS-**
5 **ORDER.**

6 Part D of title V of the Public Health Service Act
7 (42 U.S.C. 290dd et seq.) is amended by adding at the
8 end the following:

9 **“SEC. 553. FAMILY SUPPORT SERVICES FOR INDIVIDUALS**
10 **STRUGGLING WITH SUBSTANCE USE DIS-**
11 **ORDER.**

12 “(a) DEFINITIONS.—In this section—

13 “(1) the term ‘family community organization’
14 means an independent nonprofit organization that—

15 “(A) mobilizes resources within and out-
16 side of the community of families with individ-
17 uals living with addiction, to provide a support
18 network, education, and evidence-informed tools
19 for families and loved ones of individuals strug-
20 gling with substance use disorders; and

21 “(B) is governed by experts in the field of
22 addiction, which may include—

23 “(i) experts in evidence-informed
24 interventions for family members;

1 “(ii) experts in the impact of addic-
2 tion on family systems;

3 “(iii) families who have experience
4 with substance use disorders and addiction;
5 and

6 “(iv) other experts in the field of ad-
7 diction; and

8 “(2) the term ‘family support services’ means
9 resources or programs that support families that in-
10 clude an individual with substance use disorder.

11 “(b) GRANTS AUTHORIZED.—The Secretary shall
12 award grants to family community organizations to enable
13 such organizations to develop, expand, and enhance evi-
14 dence-informed family support services.

15 “(c) FEDERAL SHARE.—The Federal share of the
16 costs of a program funded by a grant under this section
17 may not exceed 85 percent.

18 “(d) USE OF FUNDS.—Grants awarded under sub-
19 section (b)—

20 “(1) shall be used to develop, expand, and en-
21 hance community and statewide evidence-informed
22 family support services; and

23 “(2) may be used to—

24 “(A) build connections between family sup-
25 port networks, including providing technical as-

1 sistance between family community organiza-
2 tions and peer support networks, and with
3 other family support services, focused on en-
4 hancing knowledge of evidence-informed inter-
5 ventions for family members and loved ones of
6 individuals living with substance use disorders
7 and reducing harm by educating service pro-
8 viders on current evidence regarding addiction
9 and the family, including—

10 “(i) behavioral health providers, in-
11 cluding such providers focused specifically
12 on family and couples therapy in the con-
13 text of addiction;

14 “(ii) primary care providers;

15 “(iii) providers of foster care services
16 or support services for grandparents,
17 guardians, and other extended family im-
18 pacted by addiction; and

19 “(iv) other family support services
20 that connect to community resources for
21 individuals with substance use disorders,
22 including non-clinical community services;

23 “(B) reduce stigma associated with the
24 family of individuals with substance use dis-
25 orders by improving knowledge about addiction

1 and its treatment, providing compassionate sup-
2 port, and dispelling myths that perpetuate such
3 stigma;

4 “(C) conduct outreach on issues relating to
5 substance use disorders and family support,
6 which may include education, training, and re-
7 sources with respect to—

8 “(i) building a resilience- and
9 strengths-based approach to prevention of,
10 and living with, addiction in the family;

11 “(ii) identifying the signs of substance
12 use disorder;

13 “(iii) adopting an approach that mini-
14 mizes harm to all family members; and

15 “(iv) families of individuals with a
16 substance use disorder, including with re-
17 spect to—

18 “(I) navigating the treatment
19 and recovery systems;

20 “(II) paying for addiction treat-
21 ment;

22 “(III) education about substance
23 use disorder; and

24 “(IV) avoiding predatory treat-
25 ment programs; and

1 “(D) connect families to evidence-informed
2 peer support programs.

3 “(e) DATA REPORTING AND PROGRAM OVER-
4 SIGHT.—With respect to a grant awarded under sub-
5 section (a), not later than 90 days after the end of the
6 first year of the grant period, and annually thereafter for
7 the duration of the grant period, the entity shall submit
8 data, as appropriate and to the extent practicable, to the
9 Secretary regarding—

10 “(1) the programs and activities funded by the
11 grant;

12 “(2) health outcomes of the population of indi-
13 viduals with a substance use disorder who received
14 services through programs supported by the grant,
15 as evaluated by an independent program evaluator
16 through the use of outcomes measures, as deter-
17 mined by the Secretary; and

18 “(3) any other information that the secretary
19 may require for the purpose of ensuring that the
20 grant recipient is complying with all the require-
21 ments of the grant.

22 “(f) AUTHORIZATION OF APPROPRIATIONS.—There
23 is authorized to be appropriated to carry out this section
24 \$5,000,000 for each of fiscal years 2021 through 2025.”.

1 **Subtitle E—Block, Report, And**
2 **Suspend Suspicious Shipments**

3 **SEC. 7041. CLARIFICATION OF PROCESS FOR REGISTRANTS**
4 **TO EXERCISE DUE DILIGENCE UPON DISCOV-**
5 **ERING A SUSPICIOUS ORDER.**

6 (a) IN GENERAL.—Paragraph (3) of section 312(a)
7 of the Controlled Substances Act (21 U.S.C. 832(a)) is
8 amended to read as follows:

9 “(3) upon discovering a suspicious order or se-
10 ries of orders—

11 “(A) exercise due diligence;

12 “(B) establish and maintain (for not less
13 than a period to be determined by the Adminis-
14 trator of the Drug Enforcement Administra-
15 tion) a record of the due diligence that was per-
16 formed;

17 “(C) decline to fill the order or series of
18 orders if the due diligence fails to resolve all of
19 the indicators that gave rise to the suspicion
20 that filling the order or series of orders would
21 cause a violation of this title by the registrant
22 or the prospective purchaser; and

23 “(D) notify the Administrator of the Drug
24 Enforcement Administration and the Special
25 Agent in Charge of the Division Office of the

1 Drug Enforcement Administration for the area
2 in which the registrant is located or conducts
3 business of—

4 “(i) each suspicious order or series of
5 orders discovered by the registrant; and

6 “(ii) the indicators giving rise to the
7 suspicion that filling the order or series of
8 orders would cause a violation of this title
9 by the registrant or the prospective pur-
10 chaser.”.

11 (b) APPLICABILITY.—Section 312(a)(3) of the Con-
12 trolled Substances Act, as amended by subsection (a),
13 shall apply beginning on the day that is 6 months after
14 the date of enactment of this Act. Until such day, section
15 312(a)(3) of the Controlled Substances Act shall apply as
16 such section 312(a)(3) was in effect on the day before the
17 date of enactment of this Act.

18 (c) REGULATIONS.—The Attorney General shall,
19 issue regulations specifying, for purposes of paragraph (3)
20 of section 312(a) of the Controlled Substances Act, as
21 added by subsection (a), the indicators that give rise to
22 a suspicion that filling an order or series of orders would
23 cause a violation of title III of the Controlled Substances
24 Act (21 U.S.C. 801 et seq.) by a registrant or a prospec-
25 tive purchaser.

1 **Subtitle F—Debarment Enforcement**
2 **ment of Bad Actor Registrants**

3 **SEC. 7051. DEBARMENT OF CERTAIN REGISTRANTS.**

4 Section 304 of the Controlled Substances Act (21
5 U.S.C. 824) is amended by adding at the end the fol-
6 lowing:

7 “(h) The Attorney General may issue an order to pro-
8 hibit, conditionally or unconditionally, and permanently or
9 for such period as the Attorney General may determine,
10 any person from being registered under this title to manu-
11 facture, distribute, or dispense a controlled substance or
12 a list I chemical, if the Attorney General finds that—

13 “(1) such person meets or has met any of the
14 conditions for suspension or revocation of registra-
15 tion under subsection (a); and

16 “(2) such person has a history of prior suspen-
17 sions or revocations of registration.”.

1 **Subtitle G—Ensuring Compliance**
2 **Against Opioid Diversion**

3 **SEC. 7061. MODIFICATION, TRANSFER, AND TERMINATION**
4 **OF REGISTRATION TO MANUFACTURE, DIS-**
5 **TRIBUTE, OR DISPENSE CONTROLLED SUB-**
6 **STANCES.**

7 Subsection (a) of section 302 of the Controlled Sub-
8 stances Act (21 U.S.C. 822) is amended by adding at the
9 end the following new paragraph:

10 “(3)(A) Except as provided in subparagraph (C), the
11 registration of any registrant under this title to manufac-
12 ture, distribute, or dispense controlled substances or list
13 I chemicals terminates if and when such registrant—

14 “(i) dies;

15 “(ii) ceases legal existence;

16 “(iii) discontinues business or professional prac-
17 tice; or

18 “(iv) surrenders such registration.

19 “(B) In the case of such a registrant who ceases legal
20 existence or discontinues business or professional practice,
21 such registrant shall promptly notify the Attorney General
22 in writing of such fact.

23 “(C) No registration under this title to manufacture,
24 distribute, or dispense controlled substances or list I
25 chemicals, and no authority conferred thereby, may be as-

1 signed or otherwise transferred except upon such condi-
2 tions as the Attorney General may specify and then only
3 pursuant to written consent. A registrant to whom a reg-
4 istration is assigned or transferred pursuant to the pre-
5 ceding sentence may not manufacture, distribute, or dis-
6 pense controlled substances or list I chemicals pursuant
7 to such registration until the Attorney General receives
8 such written consent.

9 “(D) In the case of a registrant under this title to
10 manufacture, distribute, or dispense controlled substances
11 or list I chemicals desiring to discontinue business or pro-
12 fessional practice altogether or with respect to controlled
13 substances and list I chemicals (without assigning or
14 transferring such business or professional practice to an-
15 other entity), such registrant shall return to the Attorney
16 General for cancellation—

17 “(i) the registrant’s certificate of registration;

18 “(ii) any unexecuted order forms in the reg-
19 istrant’s possession; and

20 “(iii) any other documentation that the Attor-
21 ney General may require.”.

1 **Subtitle H—Opioid Prescription**
2 **Verification**

3 **SEC. 7071. MATERIALS FOR TRAINING PHARMACISTS ON**
4 **CERTAIN CIRCUMSTANCES UNDER WHICH A**
5 **PHARMACIST MAY DECLINE TO FILL A PRE-**
6 **SCRIPTION.**

7 (a) **UPDATES TO MATERIALS.**—Section 3212(a) of
8 the SUPPORT for Patients and Communities Act (Public
9 Law 115–271) is amended by striking “Not later than 1
10 year after the date of enactment of this Act, the Secretary
11 of Health and Human Services, in consultation with the
12 Administrator of the Drug Enforcement Administration,
13 Commissioner of Food and Drugs, Director of the Centers
14 for Disease Control and Prevention, and Assistant Sec-
15 retary for Mental Health and Substance Use, shall develop
16 and disseminate” and inserting “The Secretary of Health
17 and Human Services, in consultation with the Adminis-
18 trator of the Drug Enforcement Administration, Commis-
19 sioner of Food and Drugs, Director of the Centers for Dis-
20 ease Control and Prevention, and Assistant Secretary for
21 Mental Health and Substance Use, shall develop and dis-
22 seminate not later than 1 year after the date of enactment
23 of this Act, and update periodically thereafter”.

1 (b) MATERIALS INCLUDED.—Section 3212(b) of the
2 SUPPORT for Patients and Communities Act (Public
3 Law 115–271) is amended—

4 (1) by redesignating paragraphs (1) and (2) as
5 paragraphs (2) and (3), respectively; and

6 (2) by inserting before paragraph (2), as so re-
7 designated, the following new paragraph:

8 “(1) pharmacists on how to verify the identity
9 of individuals picking up prescriptions;”.

10 (c) MATERIALS FOR TRAINING ON VERIFICATION OF
11 IDENTITY.—Section 3212 of the SUPPORT for Patients
12 and Communities Act (Public Law 115–271) is amended
13 by adding at the end the following new subsection:

14 “(d) MATERIALS FOR TRAINING ON VERIFICATION
15 OF IDENTITY OF INDIVIDUALS PICKING UP PRESCRIBED
16 MEDICATIONS.—Not later than 6 months after the date
17 of enactment of this subsection, the Secretary of Health
18 and Human Services, after seeking stakeholder input in
19 accordance with subsection (c), shall—

20 “(1) update the materials developed under sub-
21 section (a) to include information for pharmacists on
22 how to verify the identity of individuals picking up
23 prescribed medications; and

24 “(2) disseminate, as appropriate, the updated
25 materials.”.

1 **SEC. 7072. INCENTIVIZING STATES TO FACILITATE RESPON-**
2 **SIBLE, INFORMED DISPENSING OF CON-**
3 **TROLLED SUBSTANCES.**

4 (a) IN GENERAL.—Section 392A of the Public
5 Health Service Act (42 U.S.C. 280b–1) is amended—

6 (1) by redesignating subsections (c) and (d) as
7 subsections (d) and (e), respectively; and

8 (2) by inserting after subsection (b) the fol-
9 lowing new subsection:

10 “(c) PREFERENCE.—In determining the amounts of
11 grants awarded to States under subsections (a) and (b),
12 the Director of the Centers for Disease Control and Pre-
13 vention may give preference to States in accordance with
14 such criteria as the Director may specify and may choose
15 to give preference to States that—

16 “(1) maintain a prescription drug monitoring
17 program;

18 “(2) require dispensers of controlled substances
19 in schedule II, III, or IV to verify the identity of the
20 person who picks up a prescribed medication by re-
21 quiring such person to present a photo identification
22 card that is valid as determined by the respective
23 State; and

24 “(3) require dispensers of such controlled sub-
25 stances to enter certain information about the pur-
26 chase of such controlled substances into the respec-

1 tive State’s prescription drug monitoring program,
2 including—

3 “(A) the National Drug Code or, in the
4 case of compounded medications, compound
5 identifier;

6 “(B) the quantity dispensed;

7 “(C) the name of the patient;

8 “(D) the name of the ultimate user;

9 “(E) the name of the person who picks up
10 the controlled substance, if different from the
11 patient and ultimate user; and

12 “(F) the date filled.”.

13 (b) DEFINITIONS.—Subsection (d) of section 392A of
14 the Public Health Service Act (42 U.S.C. 280b–1), as re-
15 designated by subsection (a)(1), is amended to read as fol-
16 lows:

17 “(d) DEFINITIONS.—In this section:

18 “(1) CONTROLLED SUBSTANCE.—The term
19 ‘controlled substance’ has the meaning given that
20 term in section 102 of the Controlled Substances.

21 “(2) DISPENSER.—The term ‘dispenser’ means
22 a physician, pharmacist, or other person that dis-
23 penses a controlled substance to an ultimate user.

24 “(3) INDIAN TRIBE.—The term ‘Indian tribe’
25 has the meaning given that term in section 4 of the

1 Indian Self-Determination and Education Assistance
2 Act.

3 “(4) STATE.—The term ‘State’ means each of
4 the 50 States, the District of Columbia, and any
5 commonwealth or territory of the United States.

6 “(5) ULTIMATE USER.—The term ‘ultimate
7 user’ means a person who has obtained from a dis-
8 penser, and who possesses, a controlled substance
9 for the person’s own use, for the use of a member
10 of the person’s household, or for the use of an ani-
11 mal.”.

12 **Subtitle I—Suspicious Order** 13 **Identification**

14 **SEC. 7081. STRENGTHENING ARCOS.**

15 Section 307(d) of the Controlled Substances Act (21
16 U.S.C. 827(d)) is amended to read as follows:

17 “(1)(A) Every registrant under section 303 shall and
18 in such form as the Attorney General may require, make
19 reports in electronic format to the Attorney General of
20 every sale, delivery, or other disposal (other than by dis-
21 pensing by a practitioner) by the registrant of any con-
22 trolled substance, identifying by the registration number
23 assigned under this title the person or establishment (un-
24 less exempt from registration under section 302(d)) to
25 whom such sale, delivery, or other disposal was made.

1 “(B) Every registrant shall make each report re-
2 quired under subparagraph (A)—

3 “(i) not later than 30 days after the sale, deliv-
4 ery, or other disposal; or

5 “(ii) after the date on which the real-time re-
6 porting system is established under section
7 7082(e)(3) of the Commitment to Defeat the Virus
8 and Keep America Healthy Act is implemented, in
9 real time.”.

10 **SEC. 7082. SUSPICIOUS ORDERS TASK FORCE.**

11 (a) DEFINITIONS.—In this section:

12 (1) ADMINISTRATOR.—The term “Adminis-
13 trator” means the Administrator of the Drug En-
14 forcement Administration.

15 (2) CONTROLLED SUBSTANCE; DISTRIBUTOR;
16 MANUFACTURER.—The terms “controlled sub-
17 stance”, “distributor”, and “manufacturer” have the
18 meanings given those terms in section 102 of the
19 Controlled Substances Act (21 U.S.C. 802).

20 (3) REAL TIME.—The term “real time” means
21 with as little delay as technically and economically
22 feasible, as determined by the Attorney General fol-
23 lowing the program designed under subsection
24 (e)(1), but not to exceed 24 hours.

25 (4) REGISTRANT.—The term “registrant”—

1 (A) means a person registered under sec-
2 tion 303 of the Controlled Substances Act (21
3 U.S.C. 823); and

4 (B) does not include practitioner.

5 (b) ESTABLISHMENT.—The Attorney General, in
6 consultation with the Director of the Office of National
7 Drug Control Policy and the Secretary of Health and
8 Human Services, shall establish a Suspicious Order Moni-
9 toring Task Force (referred to in this section as the “Task
10 Force”).

11 (c) COMPOSITION.—

12 (1) IN GENERAL.—The Task Force shall be
13 composed of appropriate personnel from—

14 (A) the Department of Justice;

15 (B) the Drug Enforcement Administration;

16 (C) the Office of National Drug Control
17 Policy;

18 (D) the National Institute of Standards
19 and Technology; and

20 (E) other appropriate Federal, State, and
21 local law enforcement and regulatory agencies
22 with experience in investigating and prosecuting
23 illegal transactions of controlled substances as
24 determined by the Attorney General, in con-

1 sultation with the Secretary of Health and
2 Human Services.

