

Update: What to Know About PREVENT Pandemics Act Following March 15 Committee Markup

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On March 15, 2022, the Senate Health, Education, Labor and Pensions Committee (HELP) held a full committee markup to offer several amendments and vote on S. 3799, the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act (PREVENT Pandemics Act). The committee voted to report the bill as amended to the floor by a vote of 20-2, with Sens. Rand Paul (R-KY) and Mike Braun (R-IN) voting against the bill. The bill that passed includes eight of the amendments that were offered and passed by the Committee, including amendments from Senators Jackie Rosen (D-NV), Tina Smith (D-MN), Bernie Sanders (D-VT), Roger Marshall (R-KS), and Lisa Murkowski (R-AK). Additionally, the Committee adopted a managers' amendment that incorporates the newly-introduced bipartisan bill S.3819, the ARPA-H Act. As Chairwoman Murray stated in her opening testimony, after nearly a year of work, this bill includes ideas from 41 bills and 35 different members on both sides of the aisle. The bill will now head to the full Senate for floor consideration this year. Amendments to the original bill text include:

- Establishing the Advanced Research Project Authority for Health (ARPA-H) ([S. 3819](#)).
 - This amendment would authorize ARPA-H to provide grants, agreements, and further incentives in research and development transactions.
 - It would restrict funding to projects that have been unsuccessful in obtaining private sector funding, among other qualifications.
 - This amendment specifies that the president will appoint the director of the agency directly for a four-year term, and that director would report to the NIH director.
 - Private recruiting firms would have the ability to contract with ARPA-H for hiring purposes.
 - This provision would not allow agency facilities to be located in the Washington, D.C. area.

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- The Consolidated Appropriations Act of 2022 authorizes \$1 billion for its establishment within the Department of Health and Human Services (HHS). This omnibus package was signed by Pres. Biden on March 15, 2022.
 - The Energy and Commerce Committee conducted a hearing on March 17, 2022 regarding two house bills that would also authorize ARPA-H. Rep. Anna Eshoo's [H.R. 5585](#) would make ARPA-H independent of the NIH, while [H.R. 6000](#) - Cures 2.0 - introduced by Reps. Diana DeGette (D-CO) and Fred Upton (R-MI) - would authorize ARPA-H as an entity within the NIH, similar to the PREVENT Pandemics Act. This is also what the Biden administration has previously proposed.
 - House leadership backs Rep. Eshoo's bill, which will keep the agency as a separate entity from NIH. That bill will likely move with Cures 2.0 and will replace that bill's agency authorizing language.
 - Increasing manufacturing capacity for certain critical antibiotic drugs ([Smith Amendment # 1](#))
 - This allows for HHS to award contracts to increase domestic manufacturing of antibiotic drugs and would permit recipients to use funds to build, upgrade, or modify a United States facility.
 - Incentives to explore ways to lower prescription drug costs via nonprofit drug makers ([Rosen Amendment #3](#))
 - Strengthening the Domestic Medical Supply Chain ([Rosen Amendment # 2](#))
 - With this amendment, the Office of Pandemic Preparedness and Response Policy (established in S.3799) would be required to create partnerships with private entities to address medical supply needs.
 - Authorization of \$177 million in mandatory funding for the Nurse Corps in 2023 ([Sanders Amendment #1](#))
 - Requiring limitations on research on potential pandemic pathogens at a foreign institution in a country of concern ([Marshall Amendment #5](#))
 - Requiring agencies to consider the economic impacts of their regulations issued during public health emergencies ([Murkowski Amendment #1](#))
 - Requiring five percent of appropriations for HHS grant program to be reserved for awards to Indian Tribes and Tribal organizations and Tribal health departments ([Smith Amendment #2](#))
 - Modification of existing law to authorize funds for FY22-FY25 to expand grant programs for educational support for primary care physicians and health care providers in rural and underserved communities ([Rosen Amendment #1](#))

The PREVENT Pandemics Act was released earlier this year as draft legislation by Chairwoman Patty Murray (D-WA) and Ranking Member Richard Burr (R-NC), as the authors sought input from colleagues, state, local, and tribal health experts and other stakeholders to proposed changes and

additional recommendations. You can read the original draft text [here](#).

Of importance and among other provisions, this legislation:

- Modernizes the supply chain of critical medical products and seeks to better supply the Strategic National Stockpile (SNS). It also requires that the Secretary report to Congress on the state of the SNS, and to issue guidance and hold annual meetings with public health officials and stakeholders on how states, territories, and Tribes can access the SNS.
 - Would seek funds to provide grants to build State stockpiles.
 - Directs Biomedical Advanced Research and Development Authority (BARDA) to establish and maintain domestic manufacturing capacity for rapid production, as needed, and to ensure that manufacturing capacity is maintained.
- Modernizes public health data through biosurveillance and infectious disease data collection. The draft legislation seeks to modernize existing systems of HHS and update collaboration efforts among Federal departments.
 - Fund grant opportunities to state, local, or tribal health departments, community-based organizations, Indian organizations, or other public or private entities for projects that would improve health outcomes and reduce health disparities.
 - Clarifies that existing authority for the Secretary of HHS to award grants to states to carry out regional situational awareness systems should be transferred to the CDC Director.
 - Tasks the CDC with awarding funding and contracts to entities seeking to conduct genomic sequencing for public health purposes.
 - Requires the Secretary of HHS to issue guidance for collaboration among various entities for genomic sequencing of pathogens, and to support public and private partnerships.
- Provides grants to eligible entities for research and demonstration projects that support the improvement of emergency medical services and trauma care in rural areas.
 - Grants would be used for development of innovative uses of technology, establishment of trauma centers, training and education, transportation, access to prehospital care, among other opportunities.
- Seeks to create more accountability for the Center for Disease Control (CDC) by requiring the Director be subject to Senate confirmation and requiring a strategic plan from the agency every four years. Currently, the position is appointed by the President, but not subject to Senate confirmation.
- Establishes a COVID-19 Task Force to examine the origins of COVID-19 and to examine the country's response at the Federal, state and local levels. The commission would make recommendations to the Administration and Congress, and its members would be field experts appointed by Congress.

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- Clarifies the role of the Office of the Assistant Secretary for Preparedness and Response (ASPR); also requires more regular updates from this office to the committees of jurisdiction in the House and Senate.
 - Improves access to and transparency of mental health and substance abuse services during public health emergencies by directing the Substance Abuse and Mental Health Services Administration (SAMHSA) to incorporate their activities of continued support in this area in their Biennial Strategic Report to Congress, and requiring the Government Accountability Office (GAO) to report on SAMHSA's work during the COVID-19 pandemic, among other provisions.
 - Requires HHS, CDC, and the National Institute of Health (NIH) to work together, along with private entities, to better analyze research and forecast public health emergencies. The legislation creates a requirement for the Secretary of HHS to issue an annual report on such activities every year for the next five years.
 - Calls for the continuation of research on long-term effects of COVID-19 infection and the establishment of a multidisciplinary research program to develop medical products for priority viral pathogens with potential to cause a future pandemic.
 - Allows HHS to work with public and private entities to improve availability of diagnostic tests to address emerging infectious diseases in the public.
 - Improves clinical trials by requiring the Food and Drug Administration (FDA) to issue guidance on the use of digital health technologies in clinical trials; decentralized clinical trials; and other innovative designs to support development of new drugs.
 - Requires various published reports from FDA on best practices and transparency, and authorizes the FDA with expanded duties to combat drug and medical device shortages and illegal production and/or sales, among other provisions.
 - Seeks to expedite the development of new manufacturing approaches for novel drug development by creating a pilot program to reduce development time. The pilot program, which will wind down at the end of 2027, first requires the FDA to issue guidance on implementation and to provide regular reporting on projects.

Senators Murray and Burr expect the legislation to progress this year. Several other biomedical innovation and pandemic preparedness bills have been released, including, the "[Tracking Pathogens Act](#)," introduced by Sens. Bill Cassidy (R-LA) and Tammy Baldwin (D-WI); [Cures 2.0](#) (H.R. 6000), introduced by Reps. Diana DeGette (D-CO) and Fred Upton (R-MI); and [the Advanced Research Project Agency – Health Act](#) (H.R. 5585), introduced by Rep. Anna Eshoo (D-CA). The PREVENT Pandemics Act is likely to be the vehicle for these and other measures.

Sources: Senate [Press Release](#) and [PDF](#)

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