American Hospital Association™
Advancing Health in America

**Washington, D.C. Office**
800 10th Street, N.W.
Two CityCenter, Suite 400
Washington, DC 20001-4956
(202) 638-1100

July 10, 2023

The Honorable Bernie Sanders
Chairman
Committee on Health, Education, Labor and Pensions
U.S. Senate
Washington, DC 20510

The Honorable Bill Cassidy, M.D
Ranking Member
Committee on Health, Education, Labor and Pensions
U.S. Senate
Washington, DC 20510

The Honorable Robert P. Casey, Jr.
Committee on Health, Education, Labor and Pensions
U.S. Senate
Washington, DC 20510

The Honorable Mitt Romney
Committee on Health, Education, Labor and Pensions
U.S. Senate
Washington, DC 20510

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

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners — including more than 270,000 affiliated physicians, 2 million nurses and other caregivers — and the 43,000 health care leaders who belong to our professional membership groups, thank you for the opportunity to comment on the discussion draft for the reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA). We appreciate your efforts to improve our nation's preparedness and response capabilities and capacities, as well as to ensure that the nation's preparedness programs are properly funded, sustained and improved.

The AHA previously provided the Health, Education, Labor and Pensions (HELP) Committee with PAHPA reauthorization recommendations to create a more effective and stable health care system, which are listed below and further detailed in our March 29 letter.

Specifically, we urged Congress to:

- Improve the federal organizational structure for all types of emergencies, including making critical updates to the Department of Health and Human Services' (HHS) emergency preparedness playbook;

- Strengthen the national medical supply chain by increasing manufacturing redundancy, diversifying raw material and manufacturing production locations, and building capacity within the overall supply chain;
- Ensure availability of a wide variety of essential goods for medical care and provide sufficient support for the Strategic National Stockpile (SNS);
- Provide additional authorities to the Food and Drug Administration (FDA) to mitigate and prevent drug and device shortages, such as by expanding the agency's authority to establish medical device manufacturer notifications requirements and quality and resilience incentives;
- Modernize the data infrastructure in collaboration with a wide range of stakeholders, including hospitals and health systems;
- Reauthorize PAHPA's Hospital Preparedness Program (HPP) at a significantly increased level, including additional dedicated, direct-to-hospital funding and allow hospitals, health systems and hospital associations to compete to be the HPP recipient for their jurisdictions;
- Strengthen health care cybersecurity by requiring HHS and the Department of Homeland Security to dedicate human, technical and financial resources to assist hospitals and health systems to prepare, respond and recover from high impact cyberattacks such as ransomware attacks; and
- Strengthen the National Advisory Committee on Children and Disasters (NACCD) by expanding its membership and scope of authority to address additional important issues.

In addition, the AHA would like to provide the following comments related to the HELP Committee's July 3 discussion draft.

## STRENGTHEN THE HOSPITAL PREPAREDNESS PROGRAM

The discussion draft includes level funding of $385 million for the HPP, the only federal funding mechanism for health care system emergency preparedness and response.

**The HPP should be authorized at a significantly increased level. As such, we urge that the program's authorization be at least doubled for fiscal years (FY) 2024 through 2029. This investment would help prepare and equip our nationwide health care system in advance of the growing number and scope of future disasters and public health emergencies (PHEs).**

Since 2002, the HPP has provided critical funding and other resources to aid the health care system response to a wide range of emergencies via cooperative agreements with 62 health departments in all states, U.S. territories and in four cities. These investments contributed to saving lives and reducing the impact of emergencies and disasters,

particularly for localized events. However, the HPP's funding has not kept pace with the ever-changing and growing threats faced by hospitals, health care systems and communities. Authorized funding levels and annual appropriations for the HPP have significantly declined since the program began, from a high of $520 million in FY 2003, to $385 million in the most recent reauthorization in FY 2018. Additional and sustained funding will be necessary to not only restore HPP to its original capacity, but also to strengthen the program to address increasing threats to public health.

We also suggest certain changes to the program:

- Include in the HPP additional dedicated, direct-to-hospital-funding that will supplement (and not supplant) current investments. Such dedicated funding will help rebuild the program after years of underfunding and provide additional resources to hospitals and health systems to improve their preparedness;
- Hospitals and hospital associations, such as academic medical centers, health systems and state and metro hospital associations, also should be permitted to compete to serve as the HPP recipient for their jurisdiction, in addition to the current state, territorial and city health department recipients; and
- Allow HPP funding to cross state lines in order to strengthen health care emergency preparedness and response planning across multi-state regions.

**MITIGATE AND PREVENT DRUG AND DEVICE SHORTAGES**

The discussion draft does not include any enhanced or new authorities for the Food and Drug Administration (FDA) to mitigate and prevent drug and medical device shortages.