3 (2) CONSULTANTS.—The Task Force shall con-
4 sult with—

5 (A) industry members, including—

6 (i) data analytic professionals;

7 (ii) community pharmacies that dis-
8 pense controlled substances;

9 (iii) chain pharmacies that dispense
10 controlled substances;

11 (iv) distributors of controlled sub-
12 stances;

13 (v) manufacturers of controlled sub-
14 stances;

15 (vi) State and local public health offi-
16 cials; and

17 (vii) other relevant industry profes-
18 sionals; and

19 (B) relevant industry regulators and enti-
20 ties that utilize real-time reporting of trans-
21 actions, orders, or other activities with the goal
22 of identifying suspicious activity, such as appro-
23 priate personnel from the Financial Crimes En-
24 forcement Network and money transfer indus-
25 try professionals.

1 (d) MEETINGS.—

2 (1) IN GENERAL.—The Task Force shall meet
3 not less frequently than 4 times per year and at
4 such other times as may be determined necessary by
5 the Task Force.

6 (2) INITIAL MEETING.—Not later than 60 days
7 after the date of enactment of this Act, the Task
8 Force shall hold the initial meeting of the Task
9 Force.

10 (e) PRELIMINARY ORDER EVALUATION PROGRAM.—

11 (1) IN GENERAL.—

12 (A) DESIGN.—Not later than 60 days after
13 the date on which the Task Force holds the ini-
14 tial meeting required under subsection (d)(2),
15 the Task Force shall begin to design a program
16 in accordance with paragraph (2).

17 (B) PURPOSE.—The program described in
18 subparagraph (A) shall be designed to share
19 necessary data, in a limited capacity, with reg-
20 istrants in order to provide registrants with in-
21 formation to identify suspicious ordering in real
22 time.

23 (C) DEADLINE FOR COMPLETION.—Not
24 later than 8 months after the date of enactment

1 of this Act, the Task Force shall complete the
2 design required under subparagraph (A).

3 (2) REQUIREMENTS.—

4 (A) IN GENERAL.—The program required
5 under paragraph (1) shall establish a process
6 for—

7 (i) transitioning to a requirement to
8 report in real time to the Attorney General
9 under section 307(d) of the Controlled
10 Substances Act (21 U.S.C. 827(d)) every
11 sale, delivery, or other disposal by a reg-
12 istrant of any controlled substance;

13 (ii) limited sharing in real time of Au-
14 tomation of Reports and Consolidated Or-
15 ders System (commonly known as
16 “ARCOS”) data with registrants to share
17 necessary data, in a limited capacity, with
18 registrants in order to provide registrants
19 with information to identify suspicious or-
20 dering in real time; and

21 (iii) ensuring data privacy, data de-
22 identification, protection of trade secrets
23 and purchasing history.

1 (B) OTHER CONSIDERATIONS.—In design-
2 ing the program under paragraph (1), the Task
3 Force shall take into consideration—

4 (i) the inclusion of a waiver process
5 for pharmacies and other registrants un-
6 able to transmit orders electronically on
7 the date of enactment of this Act;

8 (ii) a mechanism to ensure that the
9 costs of running the program are not
10 passed through to customers of registrants,
11 unless the registrants are customers of
12 other registrants;

13 (iii) technical requirements for ensur-
14 ing that registrants may access all relevant
15 de-identified data, with output provided in
16 a standard database file format; and

17 (iv) a mechanism to ensure that the
18 program required to be designed under
19 subparagraph (A) is updated based on
20 feedback from industry members and other
21 relevant entities.

22 (3) IMPLEMENTATION.—Not later than 1 year
23 after the date of enactment of this Act, the Attorney
24 General shall—

1 (A) implement the program designed under
2 paragraph (1) to collect and share in real time
3 data for registrants to evaluate the orders of
4 controlled substances from distributors to man-
5 ufacturers and from pharmacies to distributors;
6 or

7 (B) otherwise implement a program to col-
8 lect and share in real time data for drug manu-
9 facturers and distributors, by providing access
10 to anonymized information to help drug manu-
11 facturers and distributors identify, report, and
12 stop suspicious orders of controlled substances
13 and reduce diversion rates.

14 (4) RECOMMENDED STATUTORY AND REGU-
15 LATORY CHANGES.—In designing the program re-
16 quired under paragraph (1), the Task Force—

17 (A) shall submit to the Attorney General
18 any recommendations for necessary amend-
19 ments to regulations of the Department of Jus-
20 tice relating to the requirements for ordering
21 schedule II controlled substances, so as to allow
22 uniform electronic ordering of controlled sub-
23 stances in schedules II, III, IV, and V electroni-
24 cally through the program; and

1 (B) may submit to Congress any rec-
2 ommendations for necessary legislative changes
3 so that a real-time data analytics solution can
4 be used across the United States.

5 (5) RESPONSIBILITY OF REGISTRANTS.—All
6 registered drug manufacturers and distributors shall
7 be responsible for reviewing any information made
8 available by the Attorney General and complying
9 with any regulations regarding the program designed
10 under paragraph (1) and implemented under para-
11 graph (3).

12 (f) FUNDING.—

13 (1) IN GENERAL.—The Attorney General, act-
14 ing through the Administrator, shall use amounts
15 collected as fees for distributors and registrants
16 under section 303 of the Controlled Substances Act
17 (21 U.S.C. 823) and section 1007 of the Controlled
18 Substances Import and Export Act (21 U.S.C. 957)
19 to carry out this section.

20 (2) OFFSET.—

21 (A) IN GENERAL.—The Administrator
22 may, on an equal basis and in accordance with
23 subparagraph (B), increase the fees described
24 in paragraph (1) for distributors and reg-

1 istrants to the extent necessary to defray the
2 costs of this section.

3 (B) TIERED FEE.—The Administrator
4 shall establish a tiered user fee for distributors
5 and registrants in proportion to the volume of
6 sales and purchases.

7 (g) APPLICABILITY OF FACA.—

8 (1) IN GENERAL.—Except as provided in para-
9 graph (2), the Federal Advisory Committee Act (5
10 U.S.C. App.) shall apply to the Task Force.

11 (2) TERMINATION.—The Task Force shall ter-
12 minate on the date on which the program is fully
13 implemented under subsection (e)(3).

14 (h) RULES OF CONSTRUCTION.—Nothing in this sub-
15 title shall be construed as relieving any manufacturer, dis-
16 tributor, or other registrant from the responsibilities of
17 the manufacturer, distributor, or other registrant, as the
18 case may be, to—

19 (1) identify, stop, and report suspicious orders;

20 (2) maintain effective controls against diversion
21 in accordance with section 303 of the Controlled
22 Substances Act (21 U.S.C. 823); and

23 (3) comply with the requirements established in
24 section 1301.74(b) of title 21, Code of Federal Reg-

1 ulations, or any successor regulation thereto, with
2 respect to suspicious orders.

3 **Subtitle J—Stop the Importation**
4 **and Manufacturing of Synthetic**
5 **Analogues**

6 **SEC. 7091. ESTABLISHMENT OF SCHEDULE A.**

7 Section 202 of the Controlled Substances Act (21
8 U.S.C. 812) is amended—

9 (1) in subsection (a), by striking “five schedules
10 of controlled substances, to be known as schedules I,
11 II, III, IV, and V” and inserting “six schedules of
12 controlled substances, to be known as schedules I,
13 II, III, IV, V, and A”;

14 (2) in subsection (b), by adding at the end the
15 following:

16 “(6) SCHEDULE A.—

17 “(A) IN GENERAL.—The drug or substance—

18 “(i) is or has been imported, or is offered
19 for import, into the United States;

20 “(ii) has—

21 “(I) a chemical structure that is sub-
22 stantially similar to the chemical structure
23 of a controlled substance in schedule I, II,
24 III, IV, or V; and

1 “(II) an actual or predicted stimulant,
2 depressant, or hallucinogenic effect on the
3 central nervous system that is substantially
4 similar to or greater than the stimulant,
5 depressant, or hallucinogenic effect on the
6 central nervous system of a controlled sub-
7 stance in schedule I, II, III, IV, or V; and
8 “(iii) is not—

9 “(I) listed or otherwise included in
10 any other schedule in this section or by
11 regulation of the Attorney General; and

12 “(II) with respect to a particular per-
13 son, subject to an exemption that is in ef-
14 fect for investigational use, for that person,
15 under section 505 of the Federal Food,
16 Drug, and Cosmetic Act (21 U.S.C. 355)
17 to the extent conduct with respect to such
18 substance is pursuant to such exemption.

19 “(B) PREDICTED STIMULANT, DEPRESSANT, OR
20 HALLUCINOGENIC EFFECT.—For purposes of this
21 paragraph, a predicted stimulant, depressant, or hal-
22 lucinogenic effect on the central nervous system may
23 be based on—

24 “(i)(I) the chemical structure; and

1 “(II)(aa) the structure activity relation-
2 ships; or

3 “(bb) binding receptor assays and other
4 relevant scientific information about the sub-
5 stance;

6 “(ii)(I) the current or relative potential for
7 abuse of the substance; and

8 “(II) the clandestine importation, manu-
9 facture, or distribution, or diversion from legiti-
10 mate channels, of the substance; or

11 “(iii) the capacity of the substance to
12 cause a state of dependence, including physical
13 or psychological dependence that is similar to or
14 greater than that of a controlled substance in
15 schedule I, II, III, IV, or V.”; and

16 (3) in subsection (c)—

17 (A) in the matter preceding schedule I, by
18 striking “IV, and V” and inserting “IV, V, and
19 A”; and

20 (B) by adding at the end the following:

21 “SCHEDULE A

22 “Any substance temporarily or permanently sched-
23 uled by the Attorney General in accordance with section
24 201(k).”.

1 **SEC. 7092. TEMPORARY AND PERMANENT SCHEDULING OF**
2 **SCHEDULE A SUBSTANCES.**

3 Section 201 of the Controlled Substances Act (21
4 U.S.C. 811) is amended by adding at the end the fol-
5 lowing:

6 “(k) TEMPORARY AND PERMANENT SCHEDULING OF
7 SCHEDULE A SUBSTANCES.—

8 “(1) IN GENERAL.—The Attorney General may
9 issue a temporary order adding a drug or substance
10 to schedule A if the Attorney General finds that—

11 “(A) the drug or other substance satisfies
12 the criteria for being considered a schedule A
13 substance; and

14 “(B) adding such drug or substance to
15 schedule A will assist in preventing abuse of the
16 drug or other substance.

17 “(2) DURATION OF TEMPORARY SCHEDULING
18 ORDER.—A temporary scheduling order issued under
19 paragraph (1) shall—

20 “(A) not take effect until 30 days after the
21 date of the publication by the Attorney General
22 of a notice in the Federal Register of the inten-
23 tion to issue such order and the grounds upon
24 which such order is to be issued; and

25 “(B) expire not later than 5 years after
26 the date on which the order becomes effective,

1 except that the Attorney General may, during
2 the pendency of proceedings under paragraph
3 (5), extend the temporary scheduling order for
4 up to 180 days.

5 “(3) EFFECT OF ISSUANCE OF PERMANENT
6 SCHEDULING ORDER.—A temporary scheduling
7 order issued under paragraph (1) shall be vacated
8 upon the issuance of a permanent order issued
9 under paragraph (5) with regard to the same sub-
10 stance, or upon the subsequent issuance of any
11 scheduling order under this section.

12 “(4) LIMITATION ON JUDICIAL REVIEW.—A
13 temporary scheduling order issued under paragraph
14 (1) shall not be subject to judicial review.

15 “(5) PERMANENT SCHEDULING ORDER.—

16 “(A) IN GENERAL.—Except as provided in
17 subparagraph (B), not earlier than 3 years
18 after the date on which the Attorney General
19 issues an order temporarily scheduling a drug
20 or substance under this subsection, the Attor-
21 ney General may, by rule, issue a permanent
22 order adding the drug or other substance to
23 schedule A if such drug or substance satisfies
24 the criteria for being considered a schedule A
25 substance.

1 “(B) LIMITATION.—If the Secretary of
2 Health and Human Services has determined,
3 based on relevant scientific studies and nec-
4 essary data requested by the Secretary of
5 Health and Human Services and gathered by
6 the Attorney General, that a drug or other sub-
7 stance that has been temporarily placed in
8 schedule A does not have sufficient potential for
9 abuse to warrant control in any schedule, and
10 provides written notice of such determination to
11 the Attorney General, the Attorney General—

12 “(i) may not issue a permanent sched-
13 uling order under subparagraph (A); and

14 “(ii) not later than 30 days after the
15 date on which the Attorney General re-
16 ceives such notice, shall issue an order im-
17 mediately terminating the temporary
18 scheduling order for the drug or other sub-
19 stance.

20 “(6) NOTICE TO HHS.—Before initiating pro-
21 ceedings under paragraph (1), the Attorney General
22 shall transmit notice of a temporary order proposed
23 to be issued to the Secretary of Health and Human
24 Services. In issuing an order under paragraph (1),
25 the Attorney General shall take into consideration

1 any comments submitted by the Secretary of Health
2 and Human Services in response to a notice trans-
3 mitted pursuant to this paragraph.”.

4 **SEC. 7093. PENALTIES.**

5 Section 1010 of the Controlled Substances Import
6 and Export Act (21 U.S.C. 960) is amended—

7 (1) in subsection (a), by inserting “or a drug or
8 substance in schedule A” after “controlled sub-
9 stance” each place it appears; and

10 (2) in subsection (b), by adding at the end the
11 following:

12 “(8) In the case of a violation under subsection (a)
13 involving a controlled substance in schedule A, the person
14 committing such violation shall be sentenced to a term of
15 imprisonment of not more than 20 years and if death or
16 serious bodily injury results from the use of such sub-
17 stance shall be sentenced to a term of imprisonment for
18 any term of years or for life, a fine not to exceed the great-
19 er of that authorized in accordance with the provisions of
20 title 18, United States Code, or \$1,000,000 if the defend-
21 ant is an individual or \$5,000,000 if the defendant is other
22 than an individual, or both. If any person commits such
23 a violation after a prior conviction for a felony drug of-
24 fense has become final, such person shall be sentenced to
25 a term of imprisonment of not more than 30 years and

1 if death or serious bodily injury results from the use of
2 such substance shall be sentenced to a term of imprison-
3 ment for any term of years or for life, a fine not to exceed
4 the greater of twice that authorized in accordance with
5 the provisions of title 18, United States Code, or
6 \$2,000,000 if the defendant is an individual or
7 \$10,000,000 if the defendant is other than an individual,
8 or both. Notwithstanding section 3583 of title 18, United
9 States Code, any sentence imposing a term of imprison-
10 ment under this paragraph shall, in the absence of such
11 a prior conviction, impose a term of supervised release of
12 not less than 3 years in addition to such term of imprison-
13 ment and shall, if there was such a prior conviction, im-
14 pose a term of supervised release of not less than 6 years
15 in addition to such term of imprisonment. Notwith-
16 standing the prior sentence, and notwithstanding any
17 other provision of law, the court shall not place on proba-
18 tion or suspend the sentence of any person sentenced
19 under the provisions of this paragraph which provide for
20 a mandatory term of imprisonment if death or serious
21 bodily injury results.”.

1 **SEC. 7094. FALSE LABELING OF SCHEDULE A CONTROLLED**
2 **SUBSTANCES.**

3 (a) IN GENERAL.—Section 305 of the Controlled
4 Substances Act (21 U.S.C. 825) is amended by adding at
5 the end the following:

6 “(f) FALSE LABELING OF SCHEDULE A CON-
7 TROLLED SUBSTANCES.—

8 “(1) It shall be unlawful to import or export,
9 with intent to manufacture, distribute, or dispense,
10 a schedule A substance or product containing a
11 schedule A substance, unless the substance or prod-
12 uct bears a label clearly identifying a schedule A
13 substance or product containing a schedule A sub-
14 stance by the nomenclature used by the Inter-
15 national Union of Pure and Applied Chemistry
16 (IUPAC).

17 “(2)(A) A product described in subparagraph
18 (B) is exempt from the International Union of Pure
19 and Applied Chemistry nomenclature requirement of
20 this subsection if such product is labeled in the man-
21 ner required under the Federal Food, Drug, and
22 Cosmetic Act.

23 “(B) A product is described in this subpara-
24 graph if the product—

1 “(i) is the subject of an approved applica-
2 tion as described in section 505(b) or (j) of the
3 Federal Food, Drug, and Cosmetic Act; or

4 “(ii) is exempt from the provisions of sec-
5 tion 505 of such Act relating to new drugs be-
6 cause—

7 “(I) it is intended solely for investiga-
8 tional use as described in section 505(i) of
9 such Act; and

10 “(II) such product is being used ex-
11 clusively for purposes of a clinical trial
12 that is the subject of an effective investiga-
13 tional new drug application.”.

14 (b) PENALTIES.—Section 402 of the Controlled Sub-
15 stances Act (21 U.S.C. 842) is amended—

16 (1) in subsection (a)—

17 (A) in paragraph (16), by striking “or” at
18 the end;

19 (B) by redesignating paragraph (17) as
20 paragraph (18); and

21 (C) by inserting after paragraph (16) the
22 following:

23 “(17) to violate section 305(f); or”; and

24 (2) in subsection (c)—

25 (A) in paragraph (1)—

- 1 (i) in subparagraph (B)(i), by striking
2 “(17)” and inserting “(18)”; and
3 (ii) in subparagraph (C), by inserting
4 “or (17)” after “paragraph (16)” each
5 place it appears; and
6 (B) in paragraph (2)(D), by striking
7 “(17)” and inserting “(18)”.

8 **SEC. 7095. REGISTRATION REQUIREMENTS FOR IMPORT-**
9 **ERS AND EXPORTERS OF SCHEDULE A SUB-**
10 **STANCES.**

11 Section 1008 of the Controlled Substances Import
12 and Export Act (21 U.S.C. 958) is amended by adding
13 at the end the following:

14 “(j)(1) The Attorney General shall register an appli-
15 cant to import or export a schedule A substance if—

16 “(A) the applicant demonstrates that the sched-
17 ule A substance will be used for research, analytical,
18 or industrial purposes approved by the Attorney
19 General; and

20 “(B) the Attorney General determines that such
21 registration is consistent with the public interest and
22 with the United States obligations under inter-
23 national treaties, conventions, or protocols in effect
24 on the date of enactment of this subsection.

