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July 10, 2023

The Honorable Bernard Sanders	The Honorable Bill Cassidy, M.D.
Chair	Ranking Member
Health, Education, Labor, and Pensions Committee	Health, Education, Labor, and Pensions Committee
United States Senate	United States Senate
Washington, D.C. 20510	Washington, D.C. 20510
The Honorable Robert Casey	The Honorable Mitt Romney
Member	Member
Health, Education, Labor, and Pensions Committee	Health, Education, Labor, and Pensions Committee
United States Senate	United States Senate
Washington, D.C. 20510	Washington, D.C. 20510

Dear Chair Sanders, Ranking Member Cassidy, Senator Casey, and Senator Romney:

The Association of State and Territorial Health Officials (ASTHO) is pleased to provide comments in response to the Senate Health, Education, Labor, and Pensions bipartisan discussion draft to reauthorize the Pandemic and All-Hazards Preparedness Act. As the national nonprofit organization representing state and territorial public health officials, ASTHO recognizes the need for strong federal support for state and territorial public health preparedness to maintain and advance public health emergency response capacity.

A collaborative national preparedness effort requires a clear understanding of roles, responsibilities, and resource support across federal, state, local, territorial, and tribal (SLTT) public health agencies. SLTT public health agencies are critical to our nation's ability to prepare for, respond to, and recover from public health emergencies and threats. Principally, they ensure their jurisdictions' health through their inherent—and often legal—authority to protect and promote the populations' health, safety, and general welfare. SLTT public health departments have repeatedly demonstrated their robust ability to protect the health and safety of their populations from the effects of natural and people-made disasters. Yet these capacities can degrade rapidly without the support of federal grants, policies, and community and business practices that foster coordinated planning and response activities. Below are ASTHO's comments on the discussion draft, as well as current examples of how drug shortages are impacting patient care.

Sec. 101 – Public Health Emergency Preparedness (PHEP) Program

The PHEP cooperative agreement must continue to fund existing awardees, including all states, territories and freely associated states, and four directly funded localities. State and territorial public health agencies ensure coordination and efficiency across the jurisdictions, reduce redundancy and lower inefficiency, and are essential as the locus of operation that supports community-level preparedness.

The current authorization level of \$685 million does not meet SLTT public health systems' need. Sufficient federal resources are necessary to sustain readiness capability. SLTT public health agencies must retain a well-trained staff, exercise emergency operations plans, support partnerships, navigate grant administration, and modernize systems for interoperability among agencies from the local to the federal level. Sufficient baseline federal all-hazards preparedness funding is crucial to maintaining SLTT public health readiness and bolstering our nation's ability to respond to all threats as they arise. As the country works to build up its public health infrastructure after decades of underfunding, increased efforts and ongoing resources are needed to support coordination between simultaneous efforts to modernize and strengthen jurisdictional and national readiness and capabilities. ASTHO underscores that while the PHEP program does not provide funding for a response, preparedness activities should not preclude Congress or HHS from acting swiftly in the face of a public health threat to adequately resource the boots on the ground. The most recent appropriation was \$735 million, and public health systems remain strained. The highest appropriation for PHEP was in FY03 at \$919 million. ASTHO

Sec. 102 – Improving and Enhancing Participation of EMS Organizations in the Hospital Preparedness Program (HPP)

The current authorization level for the HPP is \$385 million. Its highest appropriation was \$515 million in FY03 and FY04. Appropriations for the program have eroded to \$474 million, a vastly insufficient level given the task of preparing healthcare systems for patient surges, continuity of operations, and recovery. Public health and healthcare preparedness efforts through the HPP need increased support to build and maintain interoperable systems that reduce duplication of efforts, increase resource visibility, and meet the federal and local leadership expectations of the communities they serve. Inadequately funding this program impairs public health and healthcare systems' ability to provide competent care and services at the most trying of times. Furthermore, expanding award eligibility to other recipients further strains the program, considering its inadequate authorization funding level. ASTHO strongly supports reauthorizing the HPP at a funding level of no less than \$500 million and maintaining the current list of eligible entities for the program.

