



May 8, 2018

The Honorable Lamar Alexander United States Senate 455 Dirksen Senate Office Building Washington, DC 20510 The Honorable Patty Murray United States Senate 155 Russell Senate Office Building Washington, DC 20510

Dear Senators Alexander and Murray:

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, the American Hospital Association (AHA) appreciates the opportunity to comment on the Senate Health, Education, Labor and Pensions (HELP) Committee's discussion draft, titled the "Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018."

We commend the HELP Committee on their outreach and willingness to engage stakeholders as the work toward reauthorizing the Pandemic and All-Hazards Preparedness Act (PAHPA) proceeds. Our member hospitals and health systems play a critical role in all types of disaster and public health emergencies, and we share the Committee's goal of improving our nation's preparedness and response capabilities and capacities. In light of our shared goals, the AHA offers the following recommendations regarding the PAHPA reauthorization discussion draft.

SEC. 202: AMENDMENTS TO PREPAREDNESS AND RESPONSE PROGRAMS

The Hospital Preparedness Program Should Be Authorized at Sufficient Levels. When a disaster strikes, people turn to hospitals for help. Congress recognized that role in PAHPA by creating the Hospital Preparedness Program (HPP), the primary federal funding mechanism for health care system emergency preparedness. Since 2002, the HPP has provided critical funding and other resources to aid hospitals' response to a wide range of emergencies.

The HPP has supported greatly enhanced planning and response; facilitated the integration of public and private-sector emergency planning to increase the preparedness, response and surge capacity of hospitals; and improved state and local infrastructures that help health systems and hospitals prepare for public health emergencies. These investments have contributed to saving lives during many events, from the H1N1 influenza pandemic and the



Boston Marathon bombing to the 2017 hurricanes in Texas, Florida and Puerto Rico, mass shootings in Las Vegas and wildfires in California.

However, funding for the HPP has not kept pace with the ever-changing and growing threats faced by hospitals, health care systems and their communities. Indeed, authorized funding levels and annual appropriations for the HPP have significantly declined since the program began. In particular, HPP's highest level of appropriation was \$515 million, yet the program has eroded to only \$255 million, a vastly insufficient level given the task of preparing the health care system for a surge of patients, continuity of operations, and recovery.

The AHA believes the HPP should be authorized at a sufficient level. As such, we urge the Committee to increase the HPP's authorization level to \$515 million for fiscal years (FY) 2019 through 2023, doubling its current level of appropriated funding and representing an increase over its currently authorized level of \$374.7 million. This investment will help prepare and equip our health care system nationwide in advance of future disasters and public health emergencies. Furthermore, increasing the authorized funding level for HPP also would recognize that, as included in the Committee's discussion draft, at the current time, HPP is the only mechanism that is explicitly incentivized to fund the creation of the "regional public health emergency preparedness and response system" (per the new preferences language added at Sec. 319C-2(d)(1(A)(ii)).

Change to Sec. 319C-2(j)(1):

(j) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—For purposes of carrying out this section, there is authorized to be appropriated *\$515,000,000* for each of fiscal years 2019 through 2023.

Preparedness Programs Should Remain Distinct. The HPP and the Public Health Emergency Preparedness Program (PHEP) should continue to be aligned and coordinated but should be maintained as separate, distinct programs. The two programs serve a different but complementary purpose. PHEP, administered by the Centers for Disease Control and Prevention (CDC), builds the capacity of state and local health departments to prevent, detect and respond to emergencies. HPP, administered by the Office of the Assistant Secretary for Preparedness and Response (ASPR), prepares the health care delivery system to provide essential care to patients by ensuring surge capacity and continuity of care during disasters. Both programs are needed to save lives and protect the public from emergency-related illnesses and injuries and each should remain under the jurisdiction of the agency that currently oversee its administration.

We note that in the discussion draft, the Committee has solidified the CDC's relationship to PHEP by explicitly amending Sec. 319C-1 to state that PHEP "is acting through the director of the Centers for Disease Control and Prevention." We urge the Committee to insert parallel language for the HPP. That is, that HPP is "acting through ASPR" so as to ensure that HPP remains a distinct program under ASPR authority. This is particularly

important given the close linkage between the HPP and the new regional system envisioned by the ASPR.