1 “(2) In determining the public interest under para-
2 graph (1)(B), the Attorney General shall consider—

3 “(A) maintenance of effective controls against
4 diversion of particular controlled substances and any
5 controlled substance in schedule A compounded
6 therefrom into other than legitimate medical, sci-
7 entific, research, or industrial channels, by limiting
8 the importation and bulk manufacture of such con-
9 trolled substances to a number of establishments
10 which can produce an adequate and uninterrupted
11 supply of these substances under adequately com-
12 petitive conditions for legitimate medical, scientific,
13 research, and industrial purposes;

14 “(B) compliance with applicable State and local
15 law;

16 “(C) promotion of technical advances in the art
17 of manufacturing substances described in subpara-
18 graph (A) and the development of new substances;

19 “(D) prior conviction record of applicant under
20 Federal and State laws relating to the importation,
21 manufacture, distribution, or dispensing of sub-
22 stances described in subparagraph (A);

23 “(E) past experience in the importation and
24 manufacture of controlled substances, and the exist-

1 ence in the establishment of effective control against
2 diversion; and

3 “(F) such other factors as may be relevant to
4 and consistent with the public health and safety.

5 “(3) If an applicant is registered to import or export
6 a controlled substance in schedule I or II under subsection
7 (a), the applicant shall not be required to apply for a sepa-
8 rate registration under this subsection.”.

9 **SEC. 7096. ADDITIONAL CONFORMING AMENDMENTS.**

10 The Controlled Substances Import and Export Act
11 (21 U.S.C. 951 et seq.) is amended—

12 (1) in section 1002(a) (21 U.S.C. 952(a))—

13 (A) in the matter preceding paragraph (1),
14 by inserting “or drug or substance in schedule
15 A” after “schedule I or II”; and

16 (B) in paragraph (2), by inserting “or
17 drug or substances in schedule A” after “sched-
18 ule I or II”;

19 (2) in section 1003 (21 U.S.C. 953)—

20 (A) in subsection (c), in the matter pre-
21 ceding paragraph (1), by inserting “or drug or
22 substance in schedule A” after “schedule I or
23 II”; and

1 (B) in subsection (d), by inserting “or
2 drug or substance in schedule A” after “sched-
3 ule I or II”;

4 (3) in section 1004(1) (21 U.S.C. 954(1)), in
5 the matter preceding subparagraph (A), by inserting
6 “or drug or substance in schedule A” after “sched-
7 ule I”;

8 (4) in section 1005 (21 U.S.C. 955), by insert-
9 ing “or drug or substance in schedule A” after
10 “schedule I or II”; and

11 (5) in section 1009(a) (21 U.S.C. 959(a)), by
12 inserting “or drug or substance in schedule A” after
13 “schedule I or II”.

14 **SEC. 7097. SENTENCING REVIEW.**

15 (a) COVERED OFFENSE DEFINED.—In this section,
16 the term “covered offense” means an offense involving a
17 schedule A substance for which the penalty was estab-
18 lished under section 7093 or 7094 of this subtitle.

19 (b) SENTENCING REVIEW.—

20 (1) PETITION FOR REVIEW.—If a schedule A
21 substance that is temporarily or permanently sched-
22 uled under section 201(k) of the Controlled Sub-
23 stances Act, as added by this subtitle, is subse-
24 quently descheduled or rescheduled on a schedule
25 with lower penalties, any individual convicted of a

1 covered offense involving such schedule A substance
2 who is awaiting sentencing or is still serving a term
3 of imprisonment for such covered offense on the date
4 of the descheduling or rescheduling may petition the
5 court that imposed the sentence for a sentencing re-
6 duction hearing for such covered offense.

7 (2) SENTENCING REVIEW.—Not later than 30
8 days after the date on which a petition is filed under
9 paragraph (1), the court shall conduct a sentencing
10 reduction hearing and may modify the sentence of
11 the petitioner as if the descheduling or rescheduling
12 described in paragraph (1) had been in effect on the
13 date the covered offense was committed.

14 **SEC. 7098. RULES OF CONSTRUCTION.**

15 Nothing in this subtitle, or the amendments made by
16 this subtitle, may be construed to limit—

17 (1) the prosecution of offenses involving con-
18 trolled substance analogues under the Controlled
19 Substances Act (21 U.S.C. 801 et seq.); or

20 (2) the authority of the Attorney General to
21 temporarily or permanently schedule, reschedule, or
22 decontrol controlled substances under provisions of
23 section 201 of the Controlled Substances Act (21
24 U.S.C. 811) that are in effect on the day before the
25 date of enactment of this Act.

1 **SEC. 7099. CLARIFICATION OF CERTAIN REGISTRATION RE-**
2 **QUIREMENTS RELATED TO RESEARCH.**

3 (a) EXCEPTION FOR AGENTS OR EMPLOYEES OF
4 REGISTERED RESEARCHERS.—Section 302(c) of the Con-
5 trolled Substances Act (21 U.S.C. 822(c)) is amended in
6 paragraph (1) by striking “or dispenser” and inserting
7 “dispenser, or researcher”.

8 (b) CONFORMING AMENDMENT.—Section 102(3) of
9 the Controlled Substances Act (21 U.S.C. 802(3)) is
10 amended by striking “or dispenser” and inserting “dis-
11 penser, or researcher”.

12 (c) SINGLE REGISTRATION FOR CONTIGUOUS RE-
13 SEARCH SITES.—Section 302(e) of the Controlled Sub-
14 stances Act (21 U.S.C. 822(e)) is amended by adding at
15 the end the following new paragraph:

16 “(3) Notwithstanding paragraph (1), a person
17 registered to conduct research with a controlled sub-
18 stance under section 303(f) may conduct such re-
19 search under a single registration if such research
20 occurs exclusively on a single, contiguous campus
21 and the registrant notifies the Attorney General in
22 writing of all sites on the campus where the research
23 will be conducted or where the controlled substance
24 will be stored or administered. The registrant must
25 so notify the Attorney General prior to conducting
26 research at such additional sites.”.

1 (d) NEW INSPECTION NOT REQUIRED IN CERTAIN
2 SITUATIONS.—Section 303(f) of the Controlled Sub-
3 stances Act (21 U.S.C. 823(f)) is amended—

4 (1) by redesignating paragraphs (1) through
5 (5) as subparagraphs (A) through (E), respectively,
6 and by moving the margins of such subparagraphs
7 two ems to the right;

8 (2) by striking “(f) The” and inserting “(f)(1)
9 The”; and

10 (3) by adding at the end, after the matter fol-
11 lowing subparagraph (E), as so redesignated, the
12 following new paragraph:

13 “(2)(A) If a person is registered to conduct research
14 with a controlled substance and applies for a registration,
15 or a modification of a registration to conduct research
16 with a second controlled substance that is in the same
17 schedule or in a schedule with a higher numerical designa-
18 tion, a new inspection by the Attorney General of the reg-
19 istered location is not required.

20 “(B) Nothing in this paragraph shall prohibit the At-
21 torney General from conducting any inspection if the At-
22 torney General deems it necessary.”.

23 (e) CONTINUATION OF RESEARCH ON SUBSTANCES
24 NEWLY ADDED TO SCHEDULE I; AUTHORITY TO CON-
25 DUCT RESEARCH WITH OTHER SUBSTANCES IN SCHED-

1 ULE I.—Section 302 of the Controlled Substances Act (21
2 U.S.C. 822) is amended by adding at the end the following
3 new subsection:

4 “(h) CONTINUATION OF RESEARCH ON SUBSTANCES
5 NEWLY ADDED TO SCHEDULE I; AUTHORITY TO CON-
6 DUCT RESEARCH WITH OTHER SUBSTANCES IN SCHED-
7 ULE I.—

8 “(1) If a person is conducting research on a
9 substance at the time the substance is added to
10 schedule I, and such person is already registered to
11 conduct research with a controlled substance in
12 schedule I or II then—

13 “(A) the person shall, within 30 days of
14 the scheduling of the newly scheduled sub-
15 stance, submit a completed application for reg-
16 istration or modification of existing registration,
17 to conduct research on such substance, in ac-
18 cordance with the regulations issued by the At-
19 torney General;

20 “(B) the person may, notwithstanding sub-
21 sections (a) and (b), continue to conduct the re-
22 search on such substance until the application
23 referred to in subparagraph (A) is withdrawn
24 by the applicant or until the Attorney General
25 serves on the applicant an order to show cause

1 proposing the denial of the application pursuant
2 to section 304(c); and

3 “(C) if the Attorney General serves such
4 an order to show cause and the applicant re-
5 quests a hearing, such hearing shall be held on
6 an expedited basis and not later than 45 days
7 after the request is made, except that the hear-
8 ing may be held at a later time if so requested
9 by the applicant.

10 “(2)(A) A person who is registered to conduct
11 research with a controlled substance in schedule I
12 may, notwithstanding subsections (a) and (b), con-
13 duct research with another controlled substance in
14 schedule I, provided the following conditions are
15 met:

16 “(i) The person has applied for a modifica-
17 tion of the person’s registration to authorize re-
18 search with such other controlled substance in
19 accordance with the regulations issued by the
20 Attorney General.

21 “(ii) The Attorney General has obtained
22 verification from the Secretary that the re-
23 search protocol submitted with the application
24 is meritorious.

1 “(iii) The Attorney General has deter-
2 mined that such activity is consistent with
3 United States obligations under the Single Con-
4 vention on Narcotic Drugs, 1961. The Attorney
5 General shall make such determination not
6 later than 30 days after receiving the applica-
7 tion referred to in clause (i).

8 “(B) Nothing in this section shall be construed
9 to alter the authority of the Attorney General to ini-
10 tiate proceedings to deny, suspend, or revoke any
11 registration in accordance with sections 303 and
12 304.”.

13 (f) TREATMENT OF CERTAIN ACTIVITIES AS COINCI-
14 DENT TO RESEARCH.—Section 302 of the Controlled Sub-
15 stances Act (21 U.S.C. 822), as amended by subsection
16 (d), is further amended by adding at the end the following
17 new subsection:

18 “(i) TREATMENT OF CERTAIN ACTIVITIES AS COIN-
19 CIDENT TO RESEARCH.—

20 “(1) IN GENERAL.—Except as specified in
21 paragraph (2), a person who is registered to perform
22 research with a controlled substance may perform
23 the following activities with small quantities of that
24 substance, as set forth in the relevant statement or
25 protocol filed with the application for registration

1 approved by the Attorney General without being re-
2 quired to obtain a manufacturing registration:

3 “(A) Processing the substance to create ex-
4 tracts, tinctures, oils, solutions, derivatives, or
5 other forms of the substance consistent with the
6 approved research protocol.

7 “(B) Dosage form development for the
8 purpose of satisfying regulatory requirements
9 implemented by the Food and Drug Adminis-
10 tration for submitting an investigational new
11 drug application.

12 “(2) EXCEPTION REGARDING MARIHUANA.—

13 The authority under paragraph (1) does not include
14 authority to grow marihuana.”

15 **SEC. 7100. REVIEW OF RESEARCH REGISTRATION PROCESS.**

16 (a) REVIEW.—Not later than one year after the date
17 of the enactment of this section, the Attorney General and
18 the Secretary of Health and Human Services shall conduct
19 a review of the processes used to obtain or modify Federal
20 authorization to conduct research with controlled sub-
21 stances, including—

22 (1) an evaluation of the impacts of the amend-
23 ments made by section 7099 on the risk of the diver-
24 sion of controlled substances used in research and
25 related public safety considerations; and

1 (2) identification of opportunities to reduce any
2 unnecessary burden on persons seeking registration,
3 potential redundancies, and inefficiencies in the
4 process to obtain or modify Federal authorization to
5 conduct research with controlled substances, includ-
6 ing the process for obtaining a registration under
7 section 303 of the Controlled Substances Act (21
8 U.S.C. 823) and the process by which the Secretary
9 of Health and Human Services reviews research pro-
10 tocols.

11 (b) GUIDANCE.—Following the review described in
12 subsection (a), the Attorney General and the Secretary of
13 Health and Human Services shall, as appropriate, jointly
14 issue guidance to registrants and potential registrants
15 clarifying the process for registration under section 303
16 of the Controlled Substances Act (21 U.S.C. 823).

17 **TITLE VIII—TAX INCENTIVES TO**
18 **IMPROVE HEALTH CARE**

19 **SEC. 8001. DOMESTIC MEDICAL AND DRUG MANUFAC-**
20 **TURING CREDIT.**

21 (a) IN GENERAL.—Subpart D of part IV of sub-
22 chapter A of chapter 1 of the Internal Revenue Code of
23 1986 is amended by adding at the end the following new
24 section:

1 **“SEC. 45U. DOMESTIC MEDICAL AND DRUG MANUFAC-**
2 **TURING CREDIT.**

3 “(a) IN GENERAL.—For purposes of section 38, the
4 domestic medical and drug manufacturing credit deter-
5 mined under this section for any taxable year is an amount
6 equal to 10.5 percent of the lesser of—

7 “(1) the qualified medical and drug manufac-
8 turing income of the taxpayer for the taxable year,
9 or

10 “(2) taxable income of the taxpayer for the tax-
11 able year.

12 “(b) CREDIT LIMITED TO WAGES PAID.—

13 “(1) IN GENERAL.—The amount of the credit
14 allowable under subsection (a) for any taxable year
15 shall not exceed 50 percent of the W-2 wages of the
16 taxpayer for the taxable year.

17 “(2) W-2 WAGES.—For purposes of this sec-
18 tion—

19 “(A) IN GENERAL.—The term ‘W-2
20 wages’ means, with respect to any person for
21 any taxable year of such person, the sum of the
22 amounts described in paragraphs (3) and (8) of
23 section 6051(a) paid by such person with re-
24 spect to employment of employees by such per-
25 son during the calendar year ending during
26 such taxable year.

1 “(B) LIMITATION TO WAGES ATTRIB-
2 UTABLE TO DOMESTIC PRODUCTION.—Such
3 term shall not include any amount which is not
4 properly allocable to domestic medical and drug
5 manufacturing gross receipts for purposes of
6 subsection (c)(1).

7 “(C) RETURN REQUIREMENT.—Such term
8 shall not include any amount which is not prop-
9 erly included in a return filed with the Social
10 Security Administration on or before the 60th
11 day after the due date (including extensions)
12 for such return.

13 “(3) ACQUISITIONS, DISPOSITIONS, AND SHORT
14 TAXABLE YEARS.—The Secretary shall provide for
15 the application of this subsection in cases of a short
16 taxable year or where the taxpayer acquires, or dis-
17 poses of, the major portion of a trade or business or
18 the major portion of a separate unit of a trade or
19 business during the taxable year.

20 “(c) QUALIFIED MEDICAL AND DRUG MANUFAC-
21 TURING INCOME.—For purposes of this section—

22 “(1) IN GENERAL.—The term ‘qualified medical
23 and drug manufacturing income’ for any taxable
24 year means an amount equal to the excess (if any)
25 of—

1 “(A) the taxpayer’s domestic medical and
2 drug manufacturing gross receipts for the tax-
3 able year, over

4 “(B) the sum of—

5 “(i) the cost of goods sold that are al-
6 locable to such receipts, and

7 “(ii) other expenses, losses, or deduc-
8 tions which are properly allocable to such
9 receipts.

10 “(2) ALLOCATION METHOD.—The Secretary
11 shall prescribe rules for the proper allocation of
12 items described in paragraph (1)(B) for purposes of
13 determining qualified medical and drug manufac-
14 turing income. Such rules shall provide for the prop-
15 er allocation of items whether or not such items are
16 directly allocable to domestic medical and drug man-
17 ufacturing gross receipts.

18 “(3) SPECIAL RULES FOR DETERMINING
19 COSTS.—

20 “(A) IN GENERAL.—For purposes of deter-
21 mining costs under clause (i) of paragraph
22 (1)(B), any item or service brought into the
23 United States shall be treated as acquired by
24 purchase, and its cost shall be treated as not

1 less than its value immediately after it entered
2 the United States.

3 “(B) EXPORTS FOR FURTHER MANUFAC-
4 TURE.—In the case of any property described
5 in subparagraph (A) that had been exported by
6 the taxpayer for further manufacture, the in-
7 crease in cost or adjusted basis under subpara-
8 graph (A) shall not exceed the difference be-
9 tween the value of the property when exported
10 and the value of the property when brought
11 back into the United States after the further
12 manufacture.

13 “(4) DOMESTIC MEDICAL AND DRUG MANUFAC-
14 TURING GROSS RECEIPTS.—

15 “(A) IN GENERAL.—The term ‘domestic
16 medical and drug manufacturing gross receipts’
17 means the gross receipts of the taxpayer which
18 are derived from any sale, exchange, or other
19 disposition of—

20 “(i) any active pharmaceutical ingre-
21 dient, or

22 “(ii) any qualified countermeasure,
23 which was manufactured or produced by the
24 taxpayer in whole or in significant part within
25 the United States.

1 “(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.

7 “(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)).”

12 “(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.

21 “(d) DEFINITIONS AND SPECIAL RULES.—For purposes of this section—

23 “(1) APPLICATION OF SECTION TO PASS-THRU ENTITIES.—

1 “(A) PARTNERSHIPS AND S CORPORA-
2 TIONS.—In the case of a partnership or S cor-
3 poration—

4 “(i) this section shall be applied at the
5 partner or shareholder level,

6 “(ii) each partner or shareholder shall
7 take into account such person’s allocable
8 share of each item described in subpara-
9 graph (A) or (B) of subsection (c)(1) (de-
10 termined without regard to whether the
11 items described in such subparagraph (A)
12 exceed the items described in such sub-
13 paragraph (B)), and

14 “(iii) each partner or shareholder
15 shall be treated for purposes of subsection
16 (b) as having W-2 wages for the taxable
17 year in an amount equal to such person’s
18 allocable share of the W-2 wages of the
19 partnership or S corporation for the tax-
20 able year (as determined under regulations
21 prescribed by the Secretary).