Sec. 104 – Pilot Program to Support State Medical Stockpiles

ASTHO is pleased with the committee's consideration to have the Government Accountability Office (GAO) evaluate the impact of regional stockpiling approaches, similar to GAO's evaluation of state pilot programs to identify best practices and strategies to improve efficiency and sustainability of countermeasure distribution. We are also grateful for the language within this section clarifying that an entity receiving an award coordinate with health officials, among others. It is important to note the financial burden of maintaining state stockpiles. Therefore, we recommend that special consideration should be given to (1) how any state stockpiling program would be sustained since there is no permanent funding for such a program and (2) how such a program would connect and function with the more significant federal Strategic National Stockpile (SNS) functions.

Sec. 105 – Enhancing Domestic Wastewater Surveillance for Pathogen Detection

ASTHO supports the committee's interest in enhancing wastewater surveillance for pathogen detection at SLTT public health departments. Wasterwater surveillance, which measures pathogen levels in wastewater, was vital in evaluating community-level trends that can be used to complement traditional surveillance and interventions. During the COVID-19 pandemic, CDC launched the National Wastewater Surveillance System (NWSS) to coordinate wastewater surveillance programs that were being implemented by SLTT public health departments.¹ Up until that point, this type of surveillance was not being conducted at the national level. In 2021, 43 public health departments were using funds from CDC to support wastewater surveillance activities, with a majority of them reporting data to the NWSS.² The lessons learned from wastewater surveillance related to COVID-19 should be extended and explored in tracking other disease threats in partnership with SLTT public health departments. ASTHO supports sustainable and flexible funding to meet such goals.

Sec. 106 – Reauthorization of Mosquito Abatement for Safety and Health Program

ASTHO supports the reauthorization of the Mosquito Abatement for Safety and Health program, as well as language that would permit award recipients to use the funding to provide continuing education and training for individuals carrying out activities related to the program.

Sec. 201 – All Hazards Emergency Preparedness and Response

The past three years have demonstrated the need for Congress to support robust, fully funded public health infrastructure with sustainable annual resources, with the ultimate goal of minimizing the dependency on supplemental emergency funding. The ongoing funding and support to modernize our public health system is a move in the right direction, but the system still has a ways to go. The nation needs a continuous, robust commitment to any post-pandemic effort, similar to how the government supports domestic security through defense spending. We must modernize our federal and SLTT public health data and surveillance systems to rapidly detect and respond to public health threats domestically and globally. Foundational improvements to the nation's public health data infrastructure and continued investments in public health data modernization are necessary, while also continuing to support SLTT core public health activities, including disease surveillance and epidemiology, laboratory services, assessment, policy development and support, preparedness and response, community partnerships, communications, equity, accountability, and performance management.

The federal government must consider that the impact of all public health emergencies will not affect every population, state, territory, or region in precisely the same way. SLTT public health agencies should prepare and plan for public health by understanding communities' unique geography and demographics while recognizing the interconnected nature of our natural, built, and social systems. Vulnerable populations—including children; older adults; persons with disabilities, chronic disease, and existing mental illness; and those impacted by poverty, racism, violence, and other forms of social isolation—are likely disproportionally impacted by public health emergencies. It is also important to consider geographic vulnerability, including coastal areas, as well as rural and island nations. With the support of relevant federal agencies, SLTT public health agencies can continue to assess their distinct vulnerabilities—both locally and regionally—and prepare for, respond to, and recover from public health emergencies.

ASTHO supports the need for four separate but equally essential funding streams:

- Increased baseline public health infrastructure funding via annual appropriations that support the modernization of core public health data systems and the core functions of public health, such as daily assessment, surveillance, monitoring, testing, vaccinations, and more.
- Establishing a mandatory public health infrastructure fund outside of the annual appropriations process to provide public health jurisdictions with predictable and sustained funding.

