Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act (PREVENT Pandemics Act)

TITLE I—STRENGTHENING FEDERAL AND STATE PREPAREDNESS	
Subtitle A – Federal Leadership and Accountability	
Sec.101.Comprehensive review of the COVID–19 response.	• Establishes a Task Force with membership appointed by bipartisan Congressional and Committee leadership to examine the initial emergence of SARS-CoV-2and to examine and assess the United States' preparedness for and response to the COVID-19 pandemic, including the initial and ongoing Federal, state, and local responses to COVID-19 to identify gaps and make recommendations to the President and Congress. • Requires the submission of an interim report within 180 days of enactment and a final report to be submitted within one year, with an optional extension of an additional six months.
Sec.102.Appointment and authority of the Director of the Centers for Disease Control and Prevention.	• Requires Senate confirmation of the CDC Director and establishes specific functions of the Director. • Requires an agency-wide strategic plan to be developed every four years that describes CDC's priorities and objectives, the capabilities that need to be developed to achieve these objectives, and how CDC will leverage strategic communications, external partnerships, and coordination with other agencies. • Requires a GAO study on how CDC's programs and activities align with the strategic plan and progress in achieving performance measures. Requires the CDC Director to appear annually before the HELP and Energy and Commerce Committees, unless this requirement is waived by the Chair.

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Sec.103.Public health and medical preparedness and response coordination. .	• Provides additional authority for the Secretary of HHS to coordinate with, and request support from, other departments and agencies in leading the Federal public health and medical response to a public health emergency and includes a GAO study on the use of existing authorities for related interagency agreements. • Clarifies ASPR's role and responsibilities in public health and medical preparedness and response activities. • Requires national- and state-level full-scale exercises every five years to identify and address gaps in preparedness and response, including the ability of SNS to appropriately support the response to a large-scale, long-term public health emergency. • Requires the ASPR to appear annually before the HELP and Energy and Commerce Committees, unless this requirement is waived by the Chair. • Requires HHS to submit an annual report to Congress on the state of public health preparedness.
Sec.104.Strengthening public health communication.	• Requires the Secretary of HHS to establish a Public Health Information and Communication Advisory Committee to provide recommendations to the Secretary on communication and dissemination of scientific and evidence-based public health information during public health emergencies.
Subtitle B – State and Local Readiness	
Sec.111.Improving state and local public health security.	• Updates the CDC Public Health Emergency Preparedness (PHEP) cooperative agreements to ensure coordination between health departments and other state agencies to improve preparedness and response planning. • Requires PHEP recipients to provide technical assistance to agencies and other entities in which there is an increased risk of infectious disease outbreaks, such as residential care facilities and group homes, in order to improve preparedness and response.

Sec.112.Supporting access to mental health and substance use disorder services during public health emergencies.	• Directs the Substance Abuse and Mental Health Services Administration (SAMHSA) to support continued access to mental health and substance use disorder services during public health emergencies. • Requires SAMHSA's Strategic Plan and Biennial Report to Congress to include the agency's activities to support continued access to mental health and substance use disorder services during public health emergencies, including for at-risk individuals. • Requires the Assistant Secretary to submit a report to Congress, based on feedback from SAMHSA's advisory councils, describing steps SAMHSA can take to (1) improve the provision of mental health and substance use disorder services as part of the medical response to a public health emergency and (2) improve the provision of such services during public health emergencies. • Requires GAO to report on SAMHSA's work during the COVID-19 pandemic.
Sec.113.Trauma care reauthorization.	• Reauthorizes two grant programs to improve the provision of trauma care, including in rural areas, by increasing coordination and situational awareness within emergency medical and trauma systems and identifying and disseminating best practices. • Directs ASPR to support the improvement and coordination of emergency medical services and trauma care during a public health emergency, which may include issuing guidance for patient movement and triage and disseminating best practices and related information.
Sec.114.Assessment of containment and mitigation of infectious diseases.	• Requires a GAO report on state and territorial preparedness and response plans to mitigate the spread of COVID-19 and technical assistance provided by the federal government to support such mitigation efforts over the course of the pandemic.
TITLE II—IMPROVING PUBLIC HEALTH PREPAREDNESS AND RESPONSE CAPACITY	
Subtitle A - Addressing Disparities and Improving Public Health Emergency Responses	
Sec.201.Addressing social determinants of health and improving health outcomes.	• Authorizes a grant program to support evidence-based or evidence-informed projects to reduce health disparities and improve health outcomes by increasing