America's hospitals and health systems have long been critically concerned about shortages of a wide range of drugs and medical devices to treat patients. According to the American Society of Health-System Pharmacists, the U.S. health care system currently is experiencing the most drug shortages since 2014. Shortages of local anesthetics and basic hospital drugs, albuterol solution, common oral and ophthalmic products and attention-deficit/hyperactivity disorder treatments are affecting large numbers of hospitals and health systems and the patients they serve. Chemotherapy drugs, often without alternatives, are increasingly in short supply and have returned to the list of top-five drug classes affected by shortage.[1] Of particular concern to hospitals are the cascading impact of drug shortages on patients and the heightened stress on scarce hospital resources. Shortages can adversely affect patient care by causing delays in treatment, increasing the risk of medication errors and requiring the use of

[1] https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics

less effective alternative treatments. As a result, diseases, such as childhood leukemia, that are curable or manageable for most patients, may not be able to be treated effectively.

**Therefore, the AHA continues to strongly recommend that Congress:**

**Expand Medical Device Manufacturer Notifications.** The Coronavirus Aid, Relief, and Economic Security Act (CARES Act), provided the FDA with the authority, *during or in advance of a declared PHE*, to require device companies to notify the HHS Secretary of a permanent discontinuance in the manufacture of certain devices or an interruption in the manufacture of certain devices that is likely to lead to a meaningful disruption in supply of the device. While the new authority has been helpful, the tie to PHEs limits the FDA's ability to respond to any early signs of supply constraints or a potential shortage situation. Interruptions in supply and shortages can occur unpredictably outside of a PHE and have serious implications for public health and patient and health care personnel safety. The AHA urges Congress to amend the current device shortage notification requirements to apply more generally and not only during a PHE.

**Incentivize Quality and Resilience to Prevent Drug and Device Shortages.** While we appreciate the efforts of the Administration to help alleviate shortages, more needs to be done. As such, the AHA recommends that Congress:

- Require the FDA to develop ratings of the quality management processes of drugs and device manufacturers which are predictive of supply chain and manufacturing vulnerabilities and make these quality ratings publicly available;
- Require drug manufacturers to disclose to the FDA the locations where their products are manufactured, including contract manufacturer locations, as well as the locations from which they source key starting materials (KSM), active pharmaceutical ingredients (API) and excipients used in their finished products, in order illuminate the extent of vulnerability for a product and to allow the development of targeted supply strengthening measures;
- Require drug manufacturers to notify the FDA of unusual spikes in demand of essential drugs in order to allow the agency to take steps to mitigate or prevent any impacts on availability and prevent potential shortages; and
- Require the FDA to identify those essential drugs and devices, including their KSM, API and excipients and component parts, that should have increased domestic manufacturing capacity in order to improve the resilience of the U.S. drug and device supply chain and make recommendations to incentivize their production.

## IMPROVING FEDERAL PLANNING AND COORDINATION

The AHA appreciates the changes proposed in Sec. 201 of the discussion draft related to All-Hazards Emergency Preparedness and Response. In particular, we support the added

consideration of the needs for API, KSM and other critical components within the National Security Priority and the requirement that such considerations be included in periodic consultations on medical and public health preparedness and response activities between the Assistant Secretary of Preparedness and Response (ASPR) and White House. These changes should help shed light on medical supply chain vulnerabilities and pave the way for the development of targeted measures to strengthen the supply.

In addition, we were pleased to see the inclusion of "relevant industry, academia, professional societies, and other stakeholders" in the requirements for national-level and state-level full-scale exercises, particularly exercises involving the distribution of countermeasures. However, we recommend that this language be revised to include "hospital associations" among those stakeholders involved in planning for national and state exercises. This will help avoid the confusion that arose during the COVID-19 pandemic when federally purchased and state distributed countermeasures and other supplies were distributed to hospitals without proper information included and sometimes without any notice. These situations might have been avoided had hospitals and health systems been included in the planning and exercises conducted around the distribution of countermeasures.

The AHA appreciates certain changes made to the SNS in Sec. 202 of the discussion draft. We support the addition of language requiring that the SNS "utilize tools to enable the timely and accurate tracking, including the location and geographic distribution, of the contents of the stockpile throughout the deployment of such contents." As discussed above, we believe that this would help address concerns hospitals had during the pandemic regarding the lack of coordination in the deployment of the SNS contents, including information about what hospitals would be receiving, and when and where it would arrive.

We thank you for the opportunity to submit comments on the PAHPA reauthorization discussion draft and look forward to continuing to work with you on this important legislation. Please contact me if you have questions or feel free to have a member of your team contact Megan Cundari, AHA's senior director for federal relations, at mcundari@aha.org.

Sincerely,

/s/

Stacey Hughes
Executive Vice President