Change to Sec. 319C-2(a):

(a) IN GENERAL.—The Secretary, acting thorough the Assistant Secretary for Preparedness and Response, shall award competitive grants or cooperative agreements to eligible entities to enable such entities to improve surge capacity and enhance community and hospital preparedness for public health emergencies, including, as appropriate, capacity and preparedness to address the needs of children and other at-risk individuals.

Broadening the Definition of Eligible Awardees under the HPP. The AHA supports introducing competition into determining HPP's awardees in order to permit ASPR to fund innovation and improve the nation's health security. In addition to state and directlyfunded city public health departments, we recommend that state, regional and metropolitan hospital associations, academic medical centers and health systems be permitted to compete to be the awardee for their jurisdiction. This will allow HPP to fund those entities that present the most innovative approaches to health care delivery system readiness. A second benefit of introducing competition is the potential to address the misalignment between HPP's health care mission and its current awardees' public health mission. While most of the HPP's public health department awardees work well with their private-sector health care delivery system counterparts to enhance preparedness and response, others struggle to work collaboratively with the private health care system that they also regulate. Through this proposal, private health care entities or hospital associations that have the organizational capacity and initiative to lead sector-wide preparedness and response activities would also be able to compete for HPP funds for their state or jurisdiction, not just health departments.

Changes to Sec. 319C-2(b)(2)

- (b) ELIGIBILITY.- To be eligible for an award under subsection (a), an entity shall-...
 - (2) be an entity to improve surge capacity and enhance health care delivery system preparedness for emergencies and disasters—
 - (A) described in section 319C-1(b)(1)(A), an academic medical center, a state, regional or metropolitan hospital association or a health care system in such State; or
 - (B) described in section 319(b)(1)(B), an academic medical center, a state, regional or metropolitan hospital association, or a health care system in such political subdivision.
 - (C) submit an application at such time, in such manner, and containing such information as the Secretary may require, including the information or assurances required under section 319C-1(b)(2) and an assurance that the State will adhere to any applicable guidelines established by the Secretary.

In addition, the following conforming changes need to be made:

Change to Sec. 319C-2(i)(1) [with discussion draft amendments included]

(i) PERFORMANCE AND ACCOUNTABILITY.—

(1) IN GENERAL.—The requirements of section 319C-1(g), (i), (j), and (k) shall apply to entities receiving awards under this section (regardless of whether such entities are described under subsection (b)(1)(A), (b)(2)(A) or (b)(2)(B)) in the same manner as such requirements apply to entities under section 319C-1.

Change to Sec. 319C-2(j)(3)

(3) AWARDS FOR COMPETITIVE GRANTS OR COOPERATIVE AGREEMENTS.

(A) IN GENERAL.-From amounts appropriated for a fiscal year under paragraph (1) and not reserved under paragraph (2), the Secretary shall make awards to entities described *in subsection* (b)(2)(A) *and* (b)(2)(B) that have completed an application as described in subsection (b)(2)(C).

Ensuring Adequate Allocation of HPP Funds to Support Health Care Preparedness. According to data collected by ASPR, state and local public health department awardees have taken an average of 21 percent of the HPP award off the top for direct costs (i.e., personnel, fringe and travel) in addition to their indirect costs, for overseeing award and subcontracts. Some awardees have taken far more than 21 percent of the HPP award for their direct costs. Further, ASPR has reported that high-performing awardees tend to have lower awardee-level direct cost (ALDC). With the substantial reductions in HPP appropriations in recent years, the AHA has been very concerned that this level of skimming of limited program funds for ALDC leaves inadequate amounts for use by regional health care coalitions and health care providers to meet the critical capabilities of the HPP program. We support the efforts that ASPR's team has undertaken during the current project period to ensure the appropriate use of HPP funds. In particular, for the current HPP project period, we are pleased that ASPR has been working to improve the efficiency of the program and better supporting its partners in health care by limiting ALDC to no more than 18 percent of the HPP cooperative agreement award, which will gradually decrease to 15 percent by the last HPP budget period. The AHA supports permanently capping the ALDC to 15 percent of the HPP award moving forward.