¹ <u>https://www.cdc.gov/nwss/wastewater-surveillance.html</u>

² Kirby AE, Walters MS, Jennings WC, et al. Using Wastewater Surveillance Data to Support the COVID-19 Response — United States, 2020–2021. MMWR Morb Mortal Wkly Rep 2021;70:1242–1244. DOI: http://dx.doi.org/10.15585/mmwr.mm7036a2external icon.

- Adequate and appropriate all-hazards preparedness funding via the PHEP program and the Administration for Strategic Preparedness and Response (ASPR) HPP that strengthens the country's readiness and capabilities, such as by improving emergency operations coordination, emergency public information sharing, mass care, medical surge, and medical countermeasure dispensing and administration.
- Rapid and flexible response funding that allows for the necessary expansion of core public health and response capabilities and activities during an emergency.

Sec. 202 – Strategic National Stockpile and Material Threats

ASTHO supports increased transparency in the SNS's inputs, processes, and activities with public health officials to improve the system's integration and use. Therefore, we are pleased with the committee's inclusion of language requiring that the secretary regularly review and update best stockpile practices. We are also pleased with the included requirement that the SNS utilize tools that enable timely and accurate tracking of contents within the stockpile and throughout the deployment of such contents. With adequate annual funding, SLTT public health agencies can continue coordinating and distributing SNS assets that support public health and healthcare needs during known and unknown chemical, biological, radiological, or nuclear threats and emerging infectious diseases.

We also support:

- Continued funding to SLTT public health agencies (through CDC and ASPR) to support their logistical, warehouse, and tracking systems to ensure they can readily receive and distribute critical medical countermeasures and materials during emergencies to public health, healthcare, and first responder partners and communities.
- A thoughtful review of the SNS to examine how the nation determines stockpile inventory through distribution by establishing a national advisory committee on countermeasures.
- The advisory committee or other appropriate body should comprise a diverse group of individuals representing SLTT public health practitioners, private industry, academia, and more.

Sec. 204 – Public Health Emergency Medical Countermeasures Enterprise (PHEMCE)

ASTHO applauds the committee and its strengthening of the PHEMCE by requiring that the secretary solicit and consider input from SLTT public health departments, as well as share information related to recommendations and strategies made by the PHEMCE. In addition, we are pleased with the requirement that the secretary share information related to recommendations developed by the PHEMCE with SLTT public health departments. We also kindly request that the committee require the representation of SLTT public health officials on the PHEMCE. This will improve the efficiency of countermeasure distribution by ensuring end-to-end logistical factors. The need for a "boots on the ground" perspective regarding medical countermeasures during the COVID-19 response was apparent, and Congress should codify this representation in the PHEMCE. We therefore recommend the following addition: In 42 U.S. Code § 300hh–10a, include section (b), the following: (11) state, local, territorial, and tribal health officials.

Sec. 205 – Pilot Program for Public Health Data Availability

ASTHO welcomes the opportunity to further discuss this section with the committee in collaboration with our affiliated partners at the Council of State and Territorial Epidemiologists, Association of Public Health Laboratories, and others. There are challenges and implications related to any modifications to the underlying statute and its potential consequences to public health data and governance.

Sec. 304 – Supporting Individuals with Disabilities During Emergency Responses

ASTHO supports all policies, targeted interventions, and programs designed to enable all people to attain their highest possible level of health. Therefore, we are supportive of efforts that support individuals with disabilities during a public health emergency. For example, people with disabilities are consistently disproportionally impacted by disasters. Research shows that people with disabilities are more than twice as likely to be injured or die in a disaster. To achieve disability inclusion in emergency planning, people living with disabilities must be included in and integrated into all facets of emergency planning. Members of the disability community are subject matter experts in inclusion and key partners in planning, and therefore must be seen as equals. During the response to COVID-19, ASTHO developed a program to help close emergency preparedness inclusivity gaps for individuals who were living with a disability. As part of this work, ASTHO was able to embed specialists within 20 state and territorial public health agencies and those specialists were able to identify disability inclusion gaps and subsequent improvement plans to close those gaps.³ As special populations are fully integrated into planning and response efforts, doing so leads helps strengthen community and national resilience.

