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**Memorandum** *July 5, 2023*

# SENATE HELP RELEASES PAHPA REAUTHORIZATION DISCUSSION DRAFT

## EXECUTIVE SUMMARY

On July 3, the Senate Health, Education, Labor and Pensions (HELP) Committee released a staff-level discussion draft of its legislation aimed at reauthorizing the Pandemic and All Hazards Prevention Act (PAHPA). The proposal seeks to bolster public health emergency response efforts in the U.S., particularly through new public health **data sharing and reporting requirements**, modifications to the operations of the **strategic national stockpile** (SNS), new **medical countermeasure** requirements, and **state and local preparedness** efforts, among other items.

Notably, the discussion draft provides that the Secretary of Department of Health and Human Services (HHS) would be required to coordinate activities related to addressing long-term COVID-19 **(Long COVID)** as well as develop Long COVID-related guidance materials to be disseminated to health care providers and the public. In addition, the Committee seeks to authorize an HHS program to support eligible entities working to establish research, training, and technical assistance centers focused on **issues faced by individuals with disabilities during public health emergencies**.

- **Background.** Intended to bolster public health preparedness in the U.S., PAHPA will expire on September 30, 2023, unless reauthorized. The law is responsible for creation of: (1) the Assistant Secretary for Preparedness and Response position at HHS; (2) the Biomedical Advanced Research and Development Authority (BARDA); and (3) the ability to develop medical countermeasures. In May, the Senate HELP Committee held a hearing (TRP summary) to consider reauthorization of the bill.

While touted as a bipartisan effort, Chair Bernie Sanders (I-VT) and Ranking Member Bill Cassidy (R-LA) have yet to come to an agreement on **PAHPA spending amounts** — as are indicated by bracket amounts within the text that reflect current funding levels — as well as other policy priorities. Of note, despite having been a topic of major discussion in both the upper and lower chambers in recent months, the discussion draft makes no mention of policies to combat **drug shortages**, as were requested in the Food and Drug Administration's (FDA) fiscal year (FY) 2024 budget proposal in March (TRP analysis).

Included within the discussion draft are two **requests for information** (RFI). Democrats are requesting stakeholder feedback on a proposal to require that all BARDA- and Centers for Disease Control and Prevention (CDC)-supported products be sold to both the federal government and the U.S. commercial market at the lowest price among G7 countries and at a price that is deemed "fair

and reasonable." The proposed policy, which is opposed by Republicans, also stipulates that the price charged for drugs sold on the commercial market would be required to consider the amount spent by the federal government on research and development (R&D). Conversely, Republicans are requesting feedback on a proposal to incentivize the development of additional medical countermeasures. To do so, the Priority Review Voucher program would be extended and an additional, non-transferrable priority review voucher would be available to organizations that develop new medical countermeasures.

- **What's Next?** The Committee is requesting stakeholder feedback on the discussion draft, including provisions related to drug pricing and medical countermeasures. Public comments are to be submitted no later than Monday, July 10, 2023, at 10:00 AM ET to PHAPA2023Comments@help.senate.gov. Intel from Capitol Hill suggests that the Senate HELP Committee intends to hold a markup of this legislation sometime later this month, but nothing has been formally announced from committee leadership as of this note.

Notable items within the proposal include:

**All-Hazards Emergency Preparedness and Response** — Under the discussion draft, the Assistant Secretary for Preparedness and Response would be required to lead the development, approval, and review of requirements for countermeasures and products to inform HHS' research, development, procurement, and replenishment decisions. In consultation with the Assistant to the President for National Security Affairs, the Assistant Secretary for Preparedness and Response would be required to provide an update on specified medical and public health preparedness and response activities. Such activities would include the addition of medical product and supply capacity planning, particularly pertaining to identified supply chain vulnerabilities. Regarding medical product and supply chain capacity planning, the draft legislation would require that the Assistant Secretary for Preparedness and Response coordinate efforts to support preparedness for medical product and supply needs, including for active pharmaceutical ingredients, key starting materials, and other critical components of such products.

The discussion draft maintains the requirement that the Assistant Secretary for Preparedness and Response submit to Congress biennially a coordinated strategy for medical countermeasures and, within 180 days after the submission of such strategy, deliver an implementation strategy to Congress as well. As indicated within the draft text, the Committee has yet to come to an agreement on the 180-day deadline as well as the $250 million funding allotment for each of FYs 2024 through 2028.