Therefore, we were pleased to see that, in the new evaluation section, under Sec. 319C-1(k)(C), there is helpful language that requires an evaluation of the amount of HPP allocations that are received by eligible entities as well as the amounts received by sub-recipients and the effects of such allocations on meeting performance measures, evidence-based benchmarks and objective standards. The AHA urges the Committee to further define "sub-recipients" to include regional health care coalitions (HCCs). Most of the remaining HPP funds that are not taken in indirect and direct overhead by state and local health department is allocated

to these HCCs. By specifically identifying HCCs in this section, the evaluation required by this section would more directly demonstrate the impact of reduced allocations to HCCs due to the overhead amount kept by the current awardees, the state and local health departments.

Change to Sec. 319C-1(k)(C)

(k) Evaluation.—

(2) CONTENTS.—The evaluation under this paragraph shall include—
(C) a description of allocations with respect to amounts received by eligible entities under subsection (b) and section 319C–2(b) and amounts received by sub-recipients, *including regional health care coalitions*, and the effect of such allocations on meeting performance measures and evidence-based benchmarks and objective standards; and

HPP Funding Preference for the Progress in Establishing the Regional Public Health Emergency Preparedness and Response Systems. The Committee proposes to add language under 319C-2(d)(1)(A)(ii) directing HPP funds to be preferentially awarded to eligible entities that enhance coordination within the regional public health emergency preparedness and response systems added under 319C-3.

The AHA supports the notion of preferentially funding awardees that are able to demonstrate that they have taken such steps, potentially as "seed money" to help encourage health care providers to join such regional systems. However it is critical to note that HPP funds alone is inadequate to create the capabilities and capacities needed for such a rigorous system. This is particularly the case since virtually none of the HPP funds are granted directly to hospitals. Rather, the vast majority of HPP funds not kept by the current state and local health department awardees for their indirect and direct overhead are distributed to regional HCCs.

SEC. 203. REGIONAL PUBLIC HEALTH EMERGENCY PREPAREDNESS AND RESPONSE SYSTEMS

The AHA supports the development of voluntary regional disaster health care systems to improve preparedness and response, including improved medical surge capacity and capabilities, for patients affected by catastrophic chemical, biological, radiological or nuclear (CBRN) threats, including emerging infectious diseases. However, in order for such systems to function properly and to be sustainable they would require adequate and reliable funding that goes beyond the amounts currently available to federal preparedness programs. We look forward to working with ASPR and the Committee to further explore mechanisms that could be used to incentivize the advancement of this system, such as preferred reimbursement rates from public and private payers or other incentives.

In addition, given the novelty of the system envisioned by ASPR, we believe that there should be an evaluation of regulatory authorities and limitations that may be relevant, such as the current requirements for the Emergency Medical Treatment and Labor Act (EMTALA), the

privacy and security requirements included in the Health Insurance Portability and Privacy Act (HIPAA) and other regulations. We look forward to working with the Committee and ASPR on this as well.

The AHA offers the following comments on Sec. 203 regarding the development of guidelines for regional systems.

The Title of Section 319C-3 Should Reflect the Health Care Mission of the Regional Systems. We are concerned that the proposed title of Sec. 319C-3, "Guidelines for Regional Public Health Emergency Preparedness and Response Systems," is problematic as it references "public health" instead of health care. The regional system, as envisioned and discussed by ASPR and as described in the Committee's discussion draft, is not public health driven but rather a regional *health care* system. We are concerned that, if "public health" remains in the title, there will be confusion about which HHS agency has primary responsibility for developing the system.

The AHA recommends that the title of Sec. 319C-3 be revised to remove "public health" and to include "health care." While we do not have a strong preference to the exact title, one possibility is "Guidelines for Regional Health Care Emergency Preparedness and Response Systems." Conforming changes would need to be made to incorporate this change in other sections of the discussion draft where the regional system is named.