22 “(B) TRUSTS AND ESTATES.—In the case
23 of a trust or estate—

24 “(i) the items referred to in subpara-
25 graph (A)(ii) (as determined therein) and

1 the W-2 wages of the trust or estate for
2 the taxable year, shall be apportioned be-
3 tween the beneficiaries and the fiduciary
4 (and among the beneficiaries) under regu-
5 lations prescribed by the Secretary, and

6 “(ii) for purposes of paragraph (2),
7 adjusted gross income of the trust or es-
8 tate shall be determined as provided in sec-
9 tion 67(e) with the adjustments described
10 in such paragraph.

11 “(C) REGULATIONS.—The Secretary may
12 prescribe rules requiring or restricting the allo-
13 cation of items and wages under this paragraph
14 and may prescribe such reporting requirements
15 as the Secretary determines appropriate.

16 “(2) APPLICATION TO INDIVIDUALS.—In the
17 case of an individual, subsection (a)(2) shall be ap-
18 plied by substituting ‘adjusted gross income’ for
19 ‘taxable income’. For purposes of the preceding sen-
20 tence, adjusted gross income shall be determined
21 after application of sections 86, 135, 137, 219, 221,
22 222, and 469.

23 “(3) SPECIAL RULE FOR AFFILIATED
24 GROUPS.—

1 “(A) IN GENERAL.—All members of an ex-
2 panded affiliated group shall be treated as a
3 single corporation for purposes of this section.

4 “(B) EXPANDED AFFILIATED GROUP.—
5 For purposes of this section, the term ‘ex-
6 panded affiliated group’ means an affiliated
7 group as defined in section 1504(a), deter-
8 mined—

9 “(i) by substituting ‘more than 50
10 percent’ for ‘at least 80 percent’ each place
11 it appears, and

12 “(ii) without regard to paragraphs (2)
13 and (4) of section 1504(b).

14 “(C) ALLOCATION OF CREDIT.—Except as
15 provided in regulations, the credit under sub-
16 section (a) shall be allocated among the mem-
17 bers of the expanded affiliated group in propor-
18 tion to each member’s respective amount (if
19 any) of qualified medical and drug manufac-
20 turing income.

21 “(4) TRADE OR BUSINESS REQUIREMENT.—
22 This section shall be applied by only taking into ac-
23 count items which are attributable to the actual con-
24 duct of a trade or business.

1 “(5) COORDINATION WITH MINIMUM TAX.—For
2 purposes of determining alternative minimum tax-
3 able income under section 55, qualified medical and
4 drug manufacturing income shall be determined
5 without regard to any adjustments under sections 56
6 through 59.

7 “(6) UNRELATED BUSINESS TAXABLE IN-
8 COME.—For purposes of determining the tax im-
9 posed by section 511, subsection (a)(1)(B) shall be
10 applied by substituting ‘unrelated business taxable
11 income’ for ‘taxable income’.

12 “(7) REGULATIONS.—The Secretary shall pre-
13 scribe such regulations as are necessary to carry out
14 the purposes of this section, including regulations
15 which prevent more than 1 taxpayer from being al-
16 lowed a credit under this section with respect to any
17 activity described in subsection (c)(4)(A).”.

18 (b) TREATMENT UNDER BASE EROSION TAX.—Sec-
19 tion 59A(b)(1)(B)(ii) of such Code is amended by striking
20 “plus” at the end of subclause (I), by redesignating sub-
21 clause (II) as subclause (III), and by inserting after sub-
22 clause (I) the following new subclause:

23 “(II) the credit allowed under
24 section 38 for the taxable year which
25 is properly allocable to the domestic

1 medical and drug manufacturing cred-
2 it determined under section 45U(a),
3 plus”.

4 (c) PART OF GENERAL BUSINESS CREDIT.—Section
5 38(b) of such Code is amended by striking “plus” at the
6 end of paragraph (32), by striking the period at the end
7 of paragraph (33) and inserting “, plus”, and by adding
8 at the end the following new paragraph:

9 “(34) the domestic medical and drug manufac-
10 turing credit determined under section 45U(a).”.

11 (d) CREDIT ALLOWED AGAINST ALTERNATIVE MIN-
12 IMUM TAX.—Section 38(c)(4)(B) of such Code is amended
13 by redesignating clauses (x) through (xii) as clauses (xi)
14 through (xiii), respectively, and by inserting after clause
15 (ix) the following new clause:

16 “(x) the credit determined under sec-
17 tion 45U,”.

18 (e) CLERICAL AMENDMENT.—The table of sections
19 for subpart D of part IV of subchapter A of chapter 1
20 of such Code is amended by adding at the end the fol-
21 lowing new item:

“Sec. 45U. Domestic medical and drug manufacturing credit.”.

22 (f) EFFECTIVE DATE.—The amendments made by
23 this section shall apply to taxable years beginning after
24 December 31, 2020.

1 **SEC. 8002. QUALIFYING ADVANCED MEDICAL MANUFAC-**
2 **TURING EQUIPMENT CREDIT.**

3 (a) IN GENERAL.—Subpart E of part IV of sub-
4 chapter A of chapter 1 of the Internal Revenue Code of
5 1986 is amended by adding at the end the following new
6 section:

7 **“SEC. 48D. QUALIFYING ADVANCED MEDICAL MANUFAC-**
8 **TURING EQUIPMENT CREDIT.**

9 “(a) IN GENERAL.—For purposes of section 46, the
10 qualifying advanced medical manufacturing equipment
11 credit determined under this section for any taxable year
12 is the applicable percentage of the basis of any qualifying
13 advanced medical manufacturing equipment placed in
14 service during such taxable year.

15 “(b) APPLICABLE PERCENTAGE.—For purposes of
16 subsection (a), the applicable percentage is—

17 “(1) 30 percent in the case of equipment which
18 is placed in service before January 1, 2028,

19 “(2) 20 percent in the case of equipment which
20 is placed in service during calendar year 2028,

21 “(3) 10 percent in the case of equipment which
22 is placed in service during calendar year 2029, and

23 “(4) 0 percent in the case of equipment which
24 is placed in service after December 31, 2029.

25 “(c) QUALIFYING ADVANCED MEDICAL MANUFAC-
26 TURING EQUIPMENT.—For purposes of this section, the

1 term ‘qualifying advanced medical manufacturing equip-
2 ment’ means property of a character subject to the allow-
3 ance for depreciation—

4 “(1) which is machinery or equipment that is
5 designed and used to manufacture a—

6 “(A) drug (as such term is defined in sec-
7 tion 201(g)(1) of the Federal Food, Drug, and
8 Cosmetic Act),

9 “(B) device (as such term is defined in sec-
10 tion 201(h) of such Act), or

11 “(C) biological product (as such term is
12 defined in section 351(i) of the Public Health
13 Service Act),

14 “(2) which has been identified by the Secretary
15 (after consultation with the Secretary of Health and
16 Human Services) as machinery or equipment that—

17 “(A) incorporates novel technology or uses
18 an established technique or technology in a new
19 or innovative way, or

20 “(B) that can improve medical product
21 quality, address shortages of medicines, and
22 speed time-to-market,

23 “(3) which is placed in service in the United
24 States by the taxpayer, and

1 “(4) with respect to which depreciation is allow-
2 able.

3 “(d) CERTAIN QUALIFIED PROGRESS EXPENDI-
4 TURES RULES MADE APPLICABLE.—Rules similar to the
5 rules of subsections (c)(4) and (d) of section 46 (as in
6 effect on the day before the enactment of the Revenue
7 Reconciliation Act of 1990) shall apply for purposes of
8 this section.

9 “(e) REGULATIONS.—The Secretary shall prescribe
10 such regulations or other guidance as may be necessary
11 to carry out the purposes of this section, including regula-
12 tions which prevent abuse or fraud.”.

13 (b) TREATMENT UNDER BASE EROSION TAX.—Sec-
14 tion 59A(b)(1)(B)(ii) of such Code, as amended by section
15 8001 of this Act, is further amended by striking “plus”
16 at the end of subclause (II), by redesignating subclause
17 (III) as subclause (IV), and by inserting after subclause
18 (II) the following new subclause:

19 “(III) the credit allowed under
20 section 46 for the taxable year which
21 is properly allocable to the qualifying
22 advanced medical manufacturing
23 equipment credit determined under
24 section 48D(a), plus”.

1 (c) PART OF INVESTMENT CREDIT.—Section 46 of
 2 such Code is amended by striking “and” at the end of
 3 paragraph (5), by striking the period at the end of para-
 4 graph (6) and inserting “, and”, and by adding at the
 5 end the following new paragraph:

6 “(7) the qualifying advanced medical manufac-
 7 turing equipment credit.”.

8 (d) CLERICAL AMENDMENT.—The table of sections
 9 for subpart D of part IV of subchapter A of chapter 1
 10 of such Code is amended by adding at the end the fol-
 11 lowing new item:

“Sec. 48D. Qualifying advanced medical manufacturing equipment credit.”.

12 (e) EFFECTIVE DATE.—The amendments made by
 13 this section shall apply to periods after the date of the
 14 enactment of this section under rules similar to the rules
 15 of section 48(m) of the Internal Revenue Code of 1986
 16 (as in effect on the date of the enactment fo the Revenue
 17 Reconciliation Act of 1990).

18 **SEC. 8003. NEW MEDICAL RESEARCH EXPENDITURE COM-**
 19 **PONENT OF CREDIT FOR INCREASING RE-**
 20 **SEARCH ACTIVITIES.**

21 (a) IN GENERAL.—Section 41(a) of the Internal Rev-
 22 enue Code of 1986 is amended by striking “and” at the
 23 end of paragraph (2), by striking the period at the end
 24 of paragraph (3) and inserting “, and”, and by adding
 25 at the end the following new paragraph:

1 “(4) 14 percent of specified medical research
2 expenditures.”.

3 (b) SPECIFIED MEDICAL RESEARCH EXPENDI-
4 TURES.—Section 41(f) of such Code is amended by adding
5 at the end the following new paragraph:

6 “(7) SPECIFIED MEDICAL RESEARCH EXPENDI-
7 TURES.—

8 “(A) IN GENERAL.—The term ‘specified
9 medical research expenditures’ means amounts
10 paid or incurred for qualified research with re-
11 spect to any qualified countermeasure.

12 “(B) QUALIFIED COUNTERMEASURE.—The
13 term ‘qualified countermeasure’ has the mean-
14 ing given to such term in section 319F–1(a)(2)
15 of the Public Health Service Act (42 U.S.C.
16 247d–6a(a)(2)).”.

17 (c) DENIAL OF DOUBLE BENEFIT.—

18 (1) TAXABLE YEARS BEGINNING BEFORE JANU-
19 ARY 1, 2021.—In the case of specified medical re-
20 search expenditures (as defined in section 41(f)(7)
21 of such Code (as added by this section)) paid or in-
22 curred in taxable years beginning before January 1,
23 2021—

24 (A) such expenditures shall be treated in
25 the same manner as qualified research expenses

1 and basic research expenses under section
2 280C(e)(1) of such Code (as in effect on the
3 day before the enactment of the Tax Cuts and
4 Jobs Act), and

5 (B) the amount determined under section
6 280C(e)(2)(A) (as in effect on such day) for the
7 taxable year shall be increased by the amount
8 of credit determined for the taxable year under
9 section 41(a)(4) (as added by this section).

10 (2) TAXABLE YEARS BEGINNING AFTER DECEM-
11 BER 31, 2020.—Section 280C(e)(1) of such Code is
12 amended by striking “section 41(a)(1)” and insert-
13 ing “paragraphs (1) and (4) of section 41(a)”.

14 (d) CONFORMING AMENDMENT.—Section 41(f)(1) of
15 such Code is amended by striking “and amounts paid or
16 incurred to energy research consortiums” each place it ap-
17 pears and inserting “, amounts paid or incurred to energy
18 research consortiums, and specified medical research ex-
19 penditures”.

20 (e) EFFECTIVE DATE.—The amendments made by
21 this section shall apply to amounts paid or incurred after
22 the date of the enactment of this Act, in taxable years
23 ending after such date.

1 **SEC. 8004. REFUNDABLE PORTION OF RESEARCH CREDIT**
2 **FOR SMALL BUSINESSES ENGAGING IN SPEC-**
3 **IFIED MEDICAL RESEARCH.**

4 (a) IN GENERAL.—Section 41 of the Internal Rev-
5 enue Code of 1986 is amended by adding at the end the
6 following new subsection:

7 “(i) REFUNDABLE PORTION FOR SMALL BUSI-
8 NESSES ENGAGING IN SPECIFIED MEDICAL RESEARCH.—

9 “(1) IN GENERAL.—At the election of a medical
10 research small business, the portion of the credit de-
11 termined under this section for the taxable year
12 which is properly allocable to specified medical re-
13 search shall be treated (other than for purposes of
14 section 280C) as a credit allowed under subpart C
15 (and not this subpart).

16 “(2) MEDICAL RESEARCH SMALL BUSINESS.—
17 For purposes of this subsection, the term ‘medical
18 research small business’ means any domestic C cor-
19 poration—

20 “(A) which conducts any specified medical
21 research during the taxable year, and

22 “(B) the gross receipts of which (deter-
23 mined under the rules of subsection (c)) for the
24 taxable year do not exceed \$1,000,000.

25 “(3) SPECIFIED MEDICAL RESEARCH.—For
26 purposes of this subsection, the term ‘specified med-

1 ical research’ means any qualified research with re-
2 spect to qualified countermeasures (as defined in
3 section 319F-1(a)(2) of the Public Health Service
4 Act (42 U.S.C. 247d-6a(a)(2))).

5 “(4) ELECTION.—Any election under this sub-
6 section for any taxable year—

7 “(A) shall specify the amount of the credit
8 to which such election applies,

9 “(B) shall be made on or before the due
10 date (including extensions) of the return of tax
11 for the taxable year,

12 “(C) may not be made for any taxable year
13 with respect to any portion of the credit deter-
14 mined under this section with respect to which
15 an election is made under subsection (h), and

16 “(D) may be revoked only with the consent
17 of the Secretary.

18 “(5) REGULATIONS.—The Secretary shall pre-
19 scribe such regulations for purposes of this sub-
20 section as may be necessary or appropriate for de-
21 termining proper allocation to specified medical re-
22 search of the portion of any credit allowed to a tax-
23 payer for a taxable year under this section.”.

1 (b) CONFORMING AMENDMENT.—Section 1324(b) of
2 title 31, United States Code, is amended by inserting
3 “41(i),” after “6428,”.

4 (c) EFFECTIVE DATE.—The amendments made by
5 this section shall apply to taxable years beginning after
6 December 31, 2020.

7 **SEC. 8005. EXCEPTION FROM PASSIVE LOSS RULES FOR IN-**
8 **VESTMENTS IN SPECIFIED MEDICAL RE-**
9 **SEARCH SMALL BUSINESS PASS-THRU ENTI-**
10 **TIES.**

11 (a) IN GENERAL.—Subsection (c) of section 469 of
12 the Internal Revenue Code of 1986 is amended by redesignig-
13 nating paragraphs (4) through (7) as paragraphs (5)
14 through (8), respectively, and by inserting after paragraph
15 (3) the following new paragraph:

16 “(4) SPECIFIED MEDICAL RESEARCH ACTIVI-
17 TIES.—

18 “(A) IN GENERAL.—The term ‘passive ac-
19 tivity’ shall not include any qualified medical re-
20 search activity of the taxpayer carried on by a
21 specified medical research small business pass-
22 thru entity.

23 “(B) TREATMENT OF LOSSES AND DEDUC-
24 TIONS.—

1 “(i) IN GENERAL.—Losses or deduc-
2 tions of a taxpayer in connection with
3 qualified medical research activities carried
4 on by a specified medical research small
5 business pass-thru entity shall not be
6 treated as losses or deductions, respec-
7 tively, from a passive activity except as
8 provided in clause (ii) and subparagraph
9 (C).

10 “(ii) LIMITATION.—Clause (i) shall
11 apply to losses and deductions of a tax-
12 payer in connection with a specified med-
13 ical small business pass-thru entity for a
14 taxable year only to the extent that the ag-
15 gregate losses and deductions of the tax-
16 payer in connection with qualified medical
17 research activities of such entity for such
18 taxable year do not exceed the portion of
19 the taxpayer’s adjusted basis in the tax-
20 payer’s ownership interest in such entity
21 that is attributable to money or other
22 property contributed—

23 “(I) in exchange for such owner-
24 ship interest, and

1 “(II) specifically for use in con-
2 nection with qualified medical re-
3 search activities.

4 For purposes of the preceding sentence,
5 the taxpayer’s basis shall not include any
6 portion of such basis which is attributable
7 to an increase in a partner’s share of the
8 liabilities of a partnership that is consid-
9 ered under section 752(a) as a contribution
10 of money.

11 “(C) TREATMENT OF CARRYOVERS.—Sub-
12 paragraph (B)(i) shall not apply to the portion
13 of any loss or deduction that is carried over
14 under subsection (b) into a taxable year other
15 than the taxable year in which such loss or de-
16 duction arose.

17 “(D) QUALIFIED MEDICAL RESEARCH AC-
18 TIVITY.—For purposes of this paragraph, the
19 term ‘qualified medical research activity’ means
20 any qualified research (within the meaning of
21 section 41(d)) with respect to qualified counter-
22 measures (as defined in section 319F–1(a)(2)
23 of the Public Health Service Act (42 U.S.C.
24 247d–6a(a)(2))).

