



**Association of
American Medical Colleges**
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February 4, 2022

The Honorable Patty Murray
Chair
Senate Committee on Health, Education, Labor,
and Pensions
United States Senate
Washington, DC 20510

The Honorable Richard Burr
Ranking Member
Senate Committee on Health, Education, Labor,
and Pensions
United States Senate
Washington, DC 20510

Dear Chairwoman Murray and Ranking Member Burr:

The Association of American Medical Colleges (AAMC) greatly appreciates your bipartisan efforts to improve the country's medical and public health preparedness and is pleased to provide feedback to the discussion draft of the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act (PREVENT Pandemics Act).

The AAMC is a not-for-profit association dedicated to transforming health through medical education, health care, medical research, and community collaborations. Its members are all 155 accredited U.S. medical schools; more than 400 teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves the leaders of America's medical schools and teaching hospitals and their more than 179,000 full-time faculty members, 92,000 medical students, 140,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

As you know, AAMC members are on the front lines of the pandemic response and have seen and experienced first-hand the challenges that patients, the public health and health care systems, communities, and the nation continue to face in combatting active COVID-19 infections, addressing long-term symptoms of the disease, and grappling with the inequities heightened by the pandemic. We appreciate your efforts to learn from these experiences and intent to implement improvements through the PREVENT Pandemics Act. We have attached our initial feedback on the discussion draft, drawing in part from [our June 2021 recommendations](#), and we welcome the opportunity to provide more detailed feedback as you move forward with the legislation.

As we have noted before, we are grateful for the HELP Committee's strong and longstanding track record of bipartisan leadership in identifying and developing strategies to enhance the nation's preparedness and response, and we appreciate your continued commitment to this approach. We look forward to continued collaborations with you, the Committee, and the full Congress toward our mutual goal of improving health for all. If you have further questions on our feedback, please contact Tannaz Rasouli, Senior Director, Public Policy and Strategic Outreach, at trasouli@aamc.org.

Sincerely,

A handwritten signature in black ink that reads "Karen Fisher".

Karen Fisher, JD
Chief Public Policy Officer

AAMC FEEDBACK ON THE PREVENT PANDEMICS ACT DISCUSSION DRAFT
Submitted to the Senate Committee on Health, Education, Labor, and Pensions
February 2022

Overarching Comments

- **Investing in Preparedness Infrastructure:** Chronic underfunding has taken its toll on the nation’s preparedness framework, and under-resourced state and local health departments have been forced to manage a growing list of threats without commensurate support. The PREVENT Pandemics Act highlights a number of new promising opportunities to bolster the nation’s preparedness framework. However, to be maximally effective, robust and sustained funding in these programs and the nation’s public health infrastructure more broadly is necessary, as we noted in our [June 2021 recommendations](#). In addition to supporting robust investment in annual appropriations for federal public health agencies, the AAMC supports the Public Health Infrastructure Saves Lives Act ([S. 674](#)), which would augment annual federal support with dedicated, reliable funding to help rebuild core public health infrastructure across the country.
- **Clinical preparedness:** In addition to the need for investments in public health infrastructure, ensuring a healthy commitment to clinical preparedness, which is complementary to but distinct from public health preparedness, is essential. We appreciate that the discussion draft acknowledges both the public health and medical and health care response in various sections, such as in the National Task Force’s comprehensive review (Sec. 101) and in reauthorizing the trauma care program (Sec. 113). We recommend supplementing these mentions with additional provisions to support clinical preparedness more directly. For example, we urge you to include resources to build flexible surge capacity or support physical hospital resilience more generally; expanding existing networks to address special pathogens and disaster response; expanding telehealth; and bolstering the health care workforce. These recommendations are further described on p. 9-14 and 26–29 of our June 2021 letter.
- **Health equity:** The AAMC appreciates the discussion draft’s provisions in Title II, Subtitle A to address social determinants of health and health equity, which is a priority for the association and our members. In addition to the dedicated provisions in the subtitle, we also encourage you to weave opportunities to address health inequities and promote a community-informed approach throughout all elements of the legislation, including provisions to address data collection, workforce support, and the public health response. The AAMC detailed additional recommendations on p. 20–23 of our June 2021 letter, and encourages your consideration of recommendations provided by the [Presidential COVID-19 Health Equity Task Force](#) in October 2021.
- **Leveraging academic medicine’s expertise:** Academic medical centers are an important bridge between the public health and clinical enterprises. To the extent that the PREVENT Pandemics Act works to convene task forces, develop data standards, and more, we urge you to include the academic medicine community as a key stakeholder. Given their missions of patient care, medical education, medical research, and community collaborations, academic medical centers offer unique and valuable expertise to augment the irreplaceable role that jurisdictional health departments and other community partners play in advancing population health. We would be pleased to provide more specific recommendations around where such expertise may be valuable in the discussion draft.