<u>Timeline for the Development of Regional Systems</u>. We are concerned that the timeline set out in this section for implementing the regional systems is too short. That is, in the first year ASPR, working with stakeholders, would identify and develop a set of guidelines and make them available online. In the second year, the Government Accountability Office (GAO) would report on the implementation of the guidelines developed in the first year. And, in the third year, the GAO would issue recommendations to reduce gaps in incentives for health care facilities and hospitals to adopt the guidelines and become part of the regional systems.

We believe that the adoption of the guidelines by hospitals and health systems is unlikely to occur immediately after they are posted, even if there is preferential treatment for doing so under the HPP. There should be additional time factored in to allow for establishing and enacting a set of financial and other incentives for hospitals and healthcare systems to participate in the regional systems. This may require further changes in law, regulations or guidance, which will be time-consuming. Simply posting guidelines on a website, as stated in (b)(2) is helpful, but additional resources will be needed to implement the guidelines. In addition, as noted, the proposed timeline is too short for real sustainable change to be made.

<u>Clarifying the Intent of the Guidelines</u>. The new section 319C-3 (b)(1)(A) through (b)(1)(F), which describes the intent of the guidelines, is unclear in several respects. For instance:

• The role of HPP-funded HCCs in the regional systems is conspicuously absent from the factors that must be incorporated into the guidelines. We urge you to clarify how HCCs will integrate into the newly developed regional systems. It would be duplicative and

undermining of HCC's roles in community preparedness and response if this system is established alongside existing HCCs without consideration and leveraging of their assets.

- In (b)(1), the parenthetical "(which may include, as applicable and appropriate, existing practices such as trauma care and medical surge capacity and capabilities)" seems misplaced. Perhaps it should be inserted after "practices and protocols" in the same sentence?
- In (b)(1), it is unclear what "applicable health care facilities and hospitals" means. This should be clarified.
- Subparagraph (b)(1)(A) is unclear. It inexplicably references the capabilities of entities described in clauses (i) and (ii) of section 319C–2(b)(1)(A). This section of the Public Health Service Act refers to the health care provider component of the "partnerships" that, combined with a state or a political subdivision, can be an eligible awardee under the HPP. However, this authority in the act has been used only once. We are not certain what is intended by this subparagraph.
- In (b)(1)(C), the phrase "taking into account resiliency and geographic considerations" is unclear in context of this bullet. This should be clarified.
- In (b)(1)(E), the parenthetical "(including patients in rural areas)" seems to be misplaced. This would be clearer if it was reworded to be "Coordinated medical triage and transportation *of patients* to the appropriate hospitals or health care facilities within the regional system (*including patients in rural areas*) based on patient medical need or, as applicable and appropriate, between systems in different States or regions."

<u>Incorporating the Health Care Supply Chain into the Regional Systems</u>. The inclusion of the health care supply chain into the development of regional systems is critical as the supply chain is responsible for providing life-saving products to communities during public health emergencies. We recommend making the following changes be made.

Change to Section 319C-3(b)(1)(B)

(B) a regional approach to identifying hospitals and health care facilities based on varying capabilities and capacity to treat patients affected by such emergency, which may include informing and educating appropriate first responders to a public health emergency of the regional emergency preparedness and response capabilities and medical surge capacity of such hospitals and health care facilities in the community, as well as educating first responders and health care supply chain partners to ensure necessary products can be redirected to facilities that treat patients impacted by public health emergencies;

Further, we recommend that the health care supply chain and EMS providers be added to the list of those entities with whom ASPR must consult in section (c)(1).

<u>Considerations Section Should be Strengthened</u>. Section (c) Considerations should be strengthened to adequately emphasize the need for robust and sustainable financial and other incentives for health care providers to ensure their voluntary implementation of the guidelines.

We suggest the following changes:

- (2) consider feedback related to financial implications for health care facilities and hospitals to implement *and sustain adherence to* such guidelines, as applicable; and
- (3) consider adequate financial requirements and potential sustainable incentives (including the need to establish authorities that do not currently exist which may need to be proposed as regulation or enacted into law, as well as a plan to do so) for facilities to prepare for and respond to public health emergencies as part of a regional health care emergency preparedness and response system.