1 “(E) SPECIFIED MEDICAL RESEARCH
2 SMALL BUSINESS PASS-THRU ENTITY.—For
3 purposes of this paragraph, the term ‘specified
4 medical research small business pass-thru enti-
5 ty’ means any domestic pass-thru entity for any
6 taxable year if—

7 “(i) more than 80 percent of such en-
8 tity’s expenditures on qualified research for
9 such taxable year are paid or incurred in
10 connection with qualified medical research
11 activities, and

12 “(ii) the gross receipts (as determined
13 under the rules of section 41(h)(3)) of
14 such entity for the taxable year (and each
15 preceding taxable year) is less than
16 \$1,000,000.

17 “(F) CAPITAL EXPENDITURES TAKEN INTO
18 ACCOUNT FOR EXPENDITURES TEST.—An ex-
19 penditure shall not fail to be taken into account
20 under subparagraph (E)(i) merely because such
21 expenditure is chargeable to capital account.

22 “(G) PASS-THRU ENTITY.—For purposes
23 of this paragraph, the term ‘pass-thru entity’
24 means any partnership, S corporation, or other

1 entity identified by the Secretary as a pass-thru
2 entity for purposes of this paragraph.

3 “(H) AGGREGATION RULES.—

4 “(i) IN GENERAL.—All persons treat-
5 ed as a single employer under subsection
6 (a) or (b) of section 52, or subsection (m)
7 or (o) of section 414, shall be treated as a
8 single entity for purposes of subparagraphs
9 (E) and (F)(iii).

10 “(ii) LIMITATION WHERE ENTITY
11 WOULD NOT QUALIFY.—No entity shall be
12 treated as a specified medical research
13 small business pass-thru entity unless such
14 entity qualifies as such both with and with-
15 out the application of clause (i).”.

16 (b) MATERIAL PARTICIPATION NOT REQUIRED.—
17 Paragraph (5) of section 469(c) of the Internal Revenue
18 Code of 1986, as redesignated by subsection (a), is amend-
19 ed by striking “and (3)” in the heading and text and in-
20 serting “, (3), and (4)”.

21 (c) CERTAIN RESEARCH-RELATED DEDUCTIONS AND
22 CREDITS OF SPECIFIED MEDICAL RESEARCH SMALL
23 BUSINESS PASS-THRU ENTITIES ALLOWED FOR PUR-
24 POSES OF DETERMINING ALTERNATIVE MINIMUM TAX.—

1 (1) DEDUCTION FOR RESEARCH AND EXPERI-
2 MENTAL EXPENDITURES.—Paragraph (2) of section
3 56(b) of the Internal Revenue Code of 1986 is
4 amended by adding at the end the following new
5 subparagraph:

6 “(E) EXCEPTION FOR SPECIFIED MEDICAL
7 RESEARCH SMALL BUSINESS PASS-THRU ENTI-
8 TIES.—In the case of a specified medical re-
9 search small business pass-thru entity (as de-
10 fined in section 469(c)(4)), this paragraph shall
11 not apply to any amount allowable as a deduc-
12 tion under section 174(a).”.

13 (2) ALLOWANCE OF CERTAIN RESEARCH-RE-
14 LATED CREDITS.—Subparagraph (B) of section
15 38(c)(4) of such Code is amended by redesignating
16 clauses (ii) through (ix) as clauses (iii) through (x),
17 respectively, and by inserting after clause (i) the fol-
18 lowing new clause:

19 “(ii) the credit of an individual tax-
20 payer determined under section 41 to the
21 extent attributable to a specified medical
22 research small business pass-thru entity
23 (as defined in section 469(c)(4)),”.

24 (d) EXCEPTION TO LIMITATION ON PASS-THRU OF
25 RESEARCH CREDIT.—Subsection (g) of section 41 of such

1 Code is amended by adding at the end the following:
2 “Paragraphs (2) and (4) shall not apply with respect to
3 any specified medical research small business pass-thru
4 entity (as defined in section 469(e)(4)).”.

5 (e) EFFECTIVE DATE.—The amendments made by
6 this section shall apply to losses and credits arising in tax-
7 able years beginning after December 31, 2020.

8 **SEC. 8006. TEMPORARY CARRYOVER FOR HEALTH AND DE-**
9 **PENDENT CARE FLEXIBLE SPENDING AR-**
10 **RANGEMENTS.**

11 (a) IN GENERAL.—With respect to the 2020 plan
12 year for any health flexible spending arrangement or any
13 dependent care flexible spending arrangement, an em-
14 ployer may elect to amend its cafeteria plan to permit any
15 unused amounts remaining in such flexible spending ar-
16 rangement at the end of such plan year to be carried over
17 to the 2021 plan year, pursuant to rules similar to the
18 rules established for health flexible spending arrangements
19 under Internal Revenue Service Notice 2013–71.

20 (b) RETROACTIVE APPLICATION.—An employer shall
21 be permitted to amend its cafeteria plan to effectuate the
22 rule described in subsection (a), provided that such
23 amendment—

24 (1) is adopted before January 1, 2021; and

1 (2) provides that the rule described in such sub-
2 section shall be in effect as of the first day of the
3 2020 plan year.

4 (c) DEFINITIONS.—Any term used in this section
5 which is also used in section 125 of the Internal Revenue
6 Code of 1986 or the regulations thereunder shall have the
7 same meaning as when used in such section or regulations.

8 **SEC. 8007. INCREASE IN EXCLUSION FOR EMPLOYER-PRO-**
9 **VIDED DEPENDENT CARE ASSISTANCE.**

10 (a) IN GENERAL.—Section 129(a)(2) of the Internal
11 Revenue Code of 1986 is amended by adding at the end
12 the following new subparagraph:

13 “(D) SPECIAL RULE FOR 2020 AND 2021.—
14 In the case of any taxable year beginning dur-
15 ing 2020 or 2021, subparagraph (A) shall be
16 applied by substituting ‘\$10,500 (\$5,250’ for
17 ‘\$5,000 (\$2,500’.”.

18 (b) EFFECTIVE DATE.—The amendment made by
19 this section shall apply to taxable years beginning after
20 December 31, 2019.

21 (c) RETROACTIVE PLAN AMENDMENTS.—A plan or
22 other arrangement that otherwise satisfies all applicable
23 requirements of sections 106, 125, and 129 of the Internal
24 Revenue Code of 1986 (including any rules or regulations
25 thereunder) shall not fail to be treated as a cafeteria plan

1 or dependent care flexible spending arrangement merely
2 because such plan or arrangement is amended pursuant
3 to a provision under this section and such amendment is
4 retroactive, if—

5 (1) such amendment is adopted no later than
6 the last day of the plan year in which the amend-
7 ment is effective, and

8 (2) the plan or arrangement is operated con-
9 sistent with the terms of such amendment during
10 the period beginning on the effective date of the
11 amendment and ending on the date the amendment
12 is adopted.

13 **SEC. 8008. TEMPORARY INCREASE IN CONTRIBUTION LIM-**
14 **ITS FOR HEALTH SAVINGS ACCOUNTS.**

15 (a) IN GENERAL.—Section 223(b) of the Internal
16 Revenue Code of 1986 is amended by adding at the end
17 the following new paragraph:

18 “(9) INCREASE IN MONTHLY LIMITATIONS FOR
19 TAXABLE YEARS 2020 AND 2021.—In the case of any
20 month during a taxable year which begins after De-
21 cember 31, 2019, and before January 1, 2022, the
22 dollar amount in effect under subparagraph (A) or
23 (B) of paragraph (2) for such month shall be twice
24 the amount otherwise applicable under such sub-
25 paragraph, as determined—

1 “(A) before application of paragraph (3),
2 “(B) after application of subsection (g),
3 and
4 “(C) without regard to this paragraph.”.

5 (b) EFFECTIVE DATE.—The amendment made by
6 this section shall apply with respect to taxable years begin-
7 ning after December 31, 2019.

8 **SEC. 8009. TEMPORARY ALLOWANCE OF PAYMENTS FOR**
9 **EMPLOYMENT-RELATED EXPENSES UNDER**
10 **HEALTH SAVINGS ACCOUNTS.**

11 (a) IN GENERAL.—Section 223(d)(2) of the Internal
12 Revenue Code of 1986 is amended by adding at the end
13 the following new subparagraph:

14 “(E) INCLUSION OF EMPLOYMENT-RE-
15 LATED EXPENSES FOR TAXABLE YEARS 2020
16 AND 2021.—In the case of any taxable year
17 which begins after December 31, 2019, and be-
18 fore January 1, 2022, the term ‘qualified med-
19 ical expenses’ includes, with respect to an ac-
20 count beneficiary, any amounts paid by such
21 beneficiary for employment-related expenses (as
22 defined in section 21(b)(2)) which are incurred
23 during such taxable year.”.

24 (b) CONFORMING AMENDMENT.—Section 21(c) of
25 the Internal Revenue Code of 1986 is amended by insert-

1 ing “and any amounts paid or distributed out of a health
2 savings account which are used exclusively to pay expenses
3 described in section 223(d)(2)(E) which are incurred by
4 the taxpayer during such taxable year” before the period
5 at the end of the second sentence.

6 (c) EFFECTIVE DATE.—The amendments made by
7 this section shall apply with respect to taxable years begin-
8 ning after December 31, 2019.

9 **SEC. 8010. TREATMENT OF DIRECT PRIMARY CARE SERV-**
10 **ICE ARRANGEMENTS.**

11 (a) IN GENERAL.—Section 223(c)(1) of the Internal
12 Revenue Code of 1986 is amended by adding at the end
13 the following new subparagraph:

14 “(D) TREATMENT OF DIRECT PRIMARY
15 CARE SERVICE ARRANGEMENTS.—

16 “(i) IN GENERAL.—A direct primary
17 care service arrangement shall not be
18 treated as a health plan for purposes of
19 subparagraph (A)(ii).

20 “(ii) DIRECT PRIMARY CARE SERVICE
21 ARRANGEMENT.—For purposes of this
22 paragraph—

23 “(I) IN GENERAL.—The term ‘di-
24 rect primary care service arrange-
25 ment’ means, with respect to any indi-

1 vidual, an arrangement under which
2 such individual is provided medical
3 care (as defined in section 213(d))
4 consisting solely of primary care serv-
5 ices provided by primary care practi-
6 tioners (as defined in section
7 1833(x)(2)(A) of the Social Security
8 Act, determined without regard to
9 clause (ii) thereof), if the sole com-
10 pensation for such care is a fixed peri-
11 odic fee.

12 “(II) LIMITATION.—With respect
13 to any individual for any month, such
14 term shall not include any arrange-
15 ment if the aggregate fees for all di-
16 rect primary care service arrange-
17 ments (determined without regard to
18 this subclause) with respect to such
19 individual for such month exceed
20 \$150 (twice such dollar amount in the
21 case of an individual with any direct
22 primary care service arrangement (as
23 so determined) that covers more than
24 one individual).

1 “(iii) CERTAIN SERVICES SPECIFI-
2 CALLY EXCLUDED FROM TREATMENT AS
3 PRIMARY CARE SERVICES.—For purposes
4 of this subparagraph, the term ‘primary
5 care services’ shall not include—

6 “(I) procedures that require the
7 use of general anesthesia, and

8 “(II) laboratory services not typi-
9 cally administered in an ambulatory
10 primary care setting.

11 The Secretary, after consultation with the
12 Secretary of Health and Human Services,
13 shall issue regulations or other guidance
14 regarding the application of this clause.”.

15 (b) DIRECT PRIMARY CARE SERVICE ARRANGEMENT
16 FEES TREATED AS MEDICAL EXPENSES.—Section
17 223(d)(2)(C) of the Internal Revenue Code of 1986 is
18 amended by striking “or” at the end of clause (iii), by
19 striking the period at the end of clause (iv) and inserting
20 “, or”, and by adding at the end the following new clause:

21 “(v) any direct primary care service arrangement.”.

22 (c) INFLATION ADJUSTMENT.—Section 223(g)(1) of
23 the Internal Revenue Code of 1986 is amended—

24 (1) by inserting “, (c)(1)(D)(ii)(II),” after
25 “(b)(2),” each place such term appears, and

1 (2) in subparagraph (B), by inserting “and
2 (iii)” after “clause (ii)” in clause (i), by striking
3 “and” at the end of clause (i), by striking the period
4 at the end of clause (ii) and inserting “, and”, and
5 by inserting after clause (ii) the following new
6 clause:

7 “(iii) in the case of the dollar amount
8 in subsection (c)(1)(D)(ii)(II) for taxable
9 years beginning in calendar years after
10 2020, ‘calendar year 2019.’”.

11 (d) REPORTING OF DIRECT PRIMARY CARE SERVICE
12 ARRANGEMENT FEES ON W-2.—Section 6051(a) of the
13 Internal Revenue Code of 1986 is amended by striking
14 “and” at the end of paragraph (16), by striking the period
15 at the end of paragraph (17) and inserting “, and”, and
16 by inserting after paragraph (17) the following new para-
17 graph:

18 “(18) in the case of a direct primary care serv-
19 ice arrangement (as defined in section
20 223(c)(1)(D)(ii)) which is provided in connection
21 with employment, the aggregate fees for such ar-
22 rangement for such employee.”.

23 (e) EFFECTIVE DATE.—

24 (1) IN GENERAL.—Except as provided under
25 paragraph (2), the amendments made by this section

1 shall apply to months beginning after December 31,
2 2019, in taxable years ending after such date.

3 (2) INFLATION ADJUSTMENT.—The amend-
4 ments made by subsection (c) shall apply to taxable
5 years beginning in calendar years beginning after
6 December 31, 2020.

7 **SEC. 8011. ALLOW BOTH SPOUSES TO MAKE CATCH-UP CON-**
8 **TRIBUTIONS TO THE SAME HSA ACCOUNT.**

9 (a) IN GENERAL.—Paragraph (5) of section 223(b)
10 of the Internal Revenue Code of 1986 is amended to read
11 as follows:

12 “(5) SPECIAL RULE FOR MARRIED INDIVIDUALS
13 WITH FAMILY COVERAGE.—

14 “(A) IN GENERAL.—In the case of individ-
15 uals who are married to each other, if both
16 spouses are eligible individuals and either
17 spouse has family coverage under a high de-
18 ductible health plan as of the first day of any
19 month—

20 “(i) the limitation under paragraph
21 (1) shall be applied by not taking into ac-
22 count any other high deductible health
23 plan coverage of either spouse (and if such
24 spouses both have family coverage under
25 separate high deductible health plans, only

1 one such coverage shall be taken into ac-
2 count),

3 “(ii) such limitation (after application
4 of clause (i)) shall be reduced by the ag-
5 gregate amount paid to Archer MSAs of
6 such spouses for the taxable year, and

7 “(iii) such limitation (after application
8 of clauses (i) and (ii)) shall be divided
9 equally between such spouses unless they
10 agree on a different division.

11 “(B) TREATMENT OF ADDITIONAL CON-
12 TRIBUTION AMOUNTS.—If both spouses referred
13 to in subparagraph (A) have attained age 55
14 before the close of the taxable year, the limita-
15 tion referred to in subparagraph (A)(iii) which
16 is subject to division between the spouses shall
17 include the additional contribution amounts de-
18 termined under paragraph (3) for both spouses.
19 In any other case, any additional contribution
20 amount determined under paragraph (3) shall
21 not be taken into account under subparagraph
22 (A)(iii) and shall not be subject to division be-
23 tween the spouses.”.

1 (b) EFFECTIVE DATE.—The amendment made by
2 this section shall apply to taxable years beginning after
3 December 31, 2019.

4 **SEC. 8012. REPEAL OF CEILING ON DEDUCTIBLE AND OUT-**
5 **OF-POCKET EXPENSES UNDER A HIGH DE-**
6 **DUCTIBLE HEALTH PLAN.**

7 (a) IN GENERAL.—Subparagraph (A) of section
8 223(c)(2) of the Internal Revenue Code of 1986 is amend-
9 ed to read as follows:

10 “(A) HIGH DEDUCTIBLE HEALTH PLAN.—

11 The term ‘high deductible health plan’ means a
12 health plan which has an annual deductible
13 which is not less than—

14 “(i) \$1,000 for self-only coverage, and

15 “(ii) twice the dollar amount in clause

16 (i) for family coverage.”.

17 (b) CONFORMING AMENDMENTS.—

18 (1) Subparagraph (D) of section 223(c)(2) of
19 the Internal Revenue Code of 1986 is amended to
20 read as follows:

21 “(D) SPECIAL RULE FOR NETWORK

22 PLANS.—In the case of a plan using a network
23 of providers, such plan’s annual deductible for
24 services provided outside of such network shall

1 not be taken into account for purposes of sub-
2 section (b)(2).”.

3 (2) Clause (ii) of section 223(g)(1)(B) of such
4 Code is amended by striking “each dollar amount in
5 subsection (c)(2)(A)” and inserting “the dollar
6 amount in subsection (c)(2)(A)(i)”.

7 (c) EFFECTIVE DATE.—The amendments made by
8 this section shall apply with respect to taxable years begin-
9 ning after December 31, 2019.

10 **SEC. 8013. ON-SITE EMPLOYEE CLINICS.**

11 (a) IN GENERAL.—Paragraph (1) of section 223(c)
12 of the Internal Revenue Code of 1986, as amended by sec-
13 tion 8010 of this Act, is amended by adding at the end
14 the following new subparagraph:

15 “(E) SPECIAL RULE FOR QUALIFIED
16 ITEMS AND SERVICES.—

17 “(i) IN GENERAL.—For purposes of
18 subparagraph (A)(ii), an individual shall
19 not be treated as covered under a health
20 plan described in subclauses (I) and (II) of
21 such subparagraph merely because the in-
22 dividual is eligible to receive, or receives,
23 qualified items and services—

24 “(I) at a healthcare facility lo-
25 cated at a facility owned or leased by

1 the employer of the individual (or of
2 the individual's spouse), or

3 “(II) at a healthcare facility op-
4 erated primarily for the benefit of em-
5 ployees of the employer of the indi-
6 vidual (or of the individual's spouse).

7 “(ii) QUALIFIED ITEMS AND SERVICES
8 DEFINED.—For purposes of this subpara-
9 graph, the term ‘qualified items and serv-
10 ices’ means the following:

11 “(I) Physical examination.