**Strategic National Stockpile** — Section 319F–2 of the Public Health Service Act would require the Secretary to conduct an annual threat-based review of the SNS. If enacted, the Secretary would be required to, in the case of a countermeasure that addresses a biological agent, provide information during such reviews about whether such agent has an increased likelihood to become resistant to such countermeasure relative to other available medical countermeasures. Additionally, the discussion draft would require that the Secretary, in managing the SNS, utilize tools to enable

tracking — including the location and geographic distribution — of the contents of the SNS when its contents are deployed. Notably, the discussion draft stipulates that the Secretary would be required to notify Congress within 60 days that a determination of material threat or public health impact has been made. This 60-day timeline is subject to change as the discussion draft indicates that this time period has not been agreed upon by the Committee. Also yet to be agreed upon is the $7.1 billion to be authorized for the SNS for FYs 2024 through 2033.

**Medical Countermeasures**

- *Public Health Emergency Medical Countermeasures Enterprise* — The discussion draft would amend section 2811–1(c) of the Public Health Service Act to clarify that the Secretary share recommendations and strategies with relevant stakeholders and public health departments in a manner that does not compromise national security.

- *Transition of Certain Countermeasures Between Compensation Programs* — The discussion draft clarifies certain provisions pertaining to the ineligibility of requests made to both the Countermeasures Injury Compensation Program (CICP) and the National Vaccine Injury Compensation Program (VICP) in relation to COVID-19 vaccinations. For requests submitted under the CICP or VICP, the Secretary would be required to notify individuals within 30 days if it is determined they are ineligible for the program. The draft also certifies that individuals who are notified of their ineligibility may submit a petition for that injury within one year of receiving such notification. Additionally, the draft would amend the Public Health Service Act to clarify that individuals will not be eligible for compensation under CICP if the vaccine, at the time of administration, was included in the Vaccine Injury Table. On changes to the VICP, the bill would prevent the Secretary from revising the Vaccine Injury Table to include vaccines that the CDC has recommended for use in children or pregnant women until at least one application for the vaccine has been approved.

**Long COVID** — Under the draft bill, the Secretary of HHS would coordinate activities — including clinical, epidemiological, behavioral, and translational research and public health surveillance — related to addressing Long COVID among relevant federal agencies. Consistent with such findings, the Secretary, in conjunction with experts, would develop Long COVID-related recommendations, guidance, and educations materials to be disseminated to health care providers and the public. Within one year of enactment, and annually for the subsequent four years to follow, the Secretary would be required to submit a report to Congress detailing such research and its findings. Among other requirements, the proposal would establish a primary care technical initiative to convene providers and organizations to collect and disseminate best practices related to Long COVID care. Notably, the draft stipulates that this initiative may include support for continuing training and education for such providers.

**Public Health Data** — Under current law, the CDC, in collaboration with state public health officials, is required to establish and continuously improve a near real-time electronic, interoperable nationwide public health system to share data and information related to infectious disease outbreaks, novel emerging threats, and other public health emergencies. Under the discussion draft,

this provision would be amended to stipulate that such systems should facilitate the aggregation of relevant public health data across HHS as well as the sharing of information from applicable public health data systems. HHS would also be required to develop guidance on data elements to be reported by applicable entities to the Secretary surrounding potential infectious disease outbreaks on a cadence to be determined by HHS. This information would then be made publicly available under the Public Health Situation Awareness System Pilot Program. In addition to establishing this pilot program, the discussion draft would require the creation of a National Public Health Data Board — comprised of federal agency administrators and public health officials — to advise and make recommendations related to: (1) the implementation of data and information; and (2) potentially catastrophic infectious diseases appropriate for inclusion in the Pilot Program. These provisions would sunset on September 30, 2028.

**Staff Proposal RFIs**

- *Reasonable Pricing Requirements* — Democrats are requesting stakeholder feedback on a proposal to require that all BARDA- and CDC-supported products — including qualified countermeasures, qualified pandemic or epidemic products, security countermeasures, or related technologies — developed with support be sold to both the federal government and the U.S. commercial market at the lowest price among G7 countries and at a price that is deemed "fair and reasonable." In determining whether a price is fair and reasonable, the Secretary must consider: (1) the value of the product to public health; (2) the amount spent by the federal government on R&D; (3) the amount spent by the manufacturer on R&D; (4) whether the product provides a significant improvement in health outcomes in comparison to other therapies available at the time of approval; and (5) the cumulative expected global revenues generated by the product, among other items.