GAO Report. The GAO report described in (e) should be amended as follows:

(e) GAO Report to Congress.—

- (1) REPORT.—Not later than 2 years after the date of enactment of this section, the Comptroller General shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Finance of the Senate, and the Committee on Energy and Commerce and the Committee on Ways and Means of the House of Representatives, a report on the extent to which health care facilities, hospitals *and other health care providers* have implemented the recommended guidelines under subsection (b), including an analysis and evaluation of any challenges health care facilities, hospitals *and other health care providers* experienced in implementing such guidelines.
- (2) IMPLEMENTATION OF GUIDELINES.—The Comptroller General shall include in the report under paragraph (1), data on the preparedness and response capabilities that have been informed by the guidelines under subsection (b) to improve *community health care capability, including* health care facilities and hospital capacity and medical surge capabilities to prepare for, and respond to, public health emergencies.
- "(3) RECOMMENDATIONS.—Not later than 3 years after the date of enactment of this section, the Comptroller General shall submit to the Committees referred to in paragraph (1), recommendations to reduce gaps in incentives for *community health care partners*, *including* health care facilities and hospitals, to improve capacity and medical surge capabilities to prepare for, and respond to, public health emergencies, consistent with subsection (a). Such recommendations may take into account facilities participating in programs under section 319C–2, programs under the jurisdiction of the Centers for Medicare & Medicaid Services (including innovative health care delivery and payment models), and input from private sector financial institutions.

SEC.204: PUBLIC HEALTH SITUATIONAL AWARENESS AND BIOSURVEILLANCE CAPABILITIES

With regard to Section (c) Modernizing Public Health Situational Awareness and Biosurveillance, the AHA supports collaboration between the public health communications and surveillance network and other health information networks. We recommend the data identified for biosurveillance and situational awareness and standards selected for pilot testing and implementation expressly support the priorities of the public health communications and surveillance network.

SEC. 205: STRENGTHENING AND SUPPORTING THE PUBLIC HEALTH EMERGENCY [BRIDGE] FUND

In general, the AHA believes that a pre-approved standing fund of emergency resources would speed the public health response to disasters. We support the following principles for an immediate response fund for public health emergencies. Such a fund should:

- supplement and not supplant existing, base public health and preparedness funds;
- not preclude supplemental emergency funding based on the scope, magnitude and duration of the emergency at hand; and
- come with a mechanism to automatically replenish its funds.

Further, the fund should be used in the short-term for acute emergencies that require a rapid response to saves lives and protect the public. The HHS Secretary should administer the fund, with congressional oversight, to ensure relevant agencies receive dollars when needed for response.

The AHA appreciates the language included in Sec. 205 to strengthen existing authorities around the public health emergency fund (PHEF) and to expand its approved uses. We support the bracketed language that would be added at Sec. 319(b)(A) "to allow the Secretary to immediately respond to such public health emergency or potential public health emergency."

Further, as indicated in the bracketed term "bridge" fund in the title to this section of the discussion draft, we agree that the PHEF fund should serve as a bridge between underlying preparedness funds and supplemental emergency funds. In order to clarify this intention for the fund, the AHA asks that additional language be added.

Change to Sec. 319(c) [with discussion draft amendments included]

(c) SUPPLEMENT NOT SUPPLANT.—Funds appropriated under this section Act shall be used as a bridge between preparedness and supplemental emergency appropriations and shall be used to supplement and not supplant other Federal, State, and local public funds provided for activities under this section, nor should they supplant emergency supplemental appropriations as needed.

Further, we believe that the PHEF is intended to be an immediate response fund, and should not be used as a source for funding for long-term, ongoing health threats. Therefore, we urge the Committee to add language to the "In General" paragraph (at Sec. 319(b)(1)) or to a separate "Purposes" section to clarify that the intent of the PHEF is that it be used in the short-term for the acute, immediate response to emerging public health emergencies that require a rapid response to save lives and protect the public.

Finally, we are concerned that the PHEF will remain only a theoretical concept without any new funds available. We urge the Committee to create a mechanism to fund and replenish the PHEF and to work with Appropriations Committees to ensure PHEF receives new funding as necessary.

