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The Honorable Bernard Sanders
Chair
Committee on Health, Education, Labor
and Pensions
United States Senate

The Honorable Bill Cassidy, M.D.
Ranking Member
Committee on Health, Education, Labor
and Pensions
United States Senate

Dear Chair Sanders and Ranking Member Cassidy,

Thank you for the opportunity to respond to your Request for Information on policies for the Committee to consider during the Pandemic and All-Hazards Preparedness Act (PAHPA) reauthorization process.

The Commonwealth Fund supports independent research on health care issues and makes grants to promote better access, improved quality, and greater efficiency in health care, particularly for society's most vulnerable, including people of color, people with low income, and those who are uninsured.

Below we offer suggestions derived from the report of the Commonwealth Fund Commission on a National Public Health System. Commission staff who have contributed to these policy recommendations include Jeffrey Levi, professor of health policy and management at the George Washington University Milken Institute School of Public Health; Nicole Lurie, former HHS Assistant Secretary for Preparedness and Response; Anne Morris Reid, former HHS deputy chief of staff; and Josh Sharfstein, vice dean for public health practice and community engagement at the Johns Hopkins Bloomberg School of Public Health.

The Commission report finds that national emergency preparedness must rest on the foundation of a national public health system that is able to respond to everyday challenges. An effective system requires four elements:

1. Reducing underlying health problems that exacerbate the health impact of outbreaks;
2. Creating relationships and trust in communities and across sectors that must come together in an emergency;
3. Establishing a workforce and infrastructure that can be mobilized rapidly; and
4. Having the data needed to track and monitor day-to-day public health challenges and respond to crises.

Without these four elements already in place, the nation will always be less prepared than it could be.

Program Effectiveness

Public Health Emergency Coordination and Policy

1. The responsibilities and authorities of the Secretary of Health and Human Services (HHS) prior to or during a public health emergency (PHE)

    - **Recommendation 1**: The Act should establish an undersecretary for public health, with the authority to lead public health efforts across HHS and engage with state, local, and tribal, and territorial health agencies to develop an effective and responsive national public health system.
        - **Explanation**: Currently, HHS lacks an organizational home that is structured and resourced to lead on a wide range of public health issues in a sustainable way. This new office would be a focal point of responsibility and coordination for many disparate efforts related to public health to ensure the ASPR, in leading the response to public health emergencies, is able to work from a strong foundation in a crisis.

Medical Countermeasures (MCM) Development and Deployment

1. The Biomedical Advanced Research and Development Authority (BARDA)

    - **Recommendation 2:** The Act should provide BARDA with authority to develop countermeasures against emerging infectious diseases beyond those in the DHS material threat determination list, and to share pre-licensed relevant countermeasures with WHO and relevant countries for a research response in the event of an outbreak of a disease for which the countermeasure is being developed.
        - **Explanation:** Outbreaks are often the only time these MCMs can be tested, yet they are rare. Rapid deployment, in a research setting, of such MCMs can provide much needed evidence regarding potential efficacy, and can potentially curtail an outbreak, providing global health security and reducing potential for spread to the U.S. Obtaining evidence during outbreaks can shorten the path to product licensure.

Support for Jurisdictional Preparedness and Response Capacity

1. The Public Health Emergency Preparedness (PHEP) Cooperative Agreements

    - **Recommendation 3**: The Act should require the CDC to measure and report on the foundational capabilities of health departments receiving public health infrastructure funding and authorize CDC to tie the receipt of federal funding to progress in achieving foundational capabilities. CDC can direct key funding to these foundational capabilities through its grants, contracts, and cooperative agreements, including but not limited to PHEP.

- **Explanation**: Emergency preparedness rests on a foundation of effective day-to-day public health functioning. Where you live should not determine how well your health department protects you from public health threats. Setting minimum standards for public health across the country is essential, as environmental and infectious threats do not recognize state borders. The foundational capabilities framework has been adopted by Indiana, Ohio, Kentucky, Washington, and other states to measure improvement in core public health protections.

<u>Gaps in Current Activities & Capabilities</u>

1. What gaps do you see in the PAHPA framework, or how it has been implemented to date? (These gaps could be related to any of the programs noted above, or other aspects of the public health and medical preparedness and response ecosystem that are otherwise currently unaddressed.)
    - **Recommendation 4:** The Act should authorize and ensure stable, sustainable funding for core public health infrastructure and public health IT modernization around the country, based on best estimates of needs. As explained in the Commonwealth Fund Commission report, these are approximately $4 billion for core public health activities and $3.5 billion for IT modernization annually. If possible, these funds should be mandatory appropriations.
        - **Explanation**: Sustainable, reliable funding is essential to strengthen core public health efforts, which are essential for preparedness. However, federal funding has focused on programmatic or disease-specific functions. Moreover, public health budgeting tends to experience a "boom and bust" cycle, with surges of funding in response to emergencies followed by retrenchments. As a result, state and local public health agencies struggle to invest in long-term capacity building.
2. Additionally, aside from currently authorized programs and activities, what gaps exist in HHS' capabilities, and what types of activities or authorities are necessary for HHS to fulfill the intent of PAHPA and related laws?
    - **Recommendation 5**: The Act should provide HHS with the authority to obtain essential data during an emergency from states including data by race, and ethnicity and geography. CDC should be required to define the "essential data" for any emergency and the data standards relating to it in advance of emergencies, to enable the systems for preparing and transmitting it to be ready. However, in exceptional circumstances, CDC should be able to require additional data deemed essential. The acceptance of funds related to preparedness programs should be tied to an agreement to provide these data. When CDC uses this authority, it