Feedback on Individual Sections

Title I

- Both the federal government and states need to have roles during a pandemic, and we encourage you to consider how the legislation can delineate these roles more clearly ahead of a pandemic. Additionally, we appreciate the approach in S. 674 both to fund and to promote greater consistency in the foundational capabilities and capacities of state and local public health departments. Not only would such efforts provide technical assistance to public health officials, it also would help minimize the variability in emergency response capabilities across jurisdictions.
- We appreciate that Title I includes a provision regarding trauma care, and we believe the discussion draft would benefit from additional provisions to promote health care preparedness. As noted in the overarching comments above, we encourage you to include a new title focused on provisions to enhance clinical preparedness, such as equipping academic medical centers to build flexible surge capacity; expanding existing networks designed to support heightened clinical preparedness capacity (such as NETEC, RDHRS, and the Hospital Preparedness Program); supporting states in developing a crisis standards of care framework; strengthening state, regional, and hospital/health system-level communication and technology to monitor bed availability and support hospital capacity management; and permanently extending the telehealth waivers related to the PHE.

Sec.101. Comprehensive review of the COVID-19 response.

- The discussion draft directs Congressional leaders to appoint members to the task force and includes political party affiliation among the criteria for participation. Given the nonpartisan nature of preparedness and response, did the Committee consider directing the Government Accountability Office (GAO) to appoint the task force, or at least a portion of the membership? We note that the discussion draft directs GAO to undertake a number of other related tasks, speaking to its ability to appoint a qualified, politically neutral task force.

Sec. 102. Appointment and authority of the Director of the Centers for Disease Control and Prevention.

- While an agency-wide strategic plan is important for establishing priorities and goals, perhaps more important is ensuring that the agency is well resourced with both the funds and the authorities it needs to implement the strategic plan. To the extent that a strategic plan is required by this legislation, the AAMC recommends highlighting the need for both coordination and collaboration with other agencies.

Sec. 113. Trauma care reauthorization.

- The AAMC appreciates that the discussion draft reauthorizes the trauma care program, which represents an effective and important network of care. Reviving a dedicated stream of funding for Level I trauma centers, which are well-suited to serve as hubs during a public health emergency, and for proximate yet separate facilities, would be ideal. While the discussion draft houses the program within the Office of the Assistant Secretary for Preparedness and Response (ASPR), we note that states will be important partners, given their role in designating the level and type of trauma centers.
- We also encourage expansion of other existing networks with a dedicated focus on preparedness, as we reference on p. 11 of our June 2021 letter.
- Additionally, any funds to ramp up capacity should support telemedicine, technology, and outreach, as well a support for building or updating stand-alone “spoke” facilities.

Title II

Sec. 201. Addressing social determinants of health and improving health outcomes.