	capacity to address social determinants of health within communities, such as through disseminating strategies to address social determinant of health, ways to use technology to improve coordination with social services, and implementing best practices for improving health outcomes. • Authorizes grants to identify or facilitate the development of best practices to support improved health outcomes by addressing social determinants of health; provide technical assistance, training, and evaluation assistance to health departments; or establish or operate regional centers to develop, evaluate, and disseminate effective strategies to address social determinants of health. • Requires the Secretary to submit a report to Congress on activities funded. • Requires a GAO study on the outcomes and effectiveness of this program and coordination with related HHS programs.
Sec.202.National Academies of Sciences report.	• Requires a National Academies of Sciences, Engineering, and Medicine (or "Academies") study on the effects of health disparities on health outcomes, including related to public health emergencies. • Clarifies that the Academies may leverage relevant ongoing work to complete these requirements.
Subtitle B – Improving Public Health Data	
Sec.211.Modernizing biosurveillance capabilities and infectious disease data collection.	• Updates biosurveillance capabilities to improve public health situational awareness by: o Clarifying the Secretary's public health situational awareness authority to include modernizing applicable existing public health data systems and networks of the Department of Health and Human Services to reflect technological advancements. o Adding topics for discussion at the public meeting required under current law to improve situational awareness, such as integration of laboratory and other relevant data systems and improving electronic exchange of health information. o Updating the strategy and implementation plan to improve collaboration among Federal departments, implement lessons learned from previous public health emergencies, and identify steps the Secretary will take to

	further develop and integrate infectious disease detection, support rapid and accurate reporting of laboratory test results during a public health emergency, and improve coordination with public health officials, clinical laboratories, and other entities with expertise in public health surveillance. ○ Clarifying that an existing authority allowing the Secretary to award grants to states to establish or operate state or regional situational awareness systems should be carried out by the CDC Director
Sec.212.Genomic sequencing, analytics, and public health surveillance of pathogens.	• Requires the Secretary to issue guidance to support collaboration related to genomic sequencing of pathogens. • Directs the CDC Director, in consultation with the Director of the NIH and heads of other departments and agencies, to strengthen and expand activities related to advanced molecular detection and genomic sequencing of pathogens, including the use of genomic sequencing technologies to inform surveillance activities, enhancing the sequencing and analytics capabilities of the public health workforce, and continuing partnerships with public and private entities for these activities. • Allows the CDC to award grants, contracts, or cooperative agreements to entities with expertise in genomic sequencing for public health purposes. • Requires the Secretary to establish Centers of Excellence to support innovation in pathogen genomics and molecular epidemiology.
Sec.213.Supporting public health data availability and access.	• Amends public health data systems modernization provisions in current law by directing the CDC Director to disseminate public health data standards within two years to improve the exchange of public health data and reporting to public health data systems. • Directs ONC to conduct a study on the use of electronic data standards to order and report laboratory test results. • Directs the Secretary to improve the access, exchange, and use of public health data by updating existing, and entering into new, memoranda of understanding or data use agreements with relevant federal agencies and other public and private entities. • Allows the Secretary to work with public health departments to improve the availability of public health data, and information sharing between health

	departments, CDC, and ASPR, including information from health care facilities. • Authorizes a program to develop best practices to improve the quality and completeness of the collection of demographic data to support public health responses.
Sec.214.Epidemic forecasting and outbreak analytics.	• Authorizes the CDC Director to continue activities related to the development of capabilities for the analysis, modeling, and forecasting of public health emergencies and infectious disease outbreaks, including by leveraging the capabilities of public and private entities. • Requires the Secretary to issue an annual report on these activities for the next 5 years.
Subtitle C—Revitalizing the Public Health Workforce	
Sec.221.Improving recruitment and retention of the frontline public health workforce.	• Reauthorizes the Public Health Workforce Loan Repayment Program to provide loan repayment to individuals in exchange for working in a State, Territorial, Tribal, or local public health department. • Requires GAO to conduct an evaluation of the public health workforce in the U.S. during the COVID-19 pandemic.
Sec.222.Awards to support community health workers and community health.	• Reauthorizes a community health worker program to promote healthy behaviors and outcomes in medically underserved communities through the use of community health workers. • Directs funds to be used to recruit, hire, and train community health workers; support community health workers in providing education and outreach in their communities; address social determinants of health and eliminate health disparities; and to educate community members. • Requires GAO to submit a report to Congress on the outcomes and effectiveness of the program, as well as coordination with programs operated by HRSA.
Sec.223.Improving public health emergency response capacity.	• Improves HHS' ability to quickly mount an initial response to a public health emergency by allowing the Secretary to directly appoint up to [250] individuals per year in which there is a declared public health emergency to preparedness and response positions within HHS. • Requires an annual report to Congress and a GAO study on the use of this