- *Incentivizing Development of Additional Medical Countermeasures* — Republicans are requesting comment on a proposal to incentivize the development of additional medical countermeasures. To do so, the Priority Review Voucher program would be extended and an additional, non-transferrable priority review voucher would be available to organizations that develop new material threat or military medical countermeasures. Additionally, under the proposal, military countermeasure applications would be eligible for priority review.

**State and Local Preparedness**

- *Public Health Emergency Preparedness Program* — The draft text would appropriate additional federal funding — an amount still to be determined — to the Public Health Emergency Preparedness Program through fiscal year 2028. Other amendments to the program included in the discussion draft would impact the amount of funds that may be withheld by the federal government if certain benchmarks are not met beginning in fiscal year 2025, in addition to other technical amendments.

- *EMS Organizations in the Hospital Preparedness Program* — The Hospital Preparedness Program (HPP) administrated by Administration for Strategic Preparedness and Response (ASPR) provides federal funding to assist hospitals and health care systems prepare and

respond to public health emergencies. The draft would make amendments to the program to enhance the participation of underrepresented entities such as emergency medical services (EMS) organizations and give preference in awarding federal grants to applicants who will enhance coordination between local health care facilities and EMS organizations.

- *Medical Readiness and Response* — The discussion draft would require applicants who apply for federal funding as part of the HPP to designate a lead entity to administer and support coordination of the grant awards for participating eligible entities. In addition, the draft would require eligible entities to establish and maintain capabilities to enable regional medical operations, including systems to facilitate information sharing and coordination between grantees that are in close geographical proximity. The draft would also appropriate federal funds to the HPP through fiscal year 2028, though an amount has not yet been agreed upon.

- *State Medical Stockpiles* — Authorized under the Consolidated Appropriations Act, 2023, the State strategic stockpile is a pilot program administered by HHS that provides federal matching grant funds to five states or a consortium of states to establish or sustain a reserve of as drugs, vaccines, biological products, medical devices, and other medical resources that are necessary to respond to a public health emergency or major disaster. The purpose of the program is to supplement the SNS. The draft bill would amend this program to extend the federal matching funds available under the pilot program by one year. It would also appropriate additional federal funding for the pilot program for an additional four years through FY 2028. In addition, the measure would add additional requirements for State grantees participating in the pilot to ensure that the State is coordinating with "appropriate health care entities, health care officials, and emergency management officials" within the State.

**Other Provisions**

- *Biosecurity* — First, no later than two years after enactment, the discussion draft would establish a confidential, anonymous, voluntary, "no-fault reporting system" for accidents, near-accidents, and other safety incidents involving listed biological agents or toxins. The no-fault reporting system would be made available to individuals affiliated with laboratories within the U.S. and federally-funded entities outside of the U.S. that conduct research involving biological agents and toxins. Second, the draft legislation would task the National Science Advisory Board for Biosecurity with evaluating the effectiveness of the Federal Select Agent Program in mitigating the risks of biological threats. The board would then develop recommendations related to the modernization of the program, including a framework for an "integrated approach" for federal oversight of biological research that could raise significant biosafety and biosecurity concerns. Lastly, the discussion draft would create a $52 million grant program through which HHS would provide awards to establish or maintain at least 12 regional biocontainment laboratories.

- *Review of Regulations* — In order to carry out amendments provided for in the draft text, the bill would direct HHS to update regulations governing administration of the National Vaccine Injury Compensation Program.

- *Supporting Individuals with Disabilities During Emergency Responses* — The discussion draft would authorize an HHS program to support eligible entities working to establish research, training, and technical assistance centers focused on issues faced by individuals with disabilities during public health emergencies. These centers would provide relevant information, training, and technical assistance to states, local governments, and other entities related to the unique needs and considerations of at-risk individuals. The program would end on September 30, 2028.

**Additional Reauthorizations** — While the funding amounts are still to be determined, the draft bill would reauthorize appropriations for the following activities through FY 2028:

- Vaccine tracking and distribution;
- Emergency system for advance registration of volunteer health professionals;
- National disaster medical system; and
- Epidemic intelligence services loan repayment.

The discussion draft would also reauthorize the regional health care emergency preparedness, response systems, and authority for the temporary reassignment of state and local personnel during a public health emergency through FY 2028, among others.