SEC. 206: IMPROVING PREPAREDNESS FOR AND RESPONSETO ALL-HAZARDS BY PUBLIC HEALTH EMERGENCY VOLUNTEERS

The AHA supports the Committee's proposals to improve the ability of health professional volunteers to respond to public health emergencies regardless of state licensure requirements.

However, there is a need to address an important factor that limits the willingness and ability of health professionals to volunteer is medical liability concerns. The AHA supports the Good Samaritan Health Professional Act (H.R. 1876/S. 781), which would extend liability standards under the Volunteer Protection Act of 1997 to licensed health professionals who volunteer in another state during a disaster. While current state and federal laws provide some level of liability protections for licensed health care professionals administering health care services in response to a declared federal disaster, this legislation fills the gap in current law by extending liability protections to health care professionals crossing state lines to ensure people receive needed health care during such an emergency. We encourage the Committee to incorporate H.R. 1876/S. 781 into this discussion draft as its provisions are a positive step toward removing an impediment for physicians and other clinicians who would like to volunteer in another state during a disaster.

SEC 302: HEALTH SYSTEM INFRASTRUCTURE TO IMPROVE PREPAREDNESS AND RESPONSE

Given the importance of the supply chain in public health emergencies and national disasters, we recommend that the Committee's new Sec. 2811(b)(5) Coordination of Preparedness be amended as follows:

Such logistical support shall include working with other relevant Federal, State, local, tribal, and territorial public health officials and private sector partners to identify the critical infrastructure entities capable of assisting with, responding to, or mitigating the effect of a public health emergency under section 319, the Robert T. Stafford Disaster Relief and Emergency Assistance Act, or the National Emergencies Act, [including by establishing methods to exchange critical information *related to access, fuel availability, and federal agency coordination and to prioritize the storage, replenishment, transportation, and distribution of essential goods [meaning goods]*

consumed or used to preserve, protect or sustain life, health or safety] including health care products and deliver goods].

SEC. 304. IMPROVING EMERGENCY PREPAREDNESS AND RESPONSE CONSIDERATIONS FOR CHILDREN

The following edit should be made to Sec. 304, under "Expertise."

(2) EXPERTISE.—The team described in paragraph (1) shall be comprised of one or more pediatricians, including a developmental-behavior pediatrician *and a pediatric trauma expert*, and may also include behavioral scientists, child psychologists, epidemiologists, biostatisticians, health communications staff, and individuals with other areas of expertise, as the Secretary determines appropriate.

SEC. 305. REAUTHORIZING THE NATIONAL ADVISORY COMMITTEE ON CHILDREN AND DISASTERS

Section 2811A of the Act, as amended by the Committee's discussion draft, should include additional representatives on the National Advisory Committee on Children and Disasters representing emergency medical services providers and the Department of Transportation.

SECTION 403: STRATEGIC NATIONAL STOCKPILE

We are concerned that in public health emergencies, additions, modifications and replenishments of the strategic national stockpile (SNS) can inadvertently create a negative impact on health care facilities access to certain critical supplies and countermeasures. This was an issue that arose during the Ebola outbreaks, when CDC's procurement of additional specialized personal protective equipment compromised hospitals' access to these products.

Therefore, we recommend that the discussion draft amendments at Sec. 319F-2(a)(2))B)(ii), be further amended as follows:

(ii) planning considerations for appropriate manufacturing capacity and capability to meet the goals of such additions or modifications, *including whether such additions* or modifications would negatively impact the availability of these products to the nation's health care system.

CAVEAT ABOUT VOLUME OF REPORTING REQUIREMENTS

While we fully support the notion that federally funded preparedness and response programs must be accountable to Congress and the public for decisions regarding funding, program implementation and performance, we note that the discussion draft includes an inordinate number of reports and reporting requirements, some of which are GAO reports and others of which are direct reporting requirements for CDC, ASPR and other federal agencies. We urge the Committee to carefully consider the volume, scope and significance of mandated reporting to ensure that these federal agency obligations do not unnecessarily divert resource and attention away from their primary missions and areas of responsibility.

We thank you for the opportunity to submit comments on the PAHPA reauthorization discussion draft and look forward to continuing to working with you on this important legislation.

Sincerely,

/s/

Thomas P. Nickels Executive Vice President