should be required to make appropriate, deidentified data public and share more detailed analysis files back with states and their health care institutions.

  - **Explanation**: The absence of this authority undermined operational awareness during COVID.

- **Recommendation 6:** HHS should have the authority to require mandatory reporting of laboratory results, and their associated demographic data, to the federal government during an emergency. HHS should be required to make appropriate data public and share more detailed analysis files back with states.
  - **Explanation**: This reporting is essential for real-time understanding of a public health emergency. The ability of HHS to obtain laboratory data to forecast and manage the COVID-19 response took special provisions in the CARES Act. Waiting for Congress each time there is a crisis takes far too long and hampers the ability to respond.
- **Recommendation 7:** The Act should establish a supply chain inventory and management program at HHS. This program should permit reporting on key supplies in an emergency and provide authority to HHS for redistribution when essential for clinical care. This program should be able to operate during drug shortages of essential medications at the Secretary's direction in addition to declared emergencies.
  - **Explanation**: Public health emergencies do not affect every location the same way at the same time. As a result, demand-driven shortages–as we saw during COVID–can be addressed by redistribution of key resources. Although the enabling statute for the Strategic National Stockpile (SNS) authorizes the Secretary of HHS to "devise plans for effective and timely supply-chain management" of the SNS specifically (42 U.S.C. § 247d-6b(a)(3)(E)), additional statutory authority would be required for HHS to establish a generally applicable supply chain program.
- **Recommendation 8:** The Act should provide FDA with the authority to regulate home testing in an emergency, to support access to high quality home tests and provide a common standard for public health reporting.
  - **Explanation**: The current legal framework for home testing is insufficient to support and manage its anticipated growth. Although the FDA currently regulates medical home testing kits as medical devices, (21 C.F.R. § 800 et seq.), further statutory authorization may be needed for the FDA to impose standards with respect to novel technologies for home testing—particularly those that incorporate mechanisms for reporting public health data.

Partnerships

What specific steps could Congress take to improve partnerships with states and localities, community-based organizations, and private sector and non-government stakeholders, such as hospitals and health care providers, on preparedness and response activities? For example:

1. How can these entities be better supported in appropriately engaging with the federal government to understand available resources, capabilities, and expectations prior to, during, and following a public health emergency?

   States and localities:

   - **Recommendation 9:** In exchange for increased congressional funding for public health infrastructure, states should meet revised accreditation standards and performance requirements demonstrating that foundational capabilities protect every resident. HHS should use multiple funding mechanisms to support and incentivize states, localities, tribes, and territories to move toward, and ultimately achieve, this revised accreditation standard.

   Community-based organizations:

   - **Recommendation 10**: HHS should provide, as part of core federal public health infrastructure funds:
     - Dedicated funding to build and sustain the capacity of community-based organizations to address public health priorities, guide local data collection, and participate in decision-making. Health enterprise (or equity) zones are one model that states such as Maryland and Rhode Island have successfully implemented, and which could be scaled. In this model, community-based organizations are funded to implement a comprehensive plan to address health disparities and improve health outcomes within a defined geographic area. Ryan White HIV/AIDS Health Services Planning Councils are another model for inclusive decision-making that could be applied to public health planning and resource allocation.
     - Specific program standards or expectations that grantees work across sectors, where appropriate. For example, grant requirements related to maternal mortality can ensure that health departments or community-based organizations have structures or mechanisms in place to collaborate with health care, social services, agriculture, and transportation sectors. Another opportunity would be leveraging grant requirements to ensure that health departments or community-based organizations collaborate with mental health and substance use agencies, Medicaid and CHIP, and

education and social service sectors to promote mental health among school-aged children.

2. How can foundational programs, such as the Public Health Emergency Preparedness cooperative agreements and the Hospital Preparedness Program, be improved to ensure state, local, and health system readiness to mount effective responses?

    - See Recommendation 3 above on page 2.

Thank you again for the opportunity to submit these comments. We are happy to discuss these policy proposals in further detail at your convenience.

Sincerely,

Rachel Nuzum
Senior Vice President, Policy
The Commonwealth Fund