Sec. 306 – Research and Coordination of Activities Concerning the Long-Term Health Effects of SARS-CoV-2 Infection

ASTHO supports the inclusion of language requiring the secretary to coordinate activities concerning the long-term health effects of SARS-CoV-2 among federal departments and agencies. ASTHO has convened subject matter experts from the Office of the Assistant Secretary for Health, CDC, Council of State and Territorial Health Officials, and the National Association of Chronic Disease Directors to discuss public health's role in addressing Long COVID and we believe that there is a need to improve our data collection and surveillance capabilities, promote policies that support individuals with Long COVID, and prioritize Long COVID prevention.

Sec. 404 – Supporting Research and Laboratory Surge Capacity

ASTHO encourages the committee to consider SLTT public health departments as entities within the information-sharing network and dissemination of findings within this section.

Sec. 502 – Temporary Reassignment of State and Local Personnel During a Public Health Emergency

ASTHO is grateful that Congress continues to authorize SLTT public health agencies to temporarily reassign federally funded employees during a public health emergency, and ASTHO supports its reauthorization. During the COVID-19 emergency, ASTHO and its members saw improvement in the process of temporarily reassigning federally funded SLTT public health agency staff. In most SLTT public health agencies, this mechanism enabled increased continuity of operations that were vital for a response. However, a patchwork of systems and inconsistent policies still need to be addressed across the government. Administering flexibilities program-by-program requires a great deal of time and can create inconsistencies across programs administered by the same federal agency.

- ASTHO requests that Congress require HHS to work with its agencies to establish a "one-stop shop" for SLTT public health agencies to submit emergency reassignment requests. Should the federal employee's temporary reassignment need renewal, SLTT public health agencies should not need to repeat the entire process each time the public health agency renews an employee, nor for every discrete federal program.
- ASTHO requests that Congress amend the language to allow for the lead public health official(s) of the jurisdiction—the primary awardee of the federal grants involved—to be allowed to

³ <u>https://www.astho.org/communications/blog/embedded-one-year-review-disability-preparedness-specialists-project/</u>

submit the request on behalf of the jurisdiction rather than requiring every program administrator to do so with every technical monitor at the federal level.

This tool, available during a public health emergency declared by an HHS secretary as defined by 42 U.S. Code § 247d (a), allows SLTT public health agencies to move resources where needed while hiring additional staff and, if authorized, reducing administrative burden.

Sec. 503 – Vaccine Tracking and Distribution

During the build-up to the release of the COVID-19 vaccine in 2020-2021, there was little clarity on a CDC and HHS plan to raise public confidence in COVID-19 vaccine safety. We believe this communications strategy is imperative and must be tailored state-by-state to address our nation's diversity, as well as local concerns that may not apply nationwide. Furthermore, we believe that H-Core/ASPR should convene a meeting with ASTHO, the National Association of County and City Health Officials, and the Association of Immunization Managers to debrief on challenges and insights to ensure the successful implementation of a national vaccination program.⁴

ASTHO also strongly supports increased, stable, and, sustainable federal funding to support the public health infrastructure necessary for a successful vaccine delivery system, meet the increasing cost of vaccines, ensure continued vaccine research and development at the federal level, and provide sustainable safety-net coverage for children and adults without adequate health insurance coverage. We urge Congress to consider including authorization of an uninsured adult immunization program that would sustain infrastructure improvements made with emergency supplemental funding and provide states with predictable, adequate, and sustainable funding to promote the uptake of both routine vaccines and improve preparedness to address outbreaks. Building on the successful bi-partisan Vaccines for Children Program, this would support jurisdictions in purchasing and administering vaccines for the estimated 30 million uninsured adults who lack any coverage for recommended adult vaccines against diseases such as influenza, pneumococcal disease, hepatitis, and COVID-19. It should include provisions supporting the core pillars of vaccine purchase, provider payment, program operations, and safety monitoring. Including such in the reauthorization of PAHPA would be a significant step toward filling existing gaps in vaccine coverage among U.S. adults and providing sustained support for better preparedness.

Sec. 511 – Epidemiology Laboratory Capacity (ELC) Grants

The ELC program provides critical foundational support to SLTT public health departments to detect, prevent, and respond to emerging infectious diseases. ELC funding provides the much-needed flexibility to meet SLTT public health agencies' changing needs, while also allowing for the prioritization of health activities that are unique to certain areas across the country. Although most of its funding comes from CDC's National Center for Emerging and Zoonotic Infectious Diseases, it is a core program that allows state and local health departments to strengthen and maintain their epidemiology and laboratory capacity to respond to public health needs. Despite the vital role of ELC in supporting SLTT public health agencies, annual funding levels for the program are inadequate to maintain public health preparedness. Enhancing funding in the three core project areas within ELC—epidemiology, laboratory, and informatics—would provide additional flexibility for state and territorial health departments to enhance their staffing and infrastructure to be better prepared for the next pandemic.

⁴ https://www.astho.org/communications/newsroom/older-releases/leading-health-organizations-unite-implement-national-covid-19-vaccination-plan/

Public Health Impact of Drug Shortages

There has been substantial national attention on the impact of drug shortages across our country. The public health impact of drug shortages is significant and jeopardizes progress toward treating public health threats, such as syphilis and other childhood illnesses. For example, there are several treatment options available to those with tuberculosis. Rifapentine is part of a 12-week treatment regimen for latent tuberculosis when combined with weekly Isoniazid. This specific regimen is often preferred because it is shorter than the other treatment regimens and is easier for a patient with its once-weekly schedule, increasing the likelihood of adherence. However, there have been instances in which patients who were started on this regimen were required to switch to a different regimen as a result of the current shortage of Rifapentine, which not only decreases the likelihood of their adherence to their medication.

Similarly, there is a current shortage of penicillin G benzathine (Bicillin L-A), which is the only approved and acceptable treatment to treat syphilis in pregnant people. Untreated syphilis in pregnant women can cause miscarriage, stillbirth, or possibly contribute to a baby's death after their birth.⁵ Currently, the United States is experiencing a surge of syphilis, as reported cases of syphilis have increased by 74% since 2017 and congenital syphilis cases have increased by 203% in the past five years.⁶ State health agencies have been reporting shortages of Bicillin L-A for several months. In at least one state, local health departments have been advised to use Bicillin L-A to treat only those diagnosed with primary and secondary syphilis, along with those who are pregnant. There is also a shortage of critical chemotherapy medications such as Carboplatin⁷, Methotrexate⁸, and Cisplatin⁹ that has forced hospitals in some states to implement contingency and/or conservation strategies that directly impact patient care. Overall, we cannot overstate our concerns over potential outbreaks considering the lack of access to these critical medications. Simply put, this crisis is jeopardizing the health and well-being of countless Americans and impacting our ability to interrupt the spread of public health threats. We encourage the committee to explore opportunities that address drug shortages across the country.

Thank you for the opportunity to contribute to this important work and discuss the impact of drug shortages on patient care. We look forward to continuing the conversation in the future. Please contact Jeffrey Ekoma, ASTHO's senior director of government affairs, at <u>jekoma@astho.org</u> for additional information.

Sincerely,

Michael Fraser, PhD, MS, CAE, FCPP Chief Executive Officer Association of State and Territorial Health Officials

⁵ https://www.cdc.gov/nchhstp/pregnancy/effects/syphilis.html#:~:text=Syphilis%20in%20pregnant%20women%20can,the%20infection%20as%20as%20newborn

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^{7 &}lt;u>https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Carboplatin%20Injection&st=c</u>

 $^{8 \\ \}underline{https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Methotrexate%20Injection&st=contentsetementset$

^{9 &}lt;u>https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Cisplatin%20Injection&st=c</u>