American Hospital Association™
Advancing Health in America

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May 20, 2020

The Honorable Peter Gaynor
Administrator
Federal Emergency Management Agency
500 C St SW
Washington, DC 20472

RE: Meeting to Develop Pandemic Response; Voluntary Agreement (Docket ID FEMA–2020–0016)

Dear Administrator Gaynor:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, 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 provide input to the Federal Emergency Management Agency's (FEMA) upcoming meeting regarding the use of the Defense Production Act's (DPA) voluntary agreement clause (Section 708) to respond to the COVID-19 pandemic.

The AHA is encouraged by FEMA's willingness to use its authority under the DPA to establish a voluntary agreement of key private sector stakeholders relevant to responding to COVID-19. The unprecedented scope, scale and duration of the COVID-19 pandemic requires a "whole of nation" response that aligns and coordinates the efforts of the public and private sectors. The voluntary agreement authority under Section 708 of the DPA allows for coordination of efforts and information sharing among private sector entities during circumstances that threaten national defense and/or preparedness when such activities otherwise may not be permissible. A voluntary agreement may enhance knowledge of available capacity and minimize duplication of efforts, thereby maximizing the private sector's ability to meet the nation's critical COVID-19 needs.

We are pleased that FEMA intends to involve a broad range of private sector stakeholders in a voluntary agreement, including manufacturers, suppliers and distributors of personal protective equipment (PPE), pharmaceuticals, and other critical health and medical resources. We also agree with FEMA's intent to establish a five-year agreement period. The dynamic nature of the COVID-19 pandemic, as well as the

uncertainty about when effective therapeutics and vaccines for this novel disease will be broadly available, means that the nation may need to sustain a response over an extended timeframe. A multi-year agreement would be essential to enabling the private sector to flex resources up or down to meet the needs of the moment.

As FEMA moves toward implementing a voluntary agreement, we urge that such an agreement account for the full breadth of COVID-19 medical supply and equipment needs. In contrast to prior infectious disease outbreaks, COVID-19 has placed a strain on an extraordinarily wide range of medical supplies, equipment and medications. For the health care system to sustain its response, it will need the private sector's support in addressing the full range of these needs, and not just narrow segments like PPE. The table below includes a partial listing of the kinds of supplies and equipment that are relevant to COVID-19 treatment and response.

Partial List of Supplies, Equipment and Medicines Key to COVID-19 Treatment and Response

Personal Protective Equipment (PPE) • Isolation gowns • Surgical gowns • Gloves (non-sterile and sterile) • Surgical masks • Respirator masks (i.e., N95, in multiple sizes/types) • Alternate respirators (e.g., elastomerics, PAPRs, CAPRs) • Face shields and goggles • Head and foot coverings **Cleaning / Disinfection Supplies** • Hand soap • Alcohol-based hand sanitizer • Disinfectant wipes • UV-light disinfecting machines • Peroxide mist machines **Medications and Therapeutics** • Intubation meds (including paralytics, sedatives) • Vasopressors • IV electrolytes • Anticoagulants • Antivirals, e.g. Remdesivir (as available) • Vaccine and associated syringes, vials (as available)	**Medical Devices / Equipment** • Mechanical ventilators (and associated breathing circuits and filters) • CPAP and BiPAP machines • Intubation equipment (including associated laryngoscopes, suction equipment) • Pulse oximeters • Nasal cannulas (especially high flow type) • IV tubing and pumps • Central lines • Sterile probe covers • Dialysis equipment • Cardiac monitors (stationary and portable) • Remote monitoring equipment **Laboratory Testing Equipment** • Nasal swabs • Reagents • Viral media • Test tubes • Testing booths to separate patient and tester • Lab sample analyzers **Surge Capacity** • Mobile isolation units • Tents

To be clear, the list is not comprehensive, and we expect that some supplies and equipment may have a higher priority at a given time than others. However, the list may help the agency think holistically about the COVID-19-related needs of the field, and the types of suppliers a voluntary agreement should include. Moreover, the COVID-19 pandemic has greatly affected how non-COVID patients receive care. FEMA may need

to consider including additional supplies or services that support these changes in health care delivery, such as devices to help patients connect to care virtually.

In addition, we strongly urge FEMA to consult closely with the hospital and health system field, and with clinical experts in COVID-19 treatment to help define the initial focus of the voluntary agreement, and to inform its priorities over time. At a minimum, we encourage FEMA to include hospital leaders and COVID-19 clinical experts as representatives on the proposed "Committee for the Distribution of Medical Resources Necessary to Respond to a Pandemic." The nature of the pandemic, the health care system's capacity and our scientific and clinical knowledge about treating the disease will continue to evolve. Hospital and health system leaders can provide "on the ground" perspective on resource needs, and how to deploy them most effectively in the field. Clinical experts – including (but not limited) to those from infectious diseases, emergency medicine and critical care – can help FEMA capitalize on advances in clinical knowledge.

We also encourage FEMA to make the work of the voluntary agreement and advisory committee as transparent as possible, including, as appropriate, opportunities for public comment. The agency should share its plans for how essential products stemming from the agreement are distributed, including any factors, formulas or other mechanisms.

Lastly, to maximize the potential for a voluntary agreement, we urge FEMA to define and execute a data strategy to support it. We believe the agency will need accurate, consistently defined, and regularly tracked data that, at a minimum, captures supply availability (both in hospitals and among distributors), supply use (or "burn") rates, and geographic areas that may have higher needs. FEMA may need to draw upon multiple sources (e.g., manufacturers, states, hospitals and health systems, other federal agencies, etc.). However, we believe the agency should provide common data definitions that cut across all data sources, a single entry point or portal for all of the data to be reported into, and a consistent way for aggregating and sharing across stakeholders and with the public. The less confusion there is about what data are reported and how, the more likely it is FEMA and voluntary agreement participants will get useful data to inform their planning and decision-making.

We appreciate your leadership, and the ongoing work of the Administration to respond to this unprecedented pandemic. We look forward to continuing to work with you to offer suggestions on ensuring the voluntary agreements meet the needs of the response. Thank you for the opportunity to share our views.

Sincerely,

/s/

Ashley B. Thompson
Senior Vice President
Public Policy Analysis and Development