12 “(II) Immunizations, including
13 injections of antigens provided by em-
14 ployees.

15 “(III) Drugs or biologicals other
16 than a prescribed drug (as such term
17 is defined in section 213(d)(3)).

18 “(IV) Treatment for injuries oc-
19 ccurring in the course of employment.

20 “(V) Preventive care for chronic
21 conditions (as defined in clause (iv)).

22 “(VI) Drug testing.

23 “(VII) Hearing or vision
24 screenings and related services.

1 “(iii) AGGREGATION.—For purposes
2 of clause (i), all persons treated as a single
3 employer under subsection (b), (c), (m), or
4 (o) of section 414 shall be treated as a sin-
5 gle employer.

6 “(iv) PREVENTIVE CARE FOR CHRON-
7 IC CONDITIONS.—For purposes of this sub-
8 paragraph, the term ‘preventive care for
9 chronic conditions’ means any item or
10 service specified in the Appendix of Inter-
11 nal Revenue Service Notice 2019–45 which
12 is prescribed to treat an individual diag-
13 nosed with the associated chronic condition
14 specified in such Appendix for the purpose
15 of preventing the exacerbation of such
16 chronic condition or the development of a
17 secondary condition, including any amend-
18 ment, addition, removal, or other modifica-
19 tion made by the Secretary (pursuant to
20 the authority granted to the Secretary
21 under paragraph (2)(C)) to the items or
22 services specified in such Appendix subse-
23 quent to the date of enactment of this sub-
24 paragraph.”.

1 (b) EFFECTIVE DATE.—The amendments made by
2 this section shall apply to months in taxable years begin-
3 ning after the date of enactment of this Act.

4 **SEC. 8014. ADJUSTMENT OF MEDICAL EXPENSE DEDUC-**
5 **TION.**

6 (a) IN GENERAL.—Section 213 of the Internal Rev-
7 enue Code of 1986 is amended—

8 (1) in subsection (a), by striking “10 percent”
9 and inserting “7.5 percent”, and

10 (2) by striking subsection (f) and inserting the
11 following:

12 “(f) TEMPORARY SPECIAL RULE.—In the case of any
13 taxable year beginning after December 31, 2019, and end-
14 ing before January 1, 2022, subsection (a) shall be applied
15 with respect to a taxpayer by substituting ‘5 percent’ for
16 ‘7.5 percent’.”.

17 (b) EFFECTIVE DATE.—The amendments made by
18 this section shall apply to taxable years beginning after
19 December 31, 2019.

20 **SEC. 8015. HEALTHY WORKPLACE TAX CREDIT.**

21 (a) IN GENERAL.—In the case of an employer, there
22 shall be allowed as a credit against applicable employment
23 taxes for each calendar quarter an amount equal to 50
24 percent of the sum of—

1 (1) the qualified employee protection expenses
2 paid or incurred by the employer during such cal-
3 endar quarter,

4 (2) the qualified workplace reconfiguration ex-
5 penses paid or incurred by the employer during such
6 calendar quarter,

7 (3) the qualified workplace technology expenses
8 paid or incurred by the employer during such cal-
9 endar quarter, and

10 (4) the qualified workplace training expenses
11 paid or incurred by the employer during such cal-
12 endar quarter.

13 (b) LIMITATIONS AND REFUNDABILITY.—

14 (1) OVERALL DOLLAR LIMITATION ON CRED-
15 IT.—

16 (A) IN GENERAL.—The amount of the
17 credit allowed under subsection (a) with respect
18 to any employer for any calendar quarter shall
19 not exceed the excess (if any) of—

20 (i) the applicable dollar limit with re-
21 spect to such employer for such calendar
22 quarter, over

23 (ii) the aggregate credits allowed
24 under subsection (a) with respect to such

1 employer for all preceding calendar quar-
2 ters.

3 (B) APPLICABLE DOLLAR LIMIT.—The
4 term “applicable dollar limit” means, with re-
5 spect to any employer for any calendar quarter,
6 the sum of—

7 (i) \$1,000, multiplied so much of the
8 average number of employees employed by
9 such employer during such calendar quar-
10 ter as does not exceed 500, plus

11 (ii) \$750, multiplied by so much of
12 such average number of employees as ex-
13 ceeds 500 but does not exceed 1,000, plus

14 (iii) \$500, multiplied by so much of
15 such average number of employees as ex-
16 ceeds 1,000.

17 (2) CREDIT LIMITED TO EMPLOYMENT
18 TAXES.—The credit allowed by subsection (a) with
19 respect to any calendar quarter shall not exceed the
20 applicable employment taxes (reduced by any credits
21 allowed under subsections (e) and (f) of section
22 3111 of the Internal Revenue Code of 1986, sections
23 7001 and 7003 of the Families First Coronavirus
24 Response Act, and section 2301 of the CARES Act)
25 on the wages paid with respect to the employment

1 of all the employees of the eligible employer for such
2 calendar quarter.

3 (3) REFUNDABILITY OF EXCESS CREDIT.—

4 (A) IN GENERAL.—If the amount of the
5 credit under subsection (a) exceeds the limita-
6 tion of paragraph (2) for any calendar quarter,
7 such excess shall be treated as an overpayment
8 that shall be refunded under sections 6402(a)
9 and 6413(b) of the Internal Revenue Code of
10 1986.

11 (B) TREATMENT OF PAYMENTS.—For pur-
12 poses of section 1324 of title 31, United States
13 Code, any amounts due to the employer under
14 this paragraph shall be treated in the same
15 manner as a refund due from a credit provision
16 referred to in subsection (b)(2) of such section.

17 (c) QUALIFIED EMPLOYEE PROTECTION EX-
18 PENSES.—For purposes of this section, the term “quali-
19 fied employee protection expenses” means amounts paid
20 or incurred by the employer for—

21 (1) testing employees of the employer for
22 COVID–19 (including on a periodic basis),

23 (2) equipment to protect employees of the em-
24 ployer from contracting COVID–19, including
25 masks, gloves, and disinfectants, and

1 (3) cleaning products or services (whether pro-
2 vided by an employee of the taxpayer or a cleaning
3 service provider) related to preventing the spread of
4 COVID-19.

5 (d) QUALIFIED WORKPLACE RECONFIGURATION EX-
6 PENSES.—For purposes of this section—

7 (1) IN GENERAL.—The term “qualified work-
8 place reconfiguration expenses” means amounts paid
9 or incurred by the employer to design and recon-
10 figure retail space, work areas, break areas, or other
11 areas that employees or customers regularly use in
12 the ordinary course of the employer’s trade or busi-
13 ness if such design and reconfiguration—

14 (A) has a primary purpose of preventing
15 the spread of COVID-19,

16 (B) is with respect to an area that is lo-
17 cated in the United States and that is leased or
18 owned by the employer,

19 (C) is consistent with the purpose of the
20 property immediately before the reconfigura-
21 tion,

22 (D) is commensurate with the risks faced
23 by the employees or customers or is consistent
24 with recommendations made by the Centers for

1 Disease Control and Prevention or the Occupa-
2 tional Safety and Health Administration,

3 (E) is completed pursuant to a reconfig-
4 uration plan and no comparable reconfiguration
5 plan was in place before March 13, 2020, and

6 (F) is completed before January 1, 2021.

7 (2) REGULATIONS.—The Secretary shall pre-
8 scribe such regulations and other guidance as may
9 be necessary or appropriate to carry out the pur-
10 poses of this subsection, including guidance defining
11 primary purpose and reconfiguration plan.

12 (e) QUALIFIED WORKPLACE TECHNOLOGY EX-
13 PENSES.—For purposes of this section—

14 (1) IN GENERAL.—The term “qualified work-
15 place technology expenses” means amounts paid or
16 incurred by the employer for technology systems
17 that employees or customers use in the ordinary
18 course of the employer’s trade or business if such
19 technology system—

20 (A) has a primary purpose of preventing
21 the spread of COVID–19,

22 (B) is used for limiting physical contact
23 between customers and employees in the United
24 States,

1 (C) is commensurate with the risks faced
2 by the employees or customers or is consistent
3 with recommendations made by the Centers for
4 Disease Control and Prevention or the Occupa-
5 tional Safety and Health Administration,

6 (D) is acquired by the taxpayer after
7 March 12, 2020, and is not acquired pursuant
8 to a written binding contract entered into be-
9 fore such date, and

10 (E) is placed in service by the taxpayer be-
11 fore January 1, 2021.

12 (2) TECHNOLOGY SYSTEMS.—The term “tech-
13 nology systems” means computer software (as de-
14 fined in section 167(f)(1)) and qualified techno-
15 logical equipment (as defined in section 168(i)(2)).

16 (3) REGULATIONS.—The Secretary shall pre-
17 scribe such regulations and other guidance as may
18 be necessary or appropriate to carry out the pur-
19 poses of this subsection, including guidance defining
20 primary purpose.

21 (f) QUALIFIED WORKPLACE TRAINING EXPENSES.—
22 For purposes of this section, the term “qualified workplace
23 training expenses” means amounts paid or incurred by the
24 employer for education and training with respect to indus-
25 try best practices that ensure—

1 (1) the health and safety of employees in the
2 workplace with respect to COVID–19, and

3 (2) the prevention of the spread of COVID–19
4 in the workplace.

5 (g) OTHER DEFINITIONS.—For purposes of this sec-
6 tion—

7 (1) APPLICABLE EMPLOYMENT TAXES.—The
8 term “applicable employment taxes” means the fol-
9 lowing:

10 (A) The taxes imposed under section
11 3111(a) of the Internal Revenue Code of 1986.

12 (B) So much of the taxes imposed under
13 section 3221(a) of such Code as are attrib-
14 utable to the rate in effect under section
15 3111(a) of such Code.

16 (2) COVID–19.—Except where the context
17 clearly indicates otherwise, any reference in this sec-
18 tion to COVID–19 shall be treated as including a
19 reference to the virus which causes COVID–19.

20 (3) SECRETARY.—The term “Secretary” means
21 the Secretary of the Treasury or the Secretary’s del-
22 egate.

23 (4) OTHER TERMS.—Any term used in this sec-
24 tion (other than subsection (b)(1)(B)) which is also
25 used in chapter 21 or 22 of the Internal Revenue

1 Code of 1986 shall have the same meaning as when
2 used in such chapter.

3 (h) CERTAIN GOVERNMENTAL EMPLOYERS.—This
4 credit shall not apply to the Government of the United
5 States, the government of any State or political subdivi-
6 sion thereof, or any agency or instrumentality of any of
7 the foregoing.

8 (i) SPECIAL RULES.—

9 (1) AGGREGATION RULE.—All persons treated
10 as a single employer under subsection (a) or (b) of
11 section 52 of the Internal Revenue Code of 1986, or
12 subsection (m) or (o) of section 414 of such Code,
13 shall be treated as one employer for purposes of this
14 section.

15 (2) DENIAL OF DOUBLE BENEFIT.—

16 (A) IN GENERAL.—Rules similar to the
17 rules of paragraphs (1) and (2) of section
18 280C(b) shall apply for purposes of this section.

19 (B) EXPENSES NOT TAKEN INTO ACCOUNT
20 MORE THAN ONCE.—Any qualified workplace
21 reconfiguration expense or qualified workplace
22 technology expense shall not be treated as a
23 qualified employee protection expense and any
24 qualified workplace technology expense shall not

1 be treated as a qualified workplace reconfigura-
2 tion expense.

3 (3) THIRD-PARTY PAYORS.—Any credit allowed
4 under this section shall be treated as a credit de-
5 scribed in section 3511(d)(2) of such Code.

6 (4) ELECTION NOT TO HAVE SECTION APPLY.—
7 This section shall not apply with respect to any eligi-
8 ble employer for any calendar quarter if such em-
9 ployer elects (at such time and in such manner as
10 the Secretary may prescribe) not to have this section
11 apply.

12 (j) TRANSFERS TO CERTAIN TRUST FUNDS.—There
13 are hereby appropriated to the Federal Old-Age and Sur-
14 vivors Insurance Trust Fund and the Federal Disability
15 Insurance Trust Fund established under section 201 of
16 the Social Security Act (42 U.S.C. 401) and the Social
17 Security Equivalent Benefit Account established under
18 section 15A(a) of the Railroad Retirement Act of 1974
19 (45 U.S.C. 231n–1(a)) amounts equal to the reduction in
20 revenues to the Treasury by reason of this section (without
21 regard to this subsection). Amounts appropriated by the
22 preceding sentence shall be transferred from the general
23 fund at such times and in such manner as to replicate
24 to the extent possible the transfers which would have oc-

1 curred to such Trust Fund or Account had this section
2 not been enacted.

3 (k) TREATMENT OF DEPOSITS.—The Secretary shall
4 waive any penalty under section 6656 of the Internal Rev-
5 enue Code of 1986 for any failure to make a deposit of
6 any applicable employment taxes if the Secretary deter-
7 mines that such failure was due to the reasonable anticipa-
8 tion of the credit allowed under this section.

9 (l) REGULATIONS AND GUIDANCE.—The Secretary
10 shall prescribe such regulations and other guidance as
11 may be necessary or appropriate to carry out the purposes
12 of this section, including—

13 (1) with respect to the application of the credit
14 under subsection (a) to third-party payors (including
15 professional employer organizations, certified profes-
16 sional employer organizations, or agents under sec-
17 tion 3504 of the Internal Revenue Code of 1986),
18 regulations or other guidance allowing such payors
19 to submit documentation necessary to substantiate
20 the amount of the credit allowed under subsection
21 (a), and

22 (2) regulations or other guidance to prevent
23 abusive transactions.

1 (m) APPLICATION.—This section shall only apply to
2 amounts paid or incurred after March 12, 2020, and be-
3 fore January 1, 2021.

4 **TITLE IX—MEDICARE**
5 **PROVISIONS**
6 **Subtitle A—Telehealth**

7 **SEC. 9001. REMOVING CERTAIN GEOGRAPHIC AND ORIGI-**
8 **NATING SITE RESTRICTIONS ON THE FUR-**
9 **NISHING OF TELEHEALTH SERVICES UNDER**
10 **THE MEDICARE PROGRAM.**

11 Section 1834(m)(4)(C) of the Social Security Act (42
12 U.S.C. 1395m(m)(4)(C)) is amended—

13 (1) in clause (i), by inserting “, with respect to
14 services furnished on or after January 1, 2024,”
15 after “telecommunications system and”; and

16 (2) in clause (ii)(X), by inserting “, with re-
17 spect to services furnished on or after January 1,
18 2024,” after “but”.

19 **SEC. 9002. MAKING PERMANENT FQHC AND RHC TELE-**
20 **HEALTH PAYMENTS.**

21 Section 1834(m)(6) of the Social Security Act (42
22 U.S.C. 1395m(m)(8)), as so redesignated by section 2(7),
23 is amended—

24 (1) in the header, by striking “DURING EMER-
25 GENCY PERIOD”;

1 (2) in subparagraph (A), in the matter pre-
2 ceding clause (i), by striking “During” and inserting
3 “With respect to services furnished on or after the
4 first day of”; and

5 (3) in subparagraph (B)(i), by striking “during
6 such emergency period”.

7 **SEC. 9003. EXPANDING THE LIST OF PRACTITIONERS ELIGI-**
8 **BLE TO FURNISH TELEHEALTH SERVICES.**

9 Section 1834(m) of the Social Security Act (42
10 U.S.C. 1395m(m)) is amended—

11 (1) in paragraph (1), by striking “described in
12 section 1842(b)(18)(C)” and inserting “as defined in
13 paragraph (4)(E)”;

14 (2) in paragraph (3)(B), by inserting “de-
15 scribed in subparagraph (C) of such section” after
16 “practitioners”; and

17 (3) in paragraph (4), by amending subpara-
18 graph (E) to read as follows:

19 “(E) PRACTITIONER.—The term ‘practi-
20 tioner’ means a practitioner described in section
21 1842(b)(18)(C) and includes, with respect to
22 services furnished before January 1, 2024, any
23 supplier (other than a physician) permitted to
24 receive payment for a telehealth service under
25 this section as of the date of the enactment of

1 this subparagraph pursuant to a waiver in ef-
2 fect as of such date under section 1135.”.

3 **SEC. 9004. ALLOWING FOR THE PROVISION OF TELE-**
4 **HEALTH SERVICES VIA AUDIO-ONLY TELE-**
5 **COMMUNICATIONS SYSTEMS.**

6 Section 1834(m)(4) of the Social Security Act (42
7 U.S.C. 1395m(m)(4)) is amended by adding at the end
8 the following new subparagraph:

9 “(G) TELECOMMUNICATIONS SYSTEM.—

10 “(i) IN GENERAL.—The term ‘tele-
11 communications system’ includes, in the
12 case of a telehealth service furnished by a
13 qualified provider (as defined in clause (ii))
14 to an individual located at an originating
15 site before January 1, 2024, a communica-
16 tions system consisting of only audio capa-
17 bilities, but only if such individual does not
18 have access to a communications system
19 with audio-visual capabilities at such site.

20 “(ii) QUALIFIED PROVIDER.—For
21 purposes of clause (i), the term ‘qualified
22 provider’ means, with respect a telehealth
23 service furnished to an individual, a physi-
24 cian or practitioner who—

1 “(I) furnished to such individual
2 an item or service (other than such
3 telehealth service) for which payment
4 was made under any group health
5 plan (as defined in section 2791 of
6 the Public Health Service Act), health
7 insurance coverage (as so defined),
8 Federal health care program (as de-
9 fined in section 1128B(f)), or the
10 health care program under chapter 89
11 of title 5, United States Code, during
12 the 3-year period ending on the date
13 such telehealth service was furnished;
14 or

15 “(II) is in the same practice (as
16 determined by tax identification num-
17 ber) of a physician or practitioner who
18 furnished such an item or service to
19 such individual during such period.”.

20 **SEC. 9005. MAKING PERMANENT THE SAFE HARBOR FOR**
21 **ABSENCE OF DEDUCTIBLE FOR TELEHEALTH.**

22 (a) IN GENERAL.—Section 223(c)(2)(E) of the Inter-
23 nal Revenue Code of 1986 is amended by striking “In the
24 case of plan years beginning on or before December 31,
25 2021, a” and inserting “A”.

1 (b) CERTAIN COVERAGE DISREGARDED.—Section
 2 223(c)(1)(B)(ii) of the Internal Revenue Code of 1986 is
 3 amended by striking “(in the case of plan years beginning
 4 on or before December 31, 2021)”.

5 **SEC. 9006. REMOVING REQUIREMENT FOR FACE-TO-FACE**
 6 **VISITS BETWEEN HOME DIALYSIS PATIENTS**
 7 **AND PHYSICIANS.**

8 (a) IN GENERAL.—Section 1881(b)(3)(B) of the So-
 9 cial Security Act (42 U.S.C. 1395rr(b)(3)(B)) is amend-
 10 ed—

11 (1) in clause (i), by striking “clauses (ii) and
 12 (iii)” and inserting “clause (ii)”;

13 (2) in clause (ii), by inserting “or (iv)” after
 14 “clause (iii)”;

15 (3) by moving clause (iii) 6 ems to the left; and

16 (4) by adding at the end the following new
 17 clause:

18 “(iv) Clause (ii) shall not apply to monthly end stage
 19 renal disease-related clinical assessments furnished before
 20 January 1, 2024, in the case of an individual who has
 21 received in-person training with respect to home dialysis.”.

22 (b) WAIVER AUTHORITY.—

23 (1) IN GENERAL.—Notwithstanding any provi-
 24 sion of section 1135 of the Social Security Act (42
 25 U.S.C. 1320b–5), the Secretary of Health and

1 Human Services may, with respect to a specified
2 waiver (as defined in paragraph (2)), continue such
3 waiver in effect for any period of time before Janu-
4 ary 1, 2024.

5 (2) DEFINITION.—In this subsection, the term
6 “specified waiver” means a waiver in effect on the
7 date of the enactment of this Act that, with respect
8 to any provision of title XVIII of the Social Security
9 Act (42 U.S.C. 1395 et seq.) that requires an in-per-
10 son visit with a provider of services or supplier (as
11 such terms are defined in section 1861 of such Act
12 (42 U.S.C. 1395x)) as a prerequisite for payment of
13 any item or service under such title or for any other
14 purpose, modifies such provision to allow such visit
15 to be conducted through the use of telehealth.

16 **SEC. 9007. REPORT ON TELEHEALTH PAYMENT INTEGRITY.**

17 Not later than 1 year after the date of the enactment
18 of this Act, the Inspector General of the Department of
19 Health and Human Services shall review claims for pay-
20 ment for telehealth services furnished under the Medicare
21 program during the emergency period described in section
22 1135(g)(1)(B) of the Social Security Act (42 U.S.C.
23 1320b–5(g)(1)(B)) and submit to Congress a report on
24 any instances of waste, fraud, or abuse identified through
25 such review.

1 **SEC. 9008. INCREASING FUNDING FOR REVIEW OF TELE-**
2 **HEALTH CLAIMS.**

3 There are authorized to be appropriated to the In-
4 spector General of the Department of Health and Human
5 Services \$10,000,000 for fiscal years 2021 through 2023
6 for purposes of conducting audits and other oversight ac-
7 tivities with respect to payments made under section
8 1834(m) of the Social Security Act (42 U.S.C.
9 1395m(m)).

10 **SEC. 9009. TELEHEALTH RESOURCES.**

11 Not later than 6 months after the last day of the
12 emergency period described in section 1135(g)(1)(B) of
13 the Social Security Act (42 U.S.C. 1320b-5(g)(1)(B)), the
14 Secretary of Health and Human Services shall develop and
15 make available to physicians (as defined in section 1861(r)
16 of such Act (42 U.S.C. 1395x(r))) and practitioners (as
17 defined in section 1834(m)(4)(E) of such Act (42 U.S.C.
18 1395m(m)(4)(E))) educational resources and training ses-
19 sions on requirements relating to the furnishing of tele-
20 health services under section 1834(m) of such Act (42
21 U.S.C. 1395m(m)).

1 **Subtitle B—Protecting Access to**
2 **Innovation During COVID-19**

3 **SEC. 9011. AUTHORIZING THE EXTENSION OF PASS-**
4 **THROUGH STATUS UNDER THE MEDICARE**
5 **PROGRAM FOR CERTAIN DRUGS AND DE-**
6 **VICES IMPACTED BY COVID-19.**

7 Section 1833(t)(6) of the Social Security Act (42
8 U.S.C. 1395l(t)(6)) is amended by adding at the end the
9 following new subparagraph:

10 “(K) AUTHORITY TO EXTEND PASS-
11 THROUGH STATUS FOR CERTAIN DRUGS AND
12 DEVICES IMPACTED BY COVID-19.—

13 “(i) IN GENERAL.—Notwithstanding
14 the preceding provisions of this paragraph,
15 in the case of an eligible drug or device (as
16 defined in clause (iv)), if the Secretary de-
17 termines, prior to or on the date of the ex-
18 piration of pass-through status for such
19 drug or device (or, in the case of such a
20 drug or device whose pass-through status
21 expired before the date of the enactment of
22 this subparagraph, not later than 30 days
23 after such date), that the cost of such drug
24 or device is unable to be accurately cal-
25 culated due to the effects of COVID-19,

1 the Secretary may extend the pass-through
2 status of such eligible drug or device in ac-
3 cordance with clause (ii).

4 “(ii) EXTENSION.—The Secretary
5 may extend the pass-through status of an
6 eligible drug or device described in clause
7 (i) with respect to which a determination
8 has been made under such clause—

9 “(I) in the case of a drug or de-
10 vice whose period of pass-through sta-
11 tus expired during the emergency pe-
12 riod described in section
13 1135(g)(1)(B) before the date of the
14 enactment of this subparagraph, for a
15 period beginning on the first day after
16 such period of up to the number of
17 days occurring during such period
18 during which such drug or device had
19 pass-through status;

20 “(II) in the case of a drug or de-
21 vice whose period of pass-through sta-
22 tus would otherwise expire during
23 such emergency period on or after
24 such date of enactment—

1 “(aa) for the remainder of
2 such period; and

3 “(bb) for a period beginning
4 on the first day after such period
5 of up to the number of days oc-
6 ccurring during such period dur-
7 ing which such drug or device
8 had pass-through status (not tak-
9 ing into account any extension of
10 such status pursuant to this sub-
11 clause); and

12 “(III) in the case of a drug or
13 device not described in subclause (I)
14 or (II), by the number of days occur-
15 ring during such emergency period
16 during which such drug or device had
17 pass-through status.

18 “(iii) SPECIAL RULES FOR ALREADY-
19 EXPIRED DRUGS AND DEVICES.—In the
20 case of an eligible drug or device described
21 in clause (ii)(I) for which payment under
22 this subsection was packaged into a pay-
23 ment for a covered OPD service (or group
24 of services) and whose period of pass-

1 through status is extended in accordance
2 with such clause, the Secretary—

3 “(I) shall, for the period during
4 which such extension is in effect for
5 such drug or device—

6 “(aa) remove, during such
7 period, the packaged costs of
8 such drug or device (as deter-
9 mined by the Secretary) from the
10 payment amount under this sub-
11 section for the covered OPD serv-
12 ice (or group of services) with
13 which it is packaged; and

14 “(bb) not make any adjust-
15 ments to payment amounts under
16 this subsection for a covered
17 OPD service (or group of serv-
18 ices) for which no costs were re-
19 moved under subclause (I); and

20 “(II) may not, when calculating
21 the cost of such drug or device at the
22 end of such extension, take into ac-
23 count claims for such drug or device
24 made while such drug or device was
25 so packaged.

1 “(iv) ELIGIBLE DRUG OR DEVICE DE-
2 FINED.—For purposes of this subpara-
3 graph, the term ‘eligible drug or device’
4 means a drug, biological, or device with
5 pass-through status in effect during any
6 portion of the emergency period described
7 in section 1135(g)(1)(B) that will not be
8 (or was not) separately payable upon the
9 expiration of such status, but only if, in
10 the case of a drug or biological, such drug
11 or biological—

12 “(I) was payable based upon the
13 wholesale acquisition cost of such
14 drug or biological in lieu of the aver-
15 age sales price of such drug or biologi-
16 cal on the first date of such emer-
17 gency period; and

18 “(II) will be (or was) packaged
19 into a payment for a covered OPD
20 service (or group of services) upon ex-
21 piration of such status.”.

1 **Subtitle C—Reducing Unnecessary**
2 **Senior Hospitalizations**

3 **SEC. 9021. SNF-BASED PROVISION OF PREVENTIVE ACUTE**
4 **CARE AND HOSPITALIZATION REDUCTION**
5 **PROGRAM.**

6 Title XVIII of the Social Security Act is amended by
7 adding at the end the following new section:

8 **“SEC. 1899C. SNF-BASED PROVISION OF PREVENTIVE**
9 **ACUTE CARE AND HOSPITALIZATION REDUC-**
10 **TION PROGRAM.**

11 “(a) ESTABLISHMENT.—There is established a pro-
12 gram to be known as the ‘SNF-based Provision of Preven-
13 tive Acute Care and Hospitalization Reduction Program’
14 (in this section referred to as the ‘Program’), to be admin-
15 istered by the Secretary, for purposes of reducing unneces-
16 sary hospitalizations and emergency department visits by
17 allowing qualified group practices (as defined in section
18 1877(h)(4)) on or after January 1, 2022, to furnish items
19 and services identified under subsection (b)(3) to individ-
20 uals entitled to benefits under part A and enrolled under
21 part B residing in qualified skilled nursing facilities.

22 “(b) OPERATION OF PROGRAM.—Under the Pro-
23 gram, the Secretary shall provide for the following:

1 “(1) Certification of skilled nursing facilities as
2 qualified skilled nursing facilities under subsection
3 (c)(1).

4 “(2) Certification of group practices as quali-
5 fied group practices under subsection (c)(2).

6 “(3) Identification of minimum required non-
7 surgical items and services furnished at a hospital
8 emergency department that may be safely furnished
9 by a qualified group practice at a qualified skilled
10 nursing facility under the Program, as determined
11 as clinically appropriate by the Secretary, and that
12 such qualified group practice shall offer to furnish
13 under the Program.

14 “(4) Annual identification of additional items
15 and services furnished at a hospital emergency de-
16 partment that may be safely furnished by a qualified
17 group practice at a qualified skilled nursing facility
18 under the Program during a year and that such
19 qualified group practice may offer to furnish under
20 the Program during such year.

21 “(5) Establishment of qualifications for non-
22 physician employees who may furnish such items
23 and services at a qualified skilled nursing facility.
24 Such qualifications shall include the requirement
25 that such an employee—

1 “(A) be certified in basic life support by a
2 nationally recognized specialty board of certifi-
3 cation or equivalent certification board; and

4 “(B) have—

5 “(i) clinical experience furnishing
6 medical care—

7 “(I) in a skilled nursing facility;

8 “(II) in a hospital emergency de-
9 partment setting; or

10 “(III) as an employee of a pro-
11 vider or supplier of ambulance serv-
12 ices; or

13 “(ii) a certification in paramedicine.

14 “(6) Payment under this title for items and
15 services identified under paragraph (3) or (4) fur-
16 nished by such qualified group practices at such a
17 facility in amounts determined under subsection (d).

18 “(c) CERTIFICATIONS.—

19 “(1) QUALIFIED SKILLED NURSING FACILI-
20 TIES.—For purposes of this section, the Secretary
21 shall certify a skilled nursing facility as a qualified
22 skilled nursing facility if the facility submits an ap-
23 plication in a time and manner specified by the Sec-
24 retary and meets the following requirements:

1 “(A) The facility has on-site diagnostic
2 equipment necessary for a qualified group prac-
3 tice to furnish items and services under the
4 Program and real-time audio and visual capa-
5 bilities.

6 “(B) The facility has at least one indi-
7 vidual who meets the qualifications described in
8 paragraph (5) or a physician present 24 hours
9 a day and 7 days a week to work with the
10 qualified group practice. Such individual may
11 be a member of the staff of the qualified skilled
12 nursing facility or of the qualified group prac-
13 tice.

14 “(C) The facility ensures that residents of
15 such facility, upon entering such facility, are al-
16 lowed to specify in an advanced care directive
17 whether the resident wishes to receive items
18 and services furnished at the facility under the
19 Program in a case where communication with
20 the resident is not possible.

21 “(D) The facility ensures that individuals
22 to be furnished such items and services under
23 the Program at such facility have the oppor-
24 tunity, at their request, to instead be trans-
25 ported to a hospital emergency department.

1 “(E) The facility is not part of the Special
2 Focus Facility program of the Centers for
3 Medicare & Medicaid Services (although the fa-
4 cility may, at the discretion of the Secretary, be
5 a candidate for selection under such program).
6 Nothing in this paragraph shall affect the require-
7 ments under section 1819(b)(4).

8 “(2) QUALIFIED GROUP PRACTICES.—For pur-
9 poses of this section, the Secretary shall certify a
10 group practice as a qualified group practice for a pe-
11 riod of 3 years if the group practice submits an ap-
12 plication in a time and manner specified by the Sec-
13 retary and meets the following requirements:

14 “(A) The group practice offers to furnish
15 all minimum required items and services identi-
16 fied under subsection (b)(3) under the Pro-
17 gram.

18 “(B) The group practice submits a notifi-
19 cation to the Secretary annually specifying
20 which (if any) additional items and services
21 identified under subsection (b)(4) for a year the
22 group practice will offer to furnish for such
23 year under the Program.

24 “(C) The group practice ensures that only
25 individuals who meet the qualifications estab-

1 lished under subsection (b)(5) or a physician
2 who is part of such group practice may furnish
3 such minimum required items and services and
4 such additional items and services.

5 “(D) The group practice ensures that, in
6 the case where such minimum required items
7 and services or such additional items and serv-
8 ices are furnished by such an individual, such
9 individual furnishes such minimum required
10 items and services or additional items and serv-
11 ices under the supervision, either in-person or
12 through the use of telehealth (not including
13 store-and-forward technologies), of—

14 “(i) a physician—

15 “(I) who is board certified or
16 board eligible in emergency medicine,
17 family medicine, geriatrics, or internal
18 medicine; or

19 “(II) who has been certified by a
20 nationally recognized specialty board
21 of certification or equivalent certifi-
22 cation board in basic life support;

23 “(ii) a nurse practitioner who has
24 been certified by a nationally recognized
25 specialty board of certification or equiva-

1 lent certification board in basic life sup-
2 port; or

3 “(iii) a physician assistant who has
4 been certified by a nationally recognized
5 specialty board of certification or equiva-
6 lent certification board in basic life sup-
7 port.

8 “(E) With respect to any year in which the
9 qualified group practice would participate in the
10 Program, the Chief Actuary for the Centers for
11 Medicare & Medicaid Services determines that
12 such participation during such year will not re-
13 sult in total estimated expenditures under this
14 title for such year being greater than total esti-
15 mated expenditures under such title for such
16 year without such participation.

17 “(d) PAYMENTS.—

18 “(1) IN GENERAL.—For 2022 and each subse-
19 quent year, the Secretary shall develop a schedule of
20 payments to apply for items and services identified
21 under paragraph (3) or paragraph (4) of subsection
22 (b) furnished during such year under the Program.
23 Such payments shall be in lieu of any other pay-
24 ments that may be made under this title for such
25 items and services.

1 “(2) SHARED SAVINGS.—In the case of a year
2 for which the Secretary determines that participa-
3 tion in the Program resulted in a reduction in ex-
4 penditures under this title compared to what such
5 expenditures would have been without such partici-
6 pation, the Secretary shall—

7 “(A) pay to such qualified group practice
8 an amount equal to 37.5 percent of the esti-
9 mated amount of such reduction; and

10 “(B) in the case of each qualified skilled
11 nursing facility where such qualified group
12 practice furnished items and services under the
13 Program during such year—

14 “(i) if the qualified skilled nursing fa-
15 cility has at least a three-star rating under
16 the Five Star Quality Rating System (or a
17 successor system), pay to the facility an
18 amount that bears the same ratio to 12.5
19 percent of the estimated amount of such
20 reduction as the amount of expenditures
21 under the Program for such items and
22 services furnished with respect to individ-
23 uals at such facility by such qualified
24 group practice during such year bears to
25 the total amount of expenditures under the

1 Program for such items and services fur-
2 nished with respect to all individuals by
3 such qualified group practice during such
4 year; and

5 “(ii) in the case of a qualified skilled
6 nursing facility that is not described in
7 clause (i), retain in the Federal Hospital
8 Insurance Trust Fund under section 1817
9 the amount that the facility would have
10 been paid pursuant to clause (i) if the fa-
11 cility were described in such clause until
12 such time as the facility has at least a
13 three-star rating under the Five Star Qual-
14 ity Rating System (or a successor system),
15 at which point the Secretary shall pay such
16 amount to the facility.

17 “(3) ADVANCED ALTERNATIVE PAYMENT MOD-
18 ELS.—Paragraph (2) shall not apply to items and
19 services furnished to an individual entitled to bene-
20 fits under part A and enrolled under part B for
21 whom shared savings would otherwise be attributed
22 through an advanced alternative payment model as
23 authorized under section 1115A or section 1899.

24 “(e) EVALUATION.—

1 “(1) IN GENERAL.—With respect to a qualified
2 group practice and a qualified skilled nursing facil-
3 ity, not later than 6 months after such group prac-
4 tice begins furnishing items and services under the
5 Program (or, in the case of a qualified skilled nurs-
6 ing facility, not less than 6 months after a qualified
7 group practice first furnishes such items and serv-
8 ices at such facility), and not less than once every
9 2 years thereafter, the Secretary shall evaluate such
10 qualified group practice and such qualified facility
11 using information received under paragraph (2) on
12 such criteria as determined appropriate by the Sec-
13 retary.

14 “(2) REPORTING OF INFORMATION.—In a time
15 and manner specified by the Secretary, a qualified
16 group practice and a qualified skilled nursing facility
17 shall submit to the Secretary a report containing the
18 following information with respect to items and serv-
19 ices furnished under the Program during a reporting
20 period (as specified by the Secretary):

21 “(A) The number of individuals with re-
22 spect to whom such group practice furnished
23 such items and services in such period (or, in
24 the case of a qualified skilled nursing facility,
25 the number of individuals with respect to whom

1 such a group practice furnished such items and
2 services at such facility in such period).

3 “(B) The number of such individuals who
4 were admitted to a hospital or treated in the
5 emergency department of a hospital within 24
6 hours of being furnished such items and serv-
7 ices.

8 “(C) Other information determined appro-
9 priate by the Secretary.

10 “(3) LOSS OF QUALIFIED CERTIFICATION.—

11 “(A) IN GENERAL.—Not later than 3
12 months after a determination described in this
13 sentence is made, the Secretary may revoke the
14 certification of a qualified skilled nursing facil-
15 ity or a qualified group practice made under
16 subsection (c) if—

17 “(i) the Chief Actuary of the Centers
18 for Medicare & Medicaid Services deter-
19 mines that the participation of such skilled
20 nursing facility or such group practice in
21 the Program during a year resulted in
22 total expenditures under this title for such
23 period being greater than total expendi-
24 tures under such title would have been

1 during such period without such participa-
2 tion; or

3 “(ii) a facility is selected for the Spe-
4 cial Focus Facility program or, if the facil-
5 ity is a candidate for the Special Focus
6 Facility program, the Secretary determines
7 that the participation of such facility in the
8 Program should be terminated.

9 “(B) EXCLUSION FROM CERTIFICATION.—

10 “(i) IN GENERAL.—In the case that
11 the Secretary revokes the certification of a
12 qualified skilled nursing facility or a quali-
13 fied group practice under subparagraph
14 (A), such skilled nursing facility or such
15 group practice shall be ineligible for certifi-
16 cation as a qualified skilled nursing facility
17 or a qualified group practice (as applica-
18 ble) under subsection (c) for the applicable
19 period (as defined under clause (ii)).

20 “(ii) APPLICABLE PERIOD DE-
21 FINED.—In this subparagraph, the term
22 ‘applicable period’ means—

23 “(I) if the revocation of a facility
24 or group practice under subparagraph
25 (A) is due to the application of clause

1 (i) of such subparagraph, a 1-year pe-
2 riod beginning on the date of such
3 revocation; and

4 “(II) in the revocation of a facil-
5 ity under subparagraph (A) is due to
6 the application of clause (ii) of such
7 subparagraph, the period beginning
8 on the date of such revocation and
9 ending on the date on which the facil-
10 ity graduates from the Special Focus
11 Facility program (or, in the case of a
12 facility that is a candidate for such
13 program, the date on which the facil-
14 ity is no longer such a candidate, as
15 determined by the Secretary).

16 “(f) DETERMINATION OF BUDGET NEUTRALITY;
17 TERMINATION OF PROGRAM.—

18 “(1) DETERMINATION.—Not later than July 1,
19 2027, the Chief Actuary of the Centers for Medicare
20 & Medicaid Services shall determine whether the
21 Program has resulted in an increase in total expend-
22 itures under this title with respect to the period be-
23 ginning on January 1, 2022, and ending on Decem-
24 ber 31, 2026, compared to what such expenditures

1 would have been during such period had the Pro-
 2 gram not been in operation.

3 “(2) TERMINATION.—If the Chief Actuary
 4 makes a determination under paragraph (1) that the
 5 Program has resulted in an increase in total expend-
 6 itures under this title, the Secretary shall terminate
 7 the Program as of January 1 of the first year begin-
 8 ning after such determination.”.

9 TITLE X—APPROPRIATIONS

10 APPROPRIATIONS

11 SEC. 10001. The following sums are hereby appro-
 12 priated, out of any money in the Treasury not otherwise
 13 appropriated, for the fiscal year ending September 30,
 14 2021, and for other purposes, namely:

15 Subtitle A—Health Programs

16 DEPARTMENT OF HEALTH AND HUMAN 17 SERVICES

18 OFFICE OF THE SECRETARY

19 PUBLIC HEALTH AND SOCIAL SERVICES EMERGENCY 20 FUND

21 (INCLUDING TRANSFER OF FUNDS)

22 For an additional amount for “Public Health and So-
 23 cial Services Emergency Fund”, \$31,000,000,000, to re-
 24 main available until September 30, 2025, to prevent, pre-
 25 pare for, and respond to coronavirus, domestically or

1 internationally, including the development of necessary
2 countermeasures and vaccines, prioritizing platform-based
3 technologies with United States-based manufacturing ca-
4 pabilities, the purchase of vaccines, therapeutics,
5 diagnostics, necessary medical supplies, as well as medical
6 surge capacity, addressing blood supply chain, workforce
7 modernization, telehealth access and infrastructure, initial
8 advanced manufacturing, novel dispensing, enhancements
9 to the United States Commissioned Corps, and other pre-
10 paredness and response activities: *Provided*, That funds
11 appropriated under this paragraph in this title may be
12 used to develop and demonstrate innovations and enhance-
13 ments to manufacturing platforms to support such capa-
14 bilities: *Provided further*, That the Secretary of Health
15 and Human Services shall purchase vaccines developed
16 using funds made available under this paragraph in this
17 title to respond to an outbreak or pandemic related to
18 coronavirus in quantities determined by the Secretary to
19 be adequate to address the public health need: *Provided*
20 *further*, That products purchased by the Federal Govern-
21 ment with funds made available under this paragraph in
22 this title, including vaccines, therapeutics, and diagnostics,
23 shall be purchased in accordance with Federal Acquisition
24 Regulation guidance on fair and reasonable pricing: *Pro-*
25 *vided further*, That the Secretary may take such measures

1 authorized under current law to ensure that vaccines,
2 therapeutics, and diagnostics developed from funds pro-
3 vided in this title will be affordable in the commercial mar-
4 ket: *Provided further*, That in carrying out the previous
5 proviso, the Secretary shall not take actions that delay the
6 development of such products: *Provided further*, That the
7 Secretary shall ensure that protections remain for individ-
8 uals enrolled in group or individual health care coverage
9 with pre-existing conditions, including those linked to
10 coronavirus: *Provided further*, That products purchased
11 with funds appropriated under this paragraph in this title
12 may, at the discretion of the Secretary of Health and
13 Human Services, be deposited in the Strategic National
14 Stockpile under section 319F–2 of the Public Health Serv-
15 ice Act: *Provided further*, That of the amount appropriated
16 under this paragraph in this title, not more than
17 \$2,000,000,000 shall be for the Strategic National Stock-
18 pile under section 319F–2(a) of such Act: *Provided fur-*
19 *ther*, That funds appropriated under this paragraph in this
20 title may be transferred to, and merged with, the fund
21 authorized by section 319F–4, the Covered Counter meas-
22 ure Process Fund, of the Public Health Service Act: *Pro-*
23 *vided further*, That of the amount appropriated under this
24 paragraph in this title, not more than \$2,000,000,000, to
25 remain available until September 30, 2023, shall be for

1 activities to improve and sustain State medical stockpiles:
2 *Provided further*, That of the amount appropriated under
3 this paragraph in this title, \$20,000,000,000 shall be
4 available to the Biomedical Advanced Research and Devel-
5 opment Authority for necessary expenses of manufac-
6 turing, production, and purchase, at the discretion of the
7 Secretary, of vaccines, therapeutics, diagnostics, and small
8 molecule active pharmaceutical ingredients, including the
9 development, translation, and demonstration at scale of
10 innovations in manufacturing platforms: *Provided further*,
11 That funds in the previous proviso may be used for the
12 construction or renovation of United States-based next
13 generation manufacturing facilities, other than facilities
14 owned by the United States Government: *Provided further*,
15 That amounts provided in the eleventh proviso may be for
16 necessary expenses related to the sustained on-shore man-
17 ufacturing capacity for public health emergencies: *Pro-*
18 *vided further*, That of the amount appropriated under this
19 paragraph in this title, \$6,000,000,000 shall be for activi-
20 ties to plan, prepare for, promote, distribute, administer,
21 monitor, and track coronavirus vaccines to ensure broad-
22 based distribution, access, and vaccine coverage: *Provided*
23 *further*, That the Secretary shall coordinate funding and
24 activities outlined in the previous proviso through the Di-
25 rector of the Centers for Disease Control and Prevention:

1 *Provided further*, That the Secretary, through the Director
2 of the Centers for Disease Control and Prevention, shall
3 report to the Committees on Appropriations of the House
4 of Representatives and the Senate within 60 days of the
5 date of enactment of this title on a comprehensive
6 coronavirus vaccine distribution strategy and spend plan
7 that includes how existing infrastructure will be leveraged,
8 enhancements or new infrastructure that may be built,
9 considerations for moving and storing vaccines, guidance
10 for how States and health care providers should prepare
11 for, store, and administer vaccines, nationwide vaccination
12 targets, funding that will be distributed to States, how an
13 informational campaign to both the public and health care
14 providers will be executed, and how the vaccine distribu-
15 tion plan will focus efforts on high risk, underserved, and
16 minority populations: *Provided further*, That such plan
17 shall be updated and provided to the Committees on Ap-
18 propriations of the House of Representatives and the Sen-
19 ate 90 days after submission of the first plan: *Provided*
20 *further*, That the Secretary shall notify the Committees
21 on Appropriations of the House of Representatives and the
22 Senate 2 days in advance of any obligation in excess of
23 \$50,000,000, including contracts and interagency agree-
24 ments, from funds provided in this paragraph in this title:
25 *Provided further*, That funds appropriated under this

1 paragraph in this title may be used for the construction,
2 alteration, or renovation of nonfederally owned facilities
3 for the production of vaccines, therapeutics, diagnostics,
4 and medical supplies where the Secretary determines that
5 such a contract is necessary to secure sufficient amounts
6 of such supplies: *Provided further*, That not later than 30
7 days after enactment of this title, and every 30 days there-
8 after until funds are expended, the Secretary shall report
9 to the Committees on Appropriations of the House of Rep-
10 resentatives and the Senate on uses of funding for Oper-
11 ation Warp Speed, detailing current obligations by De-
12 partment or Agency, or component thereof broken out by
13 the coronavirus supplemental appropriations Act that pro-
14 vided the source of funds: *Provided further*, That the plan
15 outlined in the previous proviso shall include funding by
16 contract, grant, or other transaction in excess of
17 \$20,000,000 with a notation of which Department or
18 Agency, and component thereof is managing the contract:
19 *Provided further*, That such amount is designated by the
20 Congress as being for an emergency requirement pursuant
21 to section 251(b)(2)(A)(i) of the Balanced Budget and
22 Emergency Deficit Control Act of 1985.

23 For an additional amount for “Public Health and So-
24 cial Services Emergency Fund”, \$16,000,000,000, to re-
25 main available until September 30, 2023, to prevent, pre-

1 pare for, and respond to coronavirus, domestically or
2 internationally, which shall be for necessary expenses for
3 testing, contact tracing, surveillance, containment, and
4 mitigation to monitor and suppress COVID–19, including
5 tests for both active infection and prior exposure, includ-
6 ing molecular, antigen, and serological tests, the manufac-
7 turing, procurement and distribution of tests, testing
8 equipment and testing supplies, including personal protec-
9 tive equipment needed for administering tests, the devel-
10 opment and validation of rapid, molecular point-of-care
11 tests, and other tests, support for workforce, epidemiology,
12 to scale up academic, commercial, public health, and hos-
13 pital laboratories, to conduct surveillance and contact
14 tracing, support development of COVID–19 testing plans,
15 and other related activities related to COVID–19 testing:
16 *Provided*, That of the amount appropriated under this
17 paragraph in this title, not less than \$15,000,000,000
18 shall be for States, localities, territories, Tribes, Tribal or-
19 ganizations, urban Indian health organizations, or health
20 service providers to Tribes for necessary expenses for test-
21 ing, contact tracing, surveillance, containment, and miti-
22 gation, including support for workforce, epidemiology, use
23 by employers, elementary and secondary schools, child
24 care facilities, institutions of higher education, long-term
25 care facilities, or in other settings, scale up of testing by

1 public health, academic, commercial, and hospital labora-
2 tories, and community-based testing sites, health care fa-
3 cilities, and other entities engaged in COVID–19 testing,
4 and other related activities related to COVID–19 testing,
5 contact tracing, surveillance, containment, and mitigation:
6 *Provided further*, That the amount provided in the pre-
7 ceding proviso shall be made available within 30 days of
8 the date of enactment of this title: *Provided further*, That
9 the amount identified in the first proviso under this para-
10 graph in this title shall be allocated to States, localities,
11 and territories according to the formula that applied to
12 the Public Health Emergency Preparedness cooperative
13 agreement in fiscal year 2019: *Provided further*, That not
14 less than \$500,000,000 shall be allocated in coordination
15 with the Director of the Indian Health Service, to Tribes,
16 Tribal organizations, urban Indian health organizations,
17 or health service providers to Tribes: *Provided further*,
18 That the Secretary of Health and Human Services (re-
19 ferred to in this paragraph as the “Secretary”) may sat-
20 isfy the funding thresholds outlined in the first and fourth
21 provisos under this paragraph in this title by making
22 awards through other grant or cooperative agreement
23 mechanisms: *Provided further*, That the Governor or des-
24 ignee of each State, locality, territory, Tribe, or Tribal or-
25 ganization receiving funds pursuant to this title shall up-

1 date their plans, as applicable, for COVID–19 testing and
2 contact tracing submitted to the Secretary pursuant to the
3 Paycheck Protection Program and Health Care Enhance-
4 ment Act (Public Law 116–139) and submit such updates
5 to the Secretary not later than 60 days after funds appro-
6 priated in this paragraph in this title have been awarded
7 to such recipient: *Provided further*, That not later than
8 60 days after the date of enactment, and every quarter
9 thereafter until funds are expended, the Governor or des-
10 ignee of each State, locality, territory, Tribe, or Tribal or-
11 ganization receiving funds shall report to the Secretary on
12 uses of funding, detailing current commitments and obli-
13 gations broken out by the coronavirus supplemental appro-
14 priations Act that provided the source of funds: *Provided*
15 *further*, That not later than 15 days after receipt of such
16 reports, the Secretary shall summarize and report to the
17 Committees on Appropriations of the House of Represent-
18 atives and the Senate on States’ commitments and obliga-
19 tions of funding: *Provided further*, That funds an entity
20 receives from amounts described in the first proviso in this
21 paragraph may also be used for the rent, lease, purchase,
22 acquisition, construction, alteration, renovation, or equip-
23 ping of nonfederally owned facilities to improve
24 coronavirus preparedness and response capability at the
25 State and local level: *Provided further*, That such amount

1 is designated by the Congress as being for an emergency
2 requirement pursuant to section 251(b)(2)(A)(i) of the
3 Balanced Budget and Emergency Deficit Control Act of
4 1985.

5 Subtitle B—General Provisions—This Title

6 SEC. 10101. Each amount appropriated or made
7 available by this title is in addition to amounts otherwise
8 appropriated for the fiscal year involved.

9 SEC. 10102. No part of any appropriation contained
10 in this title shall remain available for obligation beyond
11 the current fiscal year unless expressly so provided herein.

12 SEC. 10103. Unless otherwise provided for by this
13 title, the additional amounts appropriated by this title to
14 appropriations accounts shall be available under the au-
15 thorities and conditions applicable to such appropriations
16 accounts for fiscal year 2020.

17 SEC. 10104. In this title, the term “coronavirus”
18 means SARS-CoV-2 or another coronavirus with pan-
19 demic potential.

20 SEC. 10105. Each amount designated in this title by
21 the Congress as being for an emergency requirement pur-
22 suant to section 251(b)(2)(A)(i) of the Balanced Budget
23 and Emergency Deficit Control Act of 1985 shall be avail-
24 able (or rescinded or transferred, if applicable) only if the

1 President subsequently so designates all such amounts
2 and transmits such designations to the Congress.

3 SEC. 10106. Any amount appropriated by this title,
4 designated by the Congress as an emergency requirement
5 pursuant to section 251(b)(2)(A)(i) of the Balanced Budg-
6 et and Emergency Deficit Control Act of 1985 and subse-
7 quently so designated by the President, and transferred
8 pursuant to transfer authorities provided by this title shall
9 retain such designation.

10 SEC. 10107. (a) STATUTORY PAYGO SCORECARDS.—
11 The budgetary effects of this title shall not be entered on
12 either PAYGO scorecard maintained pursuant to section
13 4(d) of the Statutory Pay As-You-Go Act of 2010.

14 (b) SENATE PAYGO SCORECARDS.—The budgetary
15 effects of this title shall not be entered on any PAYGO
16 scorecard maintained for purposes of section 4106 of H.
17 Con. Res. 71 (115th Congress).

18 (c) CLASSIFICATION OF BUDGETARY EFFECTS.—
19 Notwithstanding Rule 3 of the Budget Scorekeeping
20 Guidelines set forth in the joint explanatory statement of
21 the committee of conference accompanying Conference Re-
22 port 105–217 and section 250(c)(7) and (c)(8) of the Bal-
23 anced Budget and Emergency Deficit Control Act of 1985,
24 the budgetary effects of this title shall be estimated for
25 purposes of section 251 of such Act.

1 (d) ENSURING NO WITHIN-SESSION SEQUESTRA-
2 TION.—Solely for the purpose of calculating a breach with-
3 in a category for fiscal year 2020 pursuant to section
4 251(a)(6) or section 254(g) of the Balanced Budget and
5 Emergency Deficit Control Act of 1985, and notwith-
6 standing any other provision of this title, the budgetary
7 effects from this title shall be counted as amounts des-
8 ignated as being for an emergency requirement pursuant
9 to section 251(b)(2)(A) of such Act.

10 This title may be cited as the “Coronavirus Response
11 Additional Supplemental Appropriations Act, 2020”.

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