- The AAMC appreciates that the discussion draft includes resources to support efforts addressing social determinants of health. In considering the balance of resources to support the identified uses of funding, we recommend placing greater emphasis on implementation activities, which have been under-resourced relative to the identification and development of best practices. Additionally, we note the importance of sustaining funding support for such efforts over the long term to be maximally impactful.
- Similar to this section, the AAMC has endorsed the Social Determinants Accelerator Act (SDAA, S. 3039, H.R. 2503), which would authorize an interagency technical advisory panel on social determinants of health (SDOH) and create planning grants for state, local, and tribal governments to establish accelerator programs that address SDOH.

Sec. 211. Modernizing biosurveillance capabilities and infectious disease data collection.

- The AAMC supports the goals of this section and agrees that the coordination of public health activities triggered by specific laboratory test results is necessary and requires integration and standardization of reporting systems.
- We appreciate that the discussion draft proposes that HHS convene public meetings to discuss, among other topics, strategies to improve information exchange between health departments and health providers. However, we note that representatives from the clinical enterprise are not specified among participants in such meetings in the underlying statute or in the discussion draft. We encourage including representatives from academic medical centers and other providers among participating experts.

Sec. 212. Genomic sequencing, analytics, and public health surveillance of pathogens.

- The AAMC has endorsed the bipartisan Tracking Pathogens Act ([S. 3534](#)) and appreciates the commitment to enhanced genomic surveillance capabilities. Additional detail on the important role that academic medical centers play in these surveillance activities is included on p. 7-8 of our June 2021 letter.

Sec. 213. Supporting public health data availability and access.

- The AAMC is pleased the discussion draft highlights in subsection (d), opportunities to improve data linkages among federal and state health agencies and “health care providers and facilities” and “public health and clinical laboratories.” We encourage the Committee to explicitly include “academic medical centers” among the stakeholders informing the “content, form, and manner” of such information sharing and to consider convening stakeholders ahead of an emergency to determine the “minimum necessary information” that is most feasible. Additionally, as we describe on p. 25 of our June 2021 letter, academic research labs may also be able to contribute data to public health efforts in an emergency, under certain circumstances.
- We greatly appreciate the inclusion of academic medical centers in the list of eligible recipients for the proposed grant program in subsection (e) to improve public health data collection. We encourage the utilization of trustworthiness principles and patient engagement in developing strategies for providers to reach data collection goals that promote equity.
- To the extent that the committee is able, we encourage your consideration of a broader adoption of data standards to other relevant health agencies and partners beyond the CDC and state and local health departments.

Sec.214. Epidemic forecasting and outbreak analytics.

- The AAMC supports continuing epidemic forecasting and outbreak analytics efforts. We appreciate the discussion draft specifically highlights collaborative partnerships with academic institutions, though there is no mention of clinical entities. To that end, adding specifically “academic medical centers” would reinforce the importance of these partnerships in providing both an academic and clinical perspective to inform this work.

Sec. 221. Improving recruitment and retention of the frontline public health workforce.

- The AAMC supports the provision to reauthorize the Public Health Workforce Loan Repayment Program and appreciates the addition of language noting the importance of recruitment and retention. We encourage your consideration of opportunities to promote leadership opportunities for qualified public health experts and more competitive salaries for these professionals to allow public health settings to recruit and retain a strong and diverse workforce more readily.
- We encourage your consideration of other important opportunities to strengthen and diversify the health care, public health, allied health, and scientific workforces as described in our June 2021 letter on p. 26-29. For example, surges as a result of the Omicron wave have heightened shortages of nurses, medical assistants, and other key personnel, and imposing increased financial pressures on facilities. Offering grants to support wage assistance during surges would help offset some of these unique expenses during a public health emergency.
- We additionally encourage the inclusion of [S. 3244 / H.R. 5602](#), the BIO Preparedness Workforce Act of 2021, which the AAMC has endorsed. This bill would establish a loan repayment program for health professionals involved in biopreparedness and response activities or who are members of the infectious disease workforce in underserved communities.

Sec. 222. Awards to support community health workers and community health.

- The AAMC supports this section and encourages inclusion of specific funding authorization levels to facilitate implementation of this program.