	authority.
Sec. 224.Extension of authorities to support health professional volunteers at community health centers.	• Continues the Health Center Federal Tort Claims Act Volunteer Health Professionals Program.
Subtitle D—Improving Public Health Responses	
Sec.231.Centers for public health preparedness and response.	• Reauthorizes a network of Centers for Public Health Preparedness and Response to: o translate research findings or strategies into evidence-based practices to inform preparedness and response to public health emergencies; o improve awareness of these practices and other relevant scientific or public health information among health care and public health professionals and the public; o expand activities, such as through partnerships, to improve public health preparedness and response; and o provide technical assistance and expertise to health departments as appropriate.
Sec.232.Vaccine distribution plans.	• Clarifies that existing authorities of the Secretary to track the initial distribution of federally purchased vaccines to inform decision-makers during an influenza pandemic also apply to other pandemics.
TITLE III—ACCELERATING RESEARCH AND COUNTERMEASURE DISCOVERY	
Sec.301.Research and activities related to long-term health effects of SARS–CoV–2 infection.	• Directs HHS to continue conducting or supporting basic, clinical, epidemiological, behavioral, and translational research on the long-term health effects of SARS-CoV-2 infection. • Requires HHS to develop and inform recommendations, guidance, and provide educational materials for health care providers and the general public on the

	long-term effects of SARS-CoV-2 infection based on this research. • Requires HHS to submit a report to Congress with an overview of the research conducted or supported under this section and any relevant findings.
Sec.302.Research centers for pathogens of pandemic concern.	• Requires the National Institute of Allergy and Infectious Diseases (NIAID), in collaboration with ASPR and BARDA, to establish or continue a multidisciplinary research program with research centers to advance the discovery and preclinical development of medical products for priority virus families and other viral pathogens with the significant potential to cause a pandemic.
Sec.303.Improving medical countermeasure research coordination.	• Requires the NIH Director to consult with ASPR, BARDA, CDC, and the heads of other Federal agencies and offices regarding research needs to advance medical countermeasures for any agent or toxin that may cause a public health emergency, or other research needs related to emerging public health threats.
Sec.304.Accessing specimen samples and diagnostic tests.	• Requires HHS to make public policies and procedures related to public and private entities accessing specimens of pathogens to support research and development of medical countermeasures, such as tests. • Requires the Secretary to issue guidance on methods for requesting samples and additional considerations for sample access and availability. • Allows HHS to contract with public and private entities to improve the rapid development and availability of diagnostic tests to support immediate public health response activities to more quickly address emerging infectious diseases.
TITLE IV—MODERNIZING AND STRENGTHENING THE SUPPLY CHAIN FOR VITAL MEDICAL PRODUCTS	
Sec.401.Warm base manufacturing capacity for medical countermeasures.	• Directs BARDA to support the establishment and maintenance of warm-base domestic manufacturing surge capacity and capabilities so that medical countermeasures can be rapidly manufactured when needed to respond to public health emergencies. • Improves coordination and communication between private sector partners, BARDA, and FDA to ensure that this manufacturing capacity and capabilities are appropriately maintained, follow good manufacturing practices, and any related challenges are identified and addressed.

	• Amends a previously required GAO report to also consider plans for the sustainment of this manufacturing capacity and how BARDA is assessing the ability of its award recipients to rapidly manufacture medical countermeasures. • Extends the authorization for BARDA's Medical Countermeasure Innovation Partner through Fiscal Year 2028 to improve BARDA's ability to support investment in innovative medical countermeasures and related technologies.
Sec.402.Supply chain considerations for the Strategic National Stockpile.	• Amends the SNS Annual Threat-Based Review to include an assessment of the supply chains and any vulnerabilities for products that SNS plans to purchase during the period covered by the Review.
Sec.403.Strategic National Stockpile equipment maintenance.	• Clarifies that, as part of the procedures of the SNS, the Secretary should ensure that items in the stockpile are in working condition so they can be readily deployed when needed.
Sec.404.Improving transparency and predictability of processes of the Strategic National Stockpile.	• Requires the Secretary to issue guidance on how states, territories, and Tribes can access the SNS and other countermeasures, and factors the Secretary considers when making decisions related to product distribution. • Requires the Secretary to convene annual meetings with public health officials, the private sector, and other stakeholders to share information around the maintenance and use of the SNS and future procurement plans.
Sec.405.Improving supply chain flexibility for the Strategic National Stockpile.	• Authorizes the Secretary to enter into contracts to enhance surge capacity and supply chain flexibility for supplies intended for the SNS through vendor-managed inventory and warm-base domestic manufacturing capacity arrangements. • Requires a report to Congress on the use of these authorities.
Sec.406.Strategic National Stockpile contract duration.	• Requires the Secretary to issue contracts of at least two years in length, rather than making strictly volume-based procurements. • Provides flexibility to purchase additional product outside of multi-year contracts when necessary to address emerging issues, such as public health emergencies or when in the interest of national security.
Sec.407.Reimbursement for certain supplies.	• Authorizes the Secretary to sell excess products from the SNS to other entities when the cost of maintaining these products in the SNS is not appropriate to meet the needs of the SNS and the transfer of these products does not

	compromise national security. • Requires a report to Congress after two years on the use of this authority.
Sec.408.Action reporting on stockpile depletion.	• Requires the Secretary to report regularly to Congress on SNS content deployment and replenishment plans during a public health emergency.
Sec.409.Provision of medical countermeasures to Indian programs and facilities	• Clarifies that when HHS deploys products to states to respond to a public health emergency, the Secretary should also make these products directly available to Tribes that are affected by the public health emergency.
Sec.410.Grants for state strategic stockpiles.	• Authorizes a pilot program to support states in establishing, expanding, or maintaining stockpiles of medical supplies needed to respond to a public health emergency or disaster. • Requires HHS to issue guidance to all states within 180 days on best practices and strategies for maintaining stockpiles, such as the types of products that may be appropriate to maintain in a stockpile, use of vendor-managed inventory arrangements, and purchasing products made in America. • Requires a report to Congress and GAO report assessing the impacts of the pilot program and technical assistance provided by HHS to states on stockpiling.
TITLE V—ENHANCING DEVELOPMENT AND COMBATING SHORTAGES OF MEDICAL PRODUCTS	
Subtitle A—Development and Review	
Sec.501.Advancing qualified infectious disease product innovation.	• Expands eligibility for the Qualified Infectious Disease Product (QIDP) designation to include biological products. • Updates priority review eligibility for products that receive a QIDP designation to provide that the first application that requires clinical data (other than

	bioavailability studies) to demonstrate safety or effectiveness receives priority review.

Sec. 502.Modernizing clinical trials.	• Requires FDA to issue three guidances to modernize and improve clinical trials, including on the use of:
	  ○ Digital health technologies in clinical trials to help improve recruitment, participation, and data collection.
	  ○ Decentralized clinical trials to improve trial participant engagement and advance the use of flexible and novel clinical trial designs.
	  ○ Seamless, concurrent, and other innovative clinical trial designs to support the expedited development and review of drugs and biological products.
	• Facilitates international harmonization between FDA and foreign regulators with respect to the use of digital health technologies in clinical trials, decentralized clinical trials, seamless, concurrent, and other innovative clinical trial designs.

Sec.503.Accelerating countermeasure development and review	• Codifies FDA's successful Coronavirus Treatment Acceleration Program to ensure expedited action for the development and review of countermeasures during future public health emergencies.
Sec.504.Third party test evaluation during emergencies.	• Clarifies FDA's authority to consult with third parties to evaluate and make recommendations with respect to the validity, accuracy, and reliability of in vitro diagnostic tests for use during a public health emergency, which will enable FDA to prioritize its response efforts and surge where needed during future emergencies. • Requires FDA to issue guidance to facilitate such consultations with third parties.

Sec.505.Faciliating the use of real world evidence.	• Requires FDA to issue or revise guidance on the use of real-world data and real-world evidence to support regulatory decisionmaking, including with respect to real-world data and real-world evidence from products authorized for emergency use.
Sec.506.Advanced platform technologies.	• Creates an advanced platform technology designation to expedite the development and review of new treatments and countermeasures that use cutting-edge, adaptable platform technologies that can be incorporated or used in more than one drug or biological product. • Requires FDA to issue guidance on the implementation of the new designation.
Sec.507.Increasing EUA decision transparency.	• Provides FDA with authority to share more safety and effectiveness information with the public about products authorized for emergency use.
Sec.508.Improving FDA guidance and communication.	• Requires publication of a report identifying best practices across the FDA and other applicable agencies for the development, issuance, and use of guidance documents and for communications with product sponsors and other stakeholders, and a plan for implementing such best practices. • Requires FDA to publish a report on the agency's best practices for communicating with medical product sponsors and other stakeholders, and a plan for implementing such best practices.
Sec.509.GAO study and report on hiring challenges at FDA.	• Directs GAO to issue a report assessing FDA's hiring, recruiting, and retention practices, policies, and processes, and their impact on FDA's ability to carry out its public health mission, particularly in light of the COVID-19 pandemic.
Subtitle B—Mitigating Shortages	
Sec.511.Ensuring registration of foreign drug and device establishments.	• Clarifies that all foreign drug and device establishments that manufacture or process drugs or devices intended to be marketed in the United States must

	register with FDA, including products manufactured at an establishment that are not directly imported into the United States.
Sec.512.Extending expiration dates for certain drugs.	• Requires FDA to issue or revise guidance to address recommendations for drug sponsors regarding the submission of stability data in applications and establishing the longest feasible expiration dates supported by such data, in order to help mitigate or prevent potential drug shortages. • Requires FDA to issue a report on the number and type of drugs for which the Secretary has requested a labeling change to extend the expiration date and information related to the circumstances of such requests.
Sec.513.Unannounced foreign facility inspections pilot program.	• Requires FDA to conduct a pilot program to increase the conduct of unannounced inspections of foreign drug facilities, and issue a report to evaluate any differences between unannounced and announced inspections, barriers to conducting unannounced inspections, and challenges to achieving parity between domestic and foreign human drug establishment inspections.
Sec.514.Combatting counterfeit devices.	• Strengthens FDA enforcement authority against, and increases the penalties for, selling counterfeit medical devices, including personal protective equipment, in the United States.
Sec.515.Strengthening medical device supply chains.	• Requires manufacturers of certain critical medical devices to develop, maintain, and implement a redundancy risk management plan (which are currently required for drug manufacturers) to help ensure that supply chains for such devices are more resilient.
Sec.516.Preventing medical device shortages.	• Expands the circumstances when shortage notifications are required for medical devices to include circumstances that are likely to lead to a meaningful disruption in the supply of a device, or a shortage of the device or other reasonably substitutable devices.

	• Clarifies that FDA may receive voluntary notifications of supply disruptions of certain critical medical devices, and requires FDA to issue guidance to facilitate such voluntary notifications.
Sec.517.Remote records assessments for medical devices.	• Authorizes FDA to request from device manufacturers, in addition to drug manufacturers, certain records in advance of or in lieu of an inspection, and requires FDA to provide drug and device manufacturers with a rationale for its request of such records. • Requires FDA to publish guidance on how it intends to issue requests for records in advance of or in lieu of an inspection.
Sec.518.Advanced manufacturing technologies designation pilot program.	• Creates an advanced manufacturing pilot program to expedite the development and review of novel manufacturing approaches for drugs that will improve drug quality, reduce development times, and improve the availability of critical drugs. • Requires FDA to hold a public meeting and to issue guidance on the implementation of the pilot program, and to issue regular reports evaluating the impact of the program. • The pilot program will sunset after October 1, 2027.
Sec.519.Technical corrections.	• Technical corrections to the CARES Act, and to the Food, Drug, and Cosmetic Act related to the CARES Act.