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President and CEO

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Via electronic submission at <https://www.regulations.gov>

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

Re: CMS-3415-IFC: Omnibus COVID-19 Health Care Staff Vaccination

Dear Administrator Brooks-LaSure:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States. The FAH members provide patients and communities with access to high-quality, affordable care in both urban and rural areas across 46 states, plus Washington, DC and Puerto Rico. Our members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, children's, and cancer services.

We appreciate the opportunity to provide the Centers for Medicare & Medicaid Services (CMS) with our views in response to the *Omnibus COVID-19 Health Care Staff Vaccination* interim final rule with comment period, 86 Fed. Reg. 61,555 (Nov. 5, 2021) (IFC). Our comments are based on our members' experience in serving patients and their communities during the COVID-19 public health emergency (PHE). The ongoing PHE places a significant strain on hospitals and health care systems, which must quickly assess and respond to surges and emerging variants in their geographic areas and be able to direct their resources, which are

already in short supply due to the PHE, toward patient care for all patients. Thus, flexibility and appropriate use of enforcement discretion are key elements for implementing the requirements of the IFC.

Support for Flexibility in the IFC

The FAH appreciates CMS' understanding that large scale vaccination efforts take time in the normal course of business, and even more so during a pandemic. While vaccinating staff to meet the requirements of the IFC is essential, it is also critical that hospitals have the ability to manage the ongoing effects of the pandemic's strain on the workforce and to nimbly respond to an ever-changing environment, including responding to COVID-19 surges and variants. The FAH commends the IFC's provision of flexibility in multiple areas, including flexibility in tracking and documentation requirements, contingency planning, and implementation deadlines.

Tracking and Documentation Requirements

Under the IFC, "Providers and suppliers have the flexibility to use the appropriate tracking tools of their choice" in order to track and securely document vaccinations and exemptions.¹ The FAH strongly supports CMS' attention to flexibility in what constitutes sufficient proof for staff vaccinations as well as the tracking process. This allows hospitals to use familiar processes already in place and/or processes suited to hospitals' individual circumstances and helps reduce administrative burden in complying with the IFC. Moreover, because states have varying standards for hospitals to demonstrate that their health care workers are vaccinated, an additional federal standard would be unduly burdensome.

Contingency Planning

The FAH also supports the IFC's flexible provision regarding hospital contingency plans.² The FAH appreciates that the IFC allows hospitals to create a plan related to unvaccinated and exempt staff without expressly delineated requirements. Accordingly, a hospital can develop a plan aligned with its existing policies and procedures, as well as the unique situation and needs of a particular hospital, its staff and patients. Similarly, CMS takes into account that existing Emergency Preparedness policies and procedures may not need to be revised and acknowledges that staff with unknown vaccination status may be utilized in emergencies.³ This provides hospitals reassurance that if an emergency arises, hospitals can focus on patient care as opposed to checking vaccination status of each staff member supporting the hospital and its patients during the emergency.

¹ See 86 Fed. Reg. at 61,572.

² 86 Fed. Reg. at 61,619; see also 86 Fed. Reg. at 61,573.

³ 86 Fed. Reg. at 61,573.

Timing Requirements

Further, the FAH supports the IFC provisions that permit staff who have completed a primary vaccination series by the end of phase 2 to be in compliance with the IFC, even if those staff members have not yet completed the 14-day waiting period required for full vaccination. This type of flexibility provides hospitals the ability to stagger vaccinations since some staff may experience short-term side effects of the vaccine and, as a direct result of the vaccination, may miss the following days of work. Therefore, this appropriately balances achieving compliance with staff vaccinations while allowing hospitals to avoid significant disruptions in staffing availability.

Enforcement Discretion With Progressive Enforcement Approach

We urge CMS to apply flexibility in its enforcement discretion regarding the IFC requirements, in light of multiple considerations, including staffing shortages and considerations related to vaccine supply. Such enforcement discretion is particularly critical given CMS' recent announcement that it will proceed with implementing the vaccine mandate for health care workers in the 25 states, District of Columbia, and territories not affected by the federal court injunctions. FAH members operate hospitals across many states and therefore will need to comply with varying sets of requirements related to the vaccine mandate, i.e., for states where the mandate is in effect versus those where it is not, along with state requirements. As part of exercising enforcement discretion, we also urge that CMS utilize a progressive enforcement approach that allows hospitals adequate notice of any non-compliance issues with multiple opportunities to come into compliance.

Staffing Shortages

Our members are experiencing staffing shortages that existed prior to the PHE and have become significantly more pronounced and problematic due to the strain and ongoing nature of the PHE. Against this environment, in response to a vaccine mandate, some staff are choosing to leave their current positions rather than receive a vaccine, and all of these factors exacerbate staffing shortages with which hospitals were already grappling.⁴ For example, our members are experiencing shortages of medical technicians, laboratory assistants, and nurses, as well as food service, housekeeping, and sanitation staff, and in some instances, hospitals do not have enough staff to operate at full capