

H.R. 14

Commitment to Defeat the Virus and Keep America Healthy Act

Section by Section Highlighting Individual Pieces of Legislation

TITLE I— PANDEMIC PREPAREDNESS AND RESPONSE

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

H.R. 8010 - Reps. Hudson (R-NC), Tonko (D-NY), Brooks (R-IN), and Eshoo (D-CA)

This provision clarifies that the Secretary of Health and Human Services (HHS) shall lead all Federal public health and medical responses to emergencies and disasters declared by the President pursuant to the National Emergencies Act or the Robert T. Stafford Disaster Relief and Emergency Assistance Act.

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

S. 4322, Sec. 110 - Sen. Alexander (R-TN)

This provision updates the amount of funding required to be transferred to public-private partnerships by the Food and Drug Administration (FDA) and the National Institutes of Health (NIH). The Reagan-Udall Foundation and Foundation for the National Institutes of Health (FNIH) are supporting many activities to research and develop tests, treatments, and vaccines for COVID-19.

Subtitle C—Protections for Good Samaritan Health Professionals

H.R. 6283 - Reps. Ruiz (D-CA), Bucshon (R-IN), Schrier (D-WA), Marshall (R-KS), Bera (D-CA), Roe (R-TN), Ruppberger (D-MD), Hill (R-AR), Sherman (D-CA), Fitzpatrick (R-PA), Scott (D-GA), Palazzo (R-MS), Stefanik (R-NY), Stivers (R-OH), Gibbs (R-OH), and Harris (R-MD)

This provision provides limited liability protections to volunteer health care professionals in the course of providing certain health services during public-health emergencies, national emergencies, or major disasters.

Subtitle D—Medical Sheltering

H.R. 7634 - Reps. Gonzalez (R-OH), Ryan (D-OH), Joyce (R-OH), Gonzalez (D-TX), and Gottheimer (D-NJ)

This provision authorizes funding to states to contract and lease hotels in order to temporarily house individuals who have tested positive for COVID-19, have come into close contact with someone who has tested positive for COVID-19, or are displaying symptoms of COVID-19, and who are unable to safely self-isolate in their own residences.

Subtitle E—CDC campaign on COVID-19 awareness

H.R. 6572 - Reps. Bilirakis (R-FL) and Cox (D-CA)

This provision requires the Centers for Disease Control and Prevention (CDC) to award grants or enter into contracts with eligible entities to carry out a national campaign, based on available scientific evidence, to increase awareness about COVID-19.

Subtitle F—Protecting Children from COVID–19

H.R. 7029 - Reps. Gonzalez (R-OH) and Fudge (D-OH)

This provision requires the Department of Health and Human Services (HHS) to study the role of children in transmitting the virus that causes COVID-19 and disseminate best practices that will help protect children and adults from the disease in educational settings.

Subtitle G—Ensuring Understanding of COVID–19

H.R. 6701 - Reps. Eshoo (D-CA), Burgess (R-TX), DeGette (D-CO), and Guthrie (R-KY)

This provision directs the Secretary Health and Human Services (HHS) to carry out a study on the short- and long-term impacts of COVID-19 on infected and recovered individuals.

Subtitle H—Safeguarding Therapeutics

H.R. 5663 - Reps. Guthrie (R-KY) and Engel (D-NY)

This provision provides the Food and Drug Administration (FDA) with administrative destruction authority over counterfeit devices in order to allow the agency to destroy certain imported medical devices in instances where FDA believes such medical devices are adulterated, misbranded, or unapproved and may pose a threat to the public health as they currently do for drugs. Recent news reports have indicated that U.S. Customs and Border Patrol (CBP) has already intercepted counterfeit coronavirus testing kits. This provision would give FDA the authority to destroy those counterfeit products as opposed to having to store them or ship them back.

Subtitle I—Advisory Committee on Immunization Practices

H.R. 6231 - Reps. Bucshon (R-IN) and Schakowsky (D-IL)

This provision requires an expedited review of an approved vaccine by the Advisory Committee on Immunization Practices (ACIP) within 15 days of Food and Drug Administration (FDA) approval. Under current law, an ACIP-recommended vaccine must be covered by commercial health plans at zero cost-sharing for the patient. Expediting this review preserves an important public health, scientific process that will ensure access to vaccines at no cost for patients with private health insurance.

Subtitle J—Improvements to Transparency of the Pricing of COVID-19 Diagnostic Tests

H.R. 6800, Sec. 309 - Reps. Lowey (D-NY), Engel (D-NY), Maloney (D-NY), Nadler (D-NY), Neal (D-MA), Pallone (D-NJ), Scott (D-VA), Takano (D-CA), Velazquez (D-NY), Waters (D-CA), Grijalva (D-AZ), and Lofgren (D-CA)

This provision requires the Department of Health and Human Services (HHS) to conduct a survey of providers administering COVID-19 diagnostic tests to collect and publish cash prices for such tests. This boosts transparency and empowers patients with pricing information to prevent surprise bills and to force providers to compete on price.

TITLE II—DOMESTIC MANUFACTURING AND SUPPLY CHAIN

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

S. 4322, Sec. 102 - Sen. Alexander (R-TN)

This provision improves sustained manufacturing surge capacity and capabilities to produce medical countermeasures needed to respond to public health threats and ensures the Medical

Countermeasure Innovation Partner can be fully implemented to improve the advanced research and development of medical countermeasures against public health threats.

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

H.R. 6930 - Reps. Carter (R-GA), Soto (D-FL), Griffith (R-VA), McKinley (R-WV), and Crawford (R-AR)

This provision requires the Department of Health and Human Services (HHS) to submit a report to Congress on barriers to domestic manufacturing of medical products, and requires the Government Accountability Office (GAO) to assess whether the differing regulatory requirements across countries create inefficiencies in drug manufacturing. This provision also codifies the Food and Drug Administration's (FDA) advanced manufacturing technologies program, and requires FDA to annually post information related to facility inspection timelines, implement a framework to expand information sharing related to reviews and inspections with foreign regulators, and increase intra-agency coordination with respect to the review of, and feedback on, facility inspection reports.

Subtitle C—Improving the American Drug Supply Chain

H.R. 8588 - Reps. Hudson (R-NC) and Blunt Rochester (D-DE)

This provision requires the National Academies of Sciences, Engineering, and Medicine to conduct a study on the current and historical production trends of drugs and active pharmaceutical ingredients (APIs) in the U.S. and foreign countries, including an evaluation of what factors have led to the migration of drug manufacturing, recommendations to encourage domestic production of drugs and APIs, and recommendations to reduce risk of drug shortages during public health emergencies.

Subtitle D—Essential Medicines Strategic Stockpile Act

H.R. 8479 - Reps. Carter (R-GA) and Blunt Rochester (D-DE)

This provision establishes a pilot program under which the Department of Health and Human Services (HHS) awards contracts to distributors to acquire, maintain, manage, and distribute a stockpile of generic medicines at risk of shortage during a public health emergency. Under the program HHS must establish a list of no more than 50 types of drugs that could be stockpiled, and the contracted entity would be required to maintain a 6-month supply of each drug product agreed to pursuant to the contract. Additionally, the contracted entity may sell stockpiled drug product through normal commercial channels, so long as those drugs are then replaced, to ensure the availability of unexpired drugs.

Subtitle E—National Centers of Excellence in Continuous Pharmaceutical Manufacturing

H.R. 4866 - Reps. Pallone (D-NJ) and Guthrie (R-KY)

This provision amends the 21st Century Cures Act to direct Food and Drug Administration (FDA) to designate National Centers of Excellence in Continuous Pharmaceutical Manufacturing (NCEs). NCEs would work with FDA and industry to craft a national framework for continuous manufacturing implementation, including supporting additional research and development of this technology, workforce development, standardization, and collaborating with manufacturers to support adoption of continuous manufacturing.

TITLE III—STRATEGIC NATIONAL STOCKPILE IMPROVEMENTS

Subtitle A—Stockpiling for America’s Future Endeavors Act

H.R. 6516 - Rep. Brooks (R-IN) and Schrier (D-WA)

This provision permits the Strategic National Stockpile (SNS) to accept certain gifts and donations from companies and individuals. Periodically, the SNS is approached by companies with surplus product or private individuals who wish to make cash donations. Under current law, the SNS cannot accept these gifts without going through a complex transaction process. This language would allow the Secretary of Health and Human Services (HHS) to authorize these donations directly and place them into the stockpile for disbursement.

Subtitle B—Strengthening America’s Strategic National Stockpile Inventory Modernization Act

H.R. 6517 - Reps. Brooks (R-IN) and Eshoo (D-CA)

This provision authorizes the Strategic National Stockpile (SNS) to transfer to any Federal department or agency, on a reimbursable basis, any drugs, vaccines or other biological products, medical devices, and other supplies in the stockpile if the supplies are less than one year from expiry; the stockpile is able to replenish the supplies, as appropriate; and the Secretary decides the transfer is in the best interest of the United States Government. Currently, the SNS buys a product directly from manufacturers and then keeps it on the shelf until expiry. Upon expiry, the product is destroyed and the SNS must use new appropriations to restock. This legislation will have the dual benefit of saving American taxpayers money while simultaneously improving the ability of SNS to keep inventory up-to-date.

Subtitle C—Equipment maintenance

H.R. 6876 - Reps. Slotkin (D-MI) and Van Drew (R-NJ)

This provision requires the Secretary of Health and Human Services (HHS) to ensure that contents of the Strategic National Stockpile (SNS) remain in good working order and, as appropriate, have maintenance services conducted on the contents of the stockpile. The Secretary may enter into contracts for the procurement of equipment maintenance services.

Subtitle D— Medical Supplies for Pandemics

H.R. 6531 - Reps. Dingell (D-MI) and Walorski (R-IN)

This provision establishes a supply chain flexibility manufacturing pilot in order to enhance medical supply chain elasticity and maintain domestic reserves of critical medical supplies. Rather than holding billions of pieces of commercially available personal protective equipment (PPE) and other supplies, the Strategic National Stockpile (SNS) can enter into joint ventures with domestic manufactures to establish new or expanded/enhanced manufacturing lines for desirable PPE. SNS-purchased lines would be used to produce additional material on-shore during peace time operations and thus create more material in the supply chain. When surge requirements must be met during a public health emergency, the SNS would have immediate access to such lines to push total production into SNS or to certain designated points.

Subtitle E— State Stockpile Readiness

H.R. 7507 - Reps. Carter (R-GA) and O'Halleran (D-AZ)

This provision establishes a pilot program that awards grants to states to expand or maintain a strategic stockpile of commercially available drugs, medical equipment, personal protective equipment, and other products deemed by the State to be essential in the event of a public health emergency. States shall make available non-Federal contributions in cash toward such costs in an amount that is equal to and not less than the amount of Federal funds provided under this pilot

program. However, the Secretary may waive this matching fund requirement for the first two years of a state receiving a grant if the Secretary determines that such waiver is needed for a state to establish a strategic stockpile.

Subtitle F— Process Improvements and Reports

H.R. 6875, H.R. 6877, and H.R. 6878 - Reps. Slotkin (D-MI), Van Drew (R-NJ), and McKinley (R-WV)

This provision requires the Government Accountability Office (GAO) to conduct a study to investigate the feasibility of establishing user fees to offset certain Federal costs attributable to the procurement of single-source materials for the Strategic National Stockpile (SNS), and requires the Secretary of Health and Human Services (HHS) to issue a report to the Congress on all State, local, Tribal, and territorial requests for supplies from the Strategic National Stockpile (SNS) related to COVID-19, including the types and amounts of medical countermeasures requested and the outcomes of those requests. Finally, this provision requires the Secretary of Health and Human Services (HHS) to develop and implement improved, transparent processes for the use and distribution of drugs, vaccines and other biological products, medical devices, and other supplies from the Strategic National Stockpile (SNS), and identify clear plans for future communication between the SNS and States.

Subtitle G—Strategic National Stockpile Funding

H.R. 7574, Sec. 9 - Reps. Slotkin (D-MI), Brooks (R-IN), Eshoo (D-CA), Carter (R-GA), Dingell (D-MI), Walorski (R-IN), DeGette (D-CO), McKinley (R-WV), Butterfield (D-NC), Van Drew (R-NJ), Soto (D-FL), Upton (R-MI), Malinowski (D-NJ), Hudson (R-NC), Schrier (D-WA), Gianforte (R-MT), Cisneros (D-CA), Burgess (R-TX), and Neguse (D-CO)

This provision increases the annual authorization of appropriations for the Strategic National Stockpile from \$610,000,000 to \$705,000,000 for each of fiscal years 2020 through 2023.

TITLE IV—PUBLIC HEALTH INFRASTRUCTURE IMPROVEMENTS

Subtitle A—Public Health Infrastructure Modernization

H.R. 5321 - Reps. McBath (D-GA) and Carter (R-GA)

This provision requires the Department of Health and Human Services (HHS) to expand and improve the public health data systems used by the Centers for Disease Control and Prevention (CDC), and requires HHS to award grants to public health departments for the modernization of public health data systems in order to assist public health departments in assessing current data infrastructure capabilities and gaps; to improve secure public health data collection, transmission, exchange, maintenance, and analysis; to enhance the interoperability of public health data systems; to support and train related personnel; to support earlier disease and health condition detection; and to develop and disseminate related information and improved electronic case reporting.

Subtitle B—Modernizing infectious disease data collection

S. 4322, Sec. 106 - Sen. Alexander (R-TN)

This provision strengthens public health preparedness and situational awareness by integrating laboratory testing and epidemiology systems into existing surveillance programs, improving the exchange of electronic health information between health care providers, public health

departments, and federal agencies to better provide detection of infectious diseases and inform public health preparedness and response.

Subtitle C—Diagnostic Testing for Public Health Labs

H.R. 7025 - Reps. Bucshon (R-IN) and DeGette (D-CO)

This provision authorizes grants to help regional, state, or local public health laboratories purchase high-throughput diagnostic testing platforms, which simultaneously test thousands of samples using automation processes in order to support public health laboratories, hospitals, primary care facilities, physicians, and other healthcare providers in their COVID-19 testing response.

Subtitle D—Rapid Testing for Communities

H.R. 7026 - Reps. DeGette (D-CO) and Bucshon (R-IN)

This provision authorizes grants to help hospitals, primary care facilities, physicians, and other providers purchase rapid diagnostic testing equipment capable of performing same-day clinical laboratory diagnostic testing in point-of-care settings, allowing patients to receive test results directly from their health care provider in a short period of time.

Subtitle E—Public Health Workforce Loan Repayment

H.R. 6578 - Reps. Crow (D-CO) and Burgess (R-TX)

This provision establishes a loan repayment program to enhance the development, recruitment, and retention of state, local, tribal, and territorial public health department workforce.

Subtitle F—Vaccine Awareness and Disease Prevention

H.R. 2862 - Reps. Schrier (D-WA), Burgess (R-TX), Engel (D-NY), Guthrie (R-KY), Schrader (D-OR), and Bilirakis (R-FL)

S. 1895, Sec. 410-402 - Sens. Alexander (R-TN) and Murray (D-WA)

This provision authorizes a national campaign to increase awareness and knowledge of the safety and effectiveness of vaccines for the prevention and control of diseases, to combat misinformation, and to disseminate scientific and evidence-based vaccine-related information, and directs the Department of Health and Human Services (HHS) to expand and enhance programs and activities to collect, monitor, and analyze vaccination coverage data. In addition, the provision requires the National Vaccine Advisory Committee to update the report entitled, “Assessing the State of Vaccine Confidence in the United States: Recommendations from the National Vaccine Advisory Committee.”

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

H.R. 6935 - Reps. Frankel (D-FL), Bilirakis (R-FL), Dingell (D-MI), and Shalala (D-FL)

This provision authorizes a resource center for older adults that helps to disseminate best practices to seniors during and after the COVID-19 pandemic and authorizes a program at the Centers for Disease Control and Prevention (CDC) that promotes the health and well-being in older adults, improves health equity in the elderly, and reduce health care costs by engagement of state, local, territorial and tribal health departments through strategic partnerships, adoption of evidence-based programs, and enhanced coordination of efforts.

Subtitle H—Expanding Capacity for Health Outcomes

H.R. 5199 - Reps. Lujan (D-NM), Burgess (R-TX), Torres Small (D-NM), Kinzinger (R-IL), Haaland (D-NM), and Gianforte (R-MT)

This provision authorizes grants to expand the use of technology-enabled collaborative learning and capacity building models to eligible entities with experience providing services to rural, frontier, health professional shortage areas, medically underserved populations, or Indian Tribes.

Subtitle I—Community Readiness

H.R. 8605 - Reps. Kim (D-NJ) and Bilirakis (R-FL)

This provision authorizes grants to states and localities to implement early warning systems like wastewater testing and temperature tracking for COVID-19 and other diseases. Research institutions would also be eligible for the grants to continue studying early warning detection methods. Priority for grant applicants would be given to recipients in hot spot areas and areas with a high percentage of vulnerable populations such as senior citizens.

TITLE V—ADDRESSING COVID-19 HEALTH DISPARITIES

Subtitle A—Tribal Health Data Improvement

H.R. 7948 - Reps. Gianforte (R-MT), Lujan (D-NM), Rodgers (R-WA), O'Halleran (D-AZ), Mullin (R-OK), and Ruiz (D-CA)

This provision reauthorizes the National Center for Health Statistics at the Centers for Disease Control and Prevention (CDC), expands tribal access to public health care data and public health surveillance programs, and requires the CDC to take certain actions to address the collection and availability of health data for American Indians and Alaska Natives, including making public health data to the Indian Health Service, Indian tribes, Urban Indian Organizations, and tribal epidemiology centers.

Subtitle B—Tribal Medical Supplies Stockpile Access

H.R. 6352 - Reps. Horn (D-OK), Gianforte (R-MT), Gallego (D-AZ), Mullin (R-OK), Davids (D-KS), Cole (R-OK), and Haaland (D-NM)

This provision requires the Department of Health and Human Services (HHS) to deploy drugs, vaccines, biological products, medical devices, and other supplies from the Strategic National Stockpile (SNS) directly to health programs or facilities operated by the Indian Health Service (IHS), tribes, or tribal organizations for use in public health emergency responses. Currently, states' and large municipalities' public health authorities have ready access to the SNS, but IHS and tribal health authorities' access is limited and not fully guaranteed in statute.

Subtitle C—Native American Suicide Prevention

S. 1895, Sec. 413 - Sens. Alexander (R-TN) and Murray (D-WA)

This provision ensures states consult with Indian tribes, tribal organizations, urban Indian organizations, and Native Hawaiian Health Care Systems in developing youth suicide early intervention and prevention strategies.

Subtitle D—Pursuing Equity in Mental Health

H.R. 5469 - Reps. Watson Coleman (D-NJ), Adams (D-NC), Cleaver (D-MO), Davis (D-IL), Hastings (D-FL), Hayes (D-CT), Horsford (D-NV), Lee (D-CA), Norton (D-DC), and Omar (D-MN)

This provision authorizes grants targeted at high-poverty communities for culturally and linguistically appropriate mental health services, supports research into disparities in mental health; and reauthorizes the Minority Fellowship Program to support more students of color entering the health workforce.

Subtitle E—Maternal Health Quality Improvement

H.R. 4995 - Reps. Engel (D-NY), Bucshon (R-IN), Torres Small (D-NM), Latta (R-OH), Adams (D-NC), and Stivers (R-OH)

This provision authorizes several initiatives designed to improve maternal health outcomes including those that enhance data collection and coordination of health services in rural areas; train providers on how to reduce racial disparities in maternal health outcomes; expand the use of telehealth services for maternal health care; train health providers in rural areas; support innovative maternal health programs; support perinatal quality collaboratives; and integrate services for pregnant and postpartum women to reduce adverse maternal health outcomes.

TITLE VI—ADDRESSING THE IMPACTS OF COVID-19 ON MENTAL HEALTH

Subtitle A—Creating Resources to Improve Situations of Inherent Severity

H.R. 7147 - Rep. Latta (R-OH)

This provision increases authorization of appropriations for the Community Mental Health Service Block Grant and directs states to utilize a portion of the funds from the block grants for crisis care services in order to expand and improve care to individuals experiencing an acute psychiatric episode.

Subtitle B—Emergency Mental Health and Substance Use Training and Technical Assistance Center

H.R. 7316 - Rep. Rose (D-NY)

This provision establishes a technical assistance center at the Substance Abuse and Mental Health Services Administration (SAMHSA) that will support public or nonprofit entities and public health professionals seeking to establish or expand access to mental health and substance use services associated with the COVID-19 public health emergency period. The center will provide best practices and expertise to grantees to ensure the efficient and effective delivery of services in a public health emergency environment.

Subtitle C—Suicide Prevention Grants

H.R. 5619 - Reps. Stewart (R-UT) and Matsui (D-CA)

This provision authorizes grants through the Centers for Disease Control and Prevention (CDC) to state, local, and tribal health departments to expand surveillance of self-harm, and authorizes grants through the Substance Abuse and Mental Health Services Administration (SAMHSA) to hospital emergency departments for programs that help in the prevention of self-harm and suicide attempts in patients after discharge.

Subtitle D—Effective Suicide Screening in the Emergency Department

H.R. 4861 - Reps. Bilirakis (R-FL) and Engel (D-NY)

This provision authorizes grants to improve the identification, assessment, and treatment of patients in emergency departments who are at risk for suicide by developing policies and procedures for identifying and assessing individuals who are at risk of suicide; and enhancing the coordination of care for such individuals after discharge.

Subtitle E—Suicide Prevention Lifeline Improvement

H.R. 4564 - Reps. Katko (R-NY), Beyer (D-VA), and Napolitano (D-CA)

This provision increases the authorization of appropriations for the Suicide Prevention Lifeline program, directs the Department of Health and Human Services (HHS) to establish a plan for maintaining the program and authorizes the sharing of certain data from the program with the Centers for Disease Control and Prevention (CDC). In addition, the provision establishes a pilot program to research and employ innovative technologies and platforms for suicide prevention, and requires the Government Accountability Office report on the types of calls made to the Suicide Prevention Lifeline program, implementation of plans to improve service, and any recommendations to enhance the program.

Subtitle F—Campaign to Prevent Suicide

H.R. 4585 - Reps. Beyer (D-VA) and Gianforte (R-MT)

This provision directs the Centers for Disease Control and Prevention (CDC) and Substance Abuse and Mental Health Services Administration (SAMHSA) to carry out a national suicide prevention media campaign that advertises the new 9-8-8 Suicide Prevention Hotline number, when it becomes operational, raises awareness for suicide prevention resources and helps cultivate a more effective discourse on how to prevent suicide.

Subtitle G— Helping Emergency Responders Overcome

H.R. 1646 - Rep. Bera (D-CA)

This provision creates a data system at the Centers for Disease Control and Prevention (CDC) to capture public safety officer suicide incidences and study successful interventions, in addition to authorizing grants for peer support programs within hospitals, fire departments and emergency medical service agencies, and establishing the development of best practices for addressing post-traumatic stress disorder in first responders and public safety officers.

Subtitle H—Behavioral Health Intervention Guidelines

H.R. 3539 - Reps. Ferguson (R-GA), Kennedy (D-MA), Burgess (R-TX), and Panetta (D-CA)

This provision requires the Substance Abuse and Mental Health Services Administration (SAMHSA) to develop best practices for establishing and using behavioral intervention teams in elementary schools, secondary schools, and institutions of higher education. Best practices must include: how behavioral intervention teams can operate effectively and be appropriately utilized to identify individuals of concern, intervene, and manage risk; evidence-based training and threat assessment rubrics; in addition to how behavioral intervention teams can avoid predicting future behavior, inappropriately using a mental health assessment or restricting law enforcement's jurisdiction over criminal matters, endangering an individual's privacy, or creating school-to-prison pipelines.

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

H.R. 7293 - Rep. Peters (D-CA), Bilirakis (R-FL), Deutch (D-FL), and Fitzpatrick (R-PA)

This provision requires the publication of best for school-based student suicide awareness and prevention training and requires State and Tribal educational agencies receiving certain mental health grants to establish and implement a school-based student suicide awareness and prevention training policies and collect information on such activities. The training policies would be focused on grades six through twelve and would train students on self-harm and suicidal ideation.

TITLE VII—ADDRESSING THE IMPACTS OF COVID–19 ON SUBSTANCE USE DISORDER

Subtitle A— Easy Medication Access and Treatment for Opioid Addiction

H.R. 2281 - Reps. Ruiz (D-CA) and Walden (R-OR)

This provision requires the Drug Enforcement Administration (DEA) to revise regulations within 180 days of enactment to allow a practitioner to administer up to a three-day supply of narcotic drugs to an individual at one time for the purpose of maintenance or detoxification treatment. Currently, practitioners are only authorized to provide a one-day supply of these drugs and providing a three-day supply would help relieve potential acute withdrawal symptoms while a patient awaits arrangements for narcotic treatment.

Subtitle B—Access to Remote Behavioral Health Treatment

H.R. 4131 - Reps. Matsui (D-CA), Brooks (R-IN), Kuster (D-NH), Wittman (R-VA), and O'Halleran (D-AZ)

This provision increases access to substance use disorder treatment by permitting certain addiction treatment centers and community mental health centers to register with the Drug Enforcement Administration (DEA) to prescribe controlled substances via telemedicine without a prior in-person examination.

Subtitle C—PDMP Pilot Program

H.R. 3927 - Reps. McKinley (R-WV) and Blunt Rochester (D-DE)

This provision authorizes the Department of Health and Human Services (HHS) to create a pilot program to test the feasibility and outcomes of integrating a substance use disorder and behavioral health treatment locator tool into the prescription drug monitoring programs of eligible States.

Subtitle D—Family Support Services for Addiction

H.R. 5572 - Reps. Trone (D-MD) and Meuser (R-PA)

This provision authorizes the Secretary of Health and Human Services (HHS) to award grants to support family community organizations that develop, expand, and enhance evidence-informed family support services for families and family members living with substance use disorders or addiction.

Subtitle E—Block, Report, And Suspend Suspicious Shipments

H.R. 3878 - Reps. McKinley (R-WV) and Dingell (D-MI)

This provision creates additional requirements for drug manufacturers and distributors who discover a suspicious order for controlled substances. In addition to reporting the suspicious order to the Drug Enforcement Administration (DEA), a manufacturer or distributor must also exercise due diligence, decline to fill the order or series of orders, notify the DEA of each suspicious order or series of orders, and provide information on the indicators that led to the belief that filling such orders would be a violation of the Controlled Substances Act (CSA).

Subtitle F— Debarment Enforcement of Bad Actor Registrants

H.R. 4806 - Rep. Latta (R-OH)

This provision grants the Drug Enforcement Administration (DEA) debarment authority to prohibit a person or entity that has violated the Controlled Substances Act (CSA) from being able to receive a registration to manufacture, distribute, or dispense a controlled substance. A

2019 Justice Department Office of the Inspector General (OIG) report found that certain bad actor registrants that have had their registration revoked, or that have surrendered it, can reapply for registration the day after the enforcement action or surrender occurs. As a result, registrants that potentially pose a significant risk of diverting pharmaceutical opioids can be given the opportunity to do so once again.

Subtitle G—Ensuring Compliance Against Opioid Diversion

H.R. 4812 - Rep. Griffith (R-VA)

Prohibits the transfer of any controlled substance registration without written consent from the Drug Enforcement Administration (DEA). A 2018 investigative report by the Energy & Commerce Committee found that an opioid distributor and its pharmacy customer did not go through the appropriate process of transferring a registration to a new pharmacy owner. Failing to appropriately contact the DEA and verify whether the agency approved the transfer of a registration to dispense controlled substances creates a serious risk that could facilitate drug diversion by providing controlled substances to a person that has not been vetted by the appropriate regulatory authorities.

Subtitle H—Opioid Prescription Verification

H.R. 4810 - Reps. Davis (R-IL), Van Drew (R-NJ), Bucshon (R-IN), Shimkus (R-IL), and Latta (R-OH)

This provision facilitates the responsible and informed dispensing of opioids and other controlled substances, in order to curb illicit prescription shopping by encouraging pharmacists to check the identification of the person picking up a prescription and incentivizing better utilization of prescription drug monitoring programs to track patterns of abuse.

Subtitle I—Suspicious Order Identification

H.R. 4814 - Rep. Matsui (D-CA) and Johnson (R-OH)

This provision requires Drug Enforcement Administration (DEA) registrants to electronically report on the sale, delivery, or disposal (other than dispensing by a practitioner) of any controlled substance within 30 days, and establishes a Suspicious Order Monitoring Task Force, which will help design a program and make recommendations to the Attorney General to facilitate real time data sharing to and from registrants, including the limited sharing of Automation of Reports and Consolidated Orders System (ARCOS) data, in order to help identify suspicious ordering in real time.

Subtitle J—Stop the Importation and Manufacturing of Synthetic Analogues

H.R. 4963 - Reps. Katko (R-NY), Rice (D-NY), Walden (R-OR), Correa (D-CA), and Soto (D-FL)

This provision establishes a process to permit substances to be temporarily or permanently added to a new category of controlled substances, known as Schedule A, if their chemical structure is substantially similar to an existing controlled substance and they are expected to have the same or greater effect on the human body (such as fentanyl analogues). In addition, the provision applies existing criminal penalties for manufacturers, importers and exporters of Schedule A substances, and includes language to improve the process for conducting legitimate scientific research on substances placed in Schedule I and Schedule A.

TITLE VIII—TAX INCENTIVES TO IMPROVE HEALTH CARE

Sec. 8001. Domestic medical and drug manufacturing credit

H.R. 7767 - Rep. Wenstrup (R-OH)

This provision lowers tax rate on the income from the domestic manufacturing and sales of active pharmaceutical ingredients and medical countermeasures. By providing a credit of 10.5 percent of the net income from the sale of these important medical products, this effectively cuts the corporate tax rate from 21 percent in half on eligible profits. The credit is limited by the wages allocable to the domestic production, which supports good high-paying jobs in the United States.

Sec. 8002. Qualifying advanced medical manufacturing equipment credit

H.R. 7767 - Rep. Wenstrup (R-OH)

This provision creates a 30 percent tax credit for new investments in advanced manufacturing equipment or machinery used in the U.S. to manufacture medicines and medical devices. The credit phases down to 20 percent in 2028, 10 percent in 2029, and phases out in 2030.

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

H.R. 7555 - Rep. Nunes (R-CA)

This provision provides firms engaged in infection disease research a “bonus R&D credit” of 14 percent of any qualified research costs associated with the development of countermeasures, like infectious disease therapies, on top of the normal R&D credit that would apply to these same costs.

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

H.R. 7556 - Rep. Nunes (R-CA)

This provision provides pre-revenue companies with additional liquidity by allowing them to calculate their R&D tax credits and receive an annual refund of that amount. So, if a company engaged in R&D activity related to medical countermeasures generates \$10 million in R&D tax credits in a year, it would be eligible for a tax refund of \$10 million to provide it with additional liquidity to continue its drug development.

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

H.R. 7537 - Rep. Kelly (R-PA)

This provision relaxes the passive loss rules for losses and credits attributable to medical countermeasures research of pre-revenue pass-through business. This will help these smaller firms raise private funds from more investors at an earlier stage.

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

H.R. 7666 - Rep. Wenstrup (R-OH) and Rep. Axne (D-IA)

This provision allows unused 2020 plan year contribution amounts for Flexible Spending Arrangements (FSAs) and Dependent Care Flexible Spending Arrangements (DCFSA) to be rolled over into the 2021 plan year, recognizing care and expenses forgone in 2020.

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

H.R. 7666 - Rep. Wenstrup (R-OH) and Rep. Axne (D-IA)

This provision more than doubles the exclusion from employee gross income of employer-paid dependent care assistance for 2020 and 2021 to make paying for these services more affordable during the pandemic.

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

H.R. 7666 - Rep. Wenstrup (R-OH) and Rep. Axne (D-IA)

This provision doubles the contribution limits for health savings accounts in 2020 and 2021 to better enable people to pay for increased health and dependent care expenses during the pandemic.

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

This provision temporarily allows employment-related dependent care expenses to be eligible expenses for health savings accounts for 2020 and 2021.

Sec. 8010. Treatment of direct primary care service arrangements

H.R. 3708 - Rep. Nunes (R-CA) and Rep. Blumenauer (D-OR)

This provision permits a taxpayer with a direct primary care service arrangement whose fixed periodic fee does not exceed a certain threshold to contribute to a health savings account.

Sec. 8011. Allow both spouses to make catch-up contributions to the same HSA account

This provision allows both spouses that have attained age 55 to make a catch-up contribution to a health savings account.

Sec. 8012. Repeal of ceiling on deductible and out-of-pocket expenses under a high deductible health plan

H.R. 4130 - Rep. Marchant (R-TX)

This provision removes the limitation on the sum of the annual deductible and out-of-pocket expenses required under a high deductible health plan for purposes of health saving account eligibility. This change will allow many more health plans, especially in the individual market, to qualify for health savings account contributions.

Sec. 8013. On-site employee clinics

H.R. 6305 (115th Congress) - Rep. Kelly (R-PA) and Rep. Blumenauer (D-OR)

This provision permits employees to receive certain care at an employer on-site clinic and maintain their eligibility for making contributions to a health savings account, helping employees get care needed to stay healthy in the most convenient setting.

Sec. 8014. Adjustment of medical expense deduction

H.R. 7714 - Rep. Schweikert (R-AZ)

This provision reduces the adjusted gross income (AGI) threshold that must be exceeded before a taxpayer may claim a deduction amount for medical expenses. The reduction is from 10 percent to 5 percent in 2020 or 2021 and set at 7.5 percent thereafter.

Sec. 8015. Healthy Workplace Tax Credit

H.R. 7615 - Rep. Rice (R-SC); H.R. 7658 - Rep. Schweikert (R-AZ); and H.R. 8260 - Reps. Olson (R-TX) and Cuellar (D-TX)

This provision encourages and enables businesses to take the recommended steps to prevent the spread of COVID-19 in their workplaces; provides a refundable tax credit against payroll taxes for 50% of the costs incurred by the business for COVID-19 testing, personal protection equipment (PPE), disinfecting, extra cleaning, and reconfiguring workspaces; and is limited to \$1,000 per employee for a business's first 500 employees, \$750 per employees for the next 500 employees, and \$500 for each employee thereafter.

TITLE IX—MEDICARE PROVISIONS

Subtitle A—Telehealth

Rep. Nunes (R-CA) Discussion Draft

Sec. 9001. Removing certain geographic and originating site restrictions on the furnishing of telehealth services under the Medicare program

Traditionally, in order to receive a telehealth service in Medicare, a beneficiary must be in a rural area and must travel to a healthcare facility. During the Public Health Emergency these geographic and originating site restrictions, have been lifted to enable Medicare beneficiaries across the country to have the option of utilizing telehealth services from the convenience of their home. This provision extends this telehealth freedom until the end of 2023 or the end of the COVID-19 Public Health Emergency (PHE), whichever occurs later.

Sec. 9002. Making permanent FQHC and RHC telehealth payments.

Prior to the PHE waivers, FQHCs and RHCs were restricted in their ability to provide telehealth services to Medicare beneficiaries. This provision removes these restrictions until at least the end of 2023, which is critical to improving access for patients in rural and underserved areas.

Sec. 9003. Expanding the list of practitioners eligible to furnish telehealth services

Before waiver expansions during the PHE, the list of providers that were eligible to furnish telehealth was narrow, limiting opportunities for Medicare beneficiaries to access telehealth services. This provision ensures that practitioners who can now provide telehealth services in Medicare will remain eligible to utilize telehealth through at least the end of 2023.

Sec. 9004. Allowing for the provision of telehealth services via audio-only telecommunications systems

The use of audio-only telehealth during the Public Health Emergency has been critical for reaching many patients that otherwise might not be able to receive care. In rural and underserved areas, a lack of technological infrastructure can limit patients' video-conferencing capabilities. Additionally, digital literacy can also keep patients from accessing telehealth resources via video-conferencing. While more examination is needed to determine how to best incorporate audio-only telehealth, it is clear this option has a role to play moving forward. This provision will allow for continued utilization of audio-only telehealth through the end of 2023.

Sec. 9005. Making permanent the safe harbor for absence of deductible for telehealth

This provision allows high deductible health plans to provide coverage for telehealth services under the deductible. Making this policy permanent will give patients easier access to this effective and convenient type of care, potentially lowering health care costs overall.

Sec. 9006. Removing requirement for face-to-face visits between home dialysis patients and physicians

This provision extends the allowance of remote authorization of dialysis care through telehealth technologies instead of requiring an in-person visit, so long as patients receive mandatory in-person training when they start home dialysis, and the waivers for other in-person visit requirements. The Public Health Emergency has demonstrated the ability to better integrate telehealth into a variety of home health settings. This provision allows patients to continue to have the choice to utilize telehealth in receiving care such as home dialysis and other services that had in-person care requirements waived during the PHE through at least the end of 2023.

Sec. 9007. Report on telehealth payment integrity

This provision requires the HHS Office of the Inspector General to conduct a survey of telehealth claims to study potential improper payments one year after the end of the PHE. The report will assist Congress in evaluating potential threats to program integrity and inform future program management decisions.

Sec. 9008. Increasing funding for review of telehealth claims

This provision increases funding to the HHS Office of Audit Services and the Office of Investigations to ensure they have the resources necessary to handle oversight of the increase in telehealth claims since the start of the public health emergency.

Sec. 9009. Telehealth resources

This provision requires CMS offer education and training sessions to practitioners on Medicare telehealth requirements and related resources. This provision promotes proper utilization of expanded telehealth flexibility and keep providers informed of any changes in telehealth regulations.

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.

H.R. 8624 - Rep. Wenstrup (R-OH) and Rep. Bishop (D-GA)

This provision allows for the extension of pass-through status for drugs or devices whose future Medicare payment was unable to be accurately calculated due to the effects of COVID-19.

Subtitle C—Reducing Unnecessary Senior Hospitalizations

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

H.R. 6209 - Rep. Smith (R-NE) and Rep. Kuster (D-NH)

This provision establishes a program to allow qualified group practices to enter into a voluntary, value-based, shared savings model in Medicare to provide acute care services to patients in skilled nursing facilities (SNFs) via telehealth and on-site equipment. Any savings generated by the model would be shared between the SNF and the qualified group practice. SNFs that have a star rating of less than three stars can participate in the model but would not qualify for shared savings until they achieve a three-star rating. If CMS determines the program is shown to have increased expenditures over a 5-year period, the Secretary of HHS will terminate the program.

TITLE X—APPROPRIATIONS

Subtitle A—Health programs

This provision provides additional funding of \$47 billion to the Secretary of Health and Human Services to prevent, prepare for and respond to coronavirus, domestically and internationally. Funds can be used for countermeasure and vaccine development, purchase of vaccines, therapeutics, diagnostics, medical supplies and other preparedness and response activities. Funds can also be used for testing, contact tracing, surveillance, containment and mitigation to monitor and suppress COVID-19.

Subtitle B—General provisions

These provisions clarify certain conditions of the supplemental funds as well as provide definitions and guidance on how funds are to be scored for purposes of compliance with the Budget Act and PAYGO Scorecards.

This document was prepared by Energy and Commerce Committee, Ways and Means Committee, and Appropriations Committee Minority Staff as a section by section and an informational resource illustrating the range of policies in individual House and Senate bills that have been included in some form in the final legislation.