Sec. 231. Centers for public health preparedness and response.

- The AAMC appreciates the effort to improve the public health response through the support of cross-disciplinary relationships to establish centers for public health preparedness and response, which closely resembles the grant program we proposed on p. 7 of our June 2021 letter. In light of the coordinating function of the proposed centers, including coordination of health care facilities, the AAMC urges the committee to include “academic medical centers” in the list of eligible entities. Given the broad scope of academic medical centers – including patient care entities and schools of medicine, public health, nursing, and other health professions – they would be particularly well-suited to carry out this program’s objectives.

Title III

Sec. 302. Research centers for pathogens of pandemic concern.

- The AAMC supports the establishment of research centers for pathogens of pandemic concern and notes that academic medical centers are exceptionally well qualified to lead these efforts, as detailed on p. 11-12 of our June 2021 recommendation letter.
- The AAMC requests that the committee authorize funding to support the establishment and activities of the research centers proposed in this provision.

Sec. 304. Accessing specimen samples and diagnostic tests.

- The AAMC supports additional transparency in how HHS makes pathogen samples available and also in the development of related guidance.

- In subsection (b), the AAMC agrees that allowing federal contracts to increase the speed of test validation, manufacture, and dissemination of diagnostic tests makes sense. Increasing the speed of test development through these contracts could also be useful, but it is important to ensure — and clearly communicate to the public — that the expedited timeline does not undermine the validation or authorization processes for these tests. Increased investments in the development of testing technology could be an alternative solution.
- In addition to specifying State, local, and Tribal health departments for dissemination of diagnostic tests, we urge the committee to include clinical settings such as academic medical centers.

Title IV

- The AAMC appreciates the provisions in this title that would enhance manufacturing surge capacity and capabilities. A key lesson from the current pandemic is the need to promote greater geographic diversity of domestic and global vendors and to explore opportunities to increase domestic supply production.
- We also appreciate the discussion draft's attention to the Strategic National Stockpile (SNS), including evaluating the supply chain that supports it and the working condition and availability of its assets.

Sec. 404. Improving transparency and predictability of processes of the Strategic National Stockpile.

- The AAMC supports the proposal to issue guidance on how states, territories, and Tribes can access the SNS and appreciates the effort to improve transparency and predictability of the access to supplies. The AAMC encourages the committee to explicitly list representatives from the clinical enterprise, including the academic medicine community, as key participants in the annual meetings that would be required.

Title V

Sec. 502. Modernizing clinical trials.

- The AAMC supports the development of the FDA guidance documents on expanding the recruitment for, and conduct of, novel clinical trials.
- We appreciate the legislation's specificity about the elements that must be in the guidance and appreciate that the bill does not direct the FDA what the guidance should say about each. That will be an iterative process in the various affected communities once the required draft guidance is released.
- The AAMC is pleased to see an appropriate focus on privacy, security, informed consent, and data evaluation for the development of guidance for digital health technologies.
- The AAMC is generally supportive of the process of decentralized trials, provided that there are appropriate safeguards for research subjects and IRB oversight.
- Streamlined and continuous or concurrent clinical trial designs have promise but also potential increased risks to research subjects without seamless coordination of adverse event reporting and relay of data throughout the related trials. This may be adequately covered in the content description in (D), but the Committee may also want to consider stating explicitly that the guidance must include recommendations on how to ensure that considerations related to subject risk and safety are promulgated throughout the set of related trials.

Sec. 505. Facilitating the use of real world evidence.

- The AAMC supports this provision and looks forward to engaging with the FDA on these guidance documents.

Sec. 508. Improving FDA guidance and communication.

- The AAMC supports this provision.

Other Considerations

The AAMC appreciates that additional provisions may be included as the Committee proceeds through the markup process for the PREVENT Pandemics Act and understands that a provision to authorize President Joe Biden's proposed Advanced Research Projects Agency for Health (ARPA-H) is under consideration. The AAMC has prepared principles on establishment of the new entity (attached) and is happy to provide additional feedback on these principles as the committee continues its negotiations.



Association of American Medical Colleges: Principles for the Establishment of ARPA-H January 2022

Medical research supported by the National Institutes of Health (NIH) continues to lay the scientific groundwork for nearly every major medical intervention in practice today — including transplants, immunotherapies for cancer, COVID-19 vaccines and therapeutics, and countless other diagnostics, medications, vaccines, and other countermeasures. More than half of this research is conducted at medical schools and teaching hospitals, which also provide the world’s most advanced and expert patient care informed by the latest innovations in fundamental and clinical research to patients nationwide. Accordingly, academic medical centers not only play a fundamental role in creating the breakthroughs of the future, they also are actively putting those innovations into practice. Their seat at this nexus of research and care delivery provides a unique perspective both on the urgency with which patients and their providers seek new and more effective treatments, as well as the challenges and opportunities to accelerate our progress.

As lawmakers consider pending legislation to establish the president’s proposed Advanced Research Projects Agency for Health (ARPA-H), the AAMC recommends the following general principles for consideration alongside legislative proposals to promote the success both of the new entity and of the existing medical research enterprise.

- **Funding for ARPA-H should supplement and not supplant investments in the NIH base budget. Additionally, providing greater stability in funding, such as through an advanced appropriation for ARPA-H, would allow greater flexibility and strategic planning in decision-making.**
- **While there are advantages to housing ARPA-H either within or outside of the NIH, the AAMC recommends that ARPA-H be established within the NIH.** Situating the new entity as part of the NIH would facilitate necessary collaboration and allow it to leverage existing infrastructure and begin its substantive work almost immediately, rather than being forced to spend its early days establishing this logistical framework. To the extent that lawmakers would like to facilitate an approach at ARPA-H that differs from NIH’s existing culture, the AAMC suggests that geographically locating the primary headquarters away from the main NIH campus in Bethesda, Md., could help achieve this objective, in addition to the unique authorities and objectives assigned to the new entity.
- **To facilitate ARPA-H’s success and promote an appropriate level of oversight, legislation should require ARPA-H to establish an advisory board that would have the authority to review portfolios at 6- or 12-month intervals and to evaluate progress on the selected projects.** This board should be comprised of representatives from federal agencies, as well as, importantly, external stakeholders from academia, scientific societies, industry, and patient advocates. While the ARPA-H director should consult with other federal agencies to avoid duplication of efforts, it will be equally, if not more, essential for external stakeholders to inform and be engaged in the new entity’s efforts.

- **Legislation to authorize ARPA-H should emphasize the importance of recruiting and retaining a diverse workforce.** This includes diversity across multiple dimensions including race, ethnicity, and gender as well as career stage and geographic location.

- **Legislation to authorize ARPA-H should not be overly prescriptive, to allow the initiative some flexibility to adjust and respond to lessons in real-time as projects are funded and get underway.**
 - Many biomedical research projects require a much longer time commitment to reach meaningful milestones relative to work on engineering projects and defense work. Rigid project timelines and personnel term limits that are grounded in the experience of the physical sciences will be counterproductive. The dynamic nature of biomedical science suggests that there should be some level of elasticity built into the goals.
 - The AAMC supports permitting ARPA-H to grant bonuses for successful projects and suggests granting ARPA-H the flexibility to determine the appropriate award amount.

- **While ARPA-H is intended to support research to bridge the “valley of death,” the commercialization potential of a given research proposal should not be a statutory requirement for funding decisions.** Barriers beyond the auspices of NIH and ARPA-H, such as liability concerns and the challenge of meeting meaningful clinical endpoints, are likely to affect the ability of the new entity to deliver a tangible “product” to patients on an accelerated timeline, but should not prevent support for promising research questions. High-risk, high-reward research should be emphasized, and additional flexibility should be offered for interdisciplinary or multi-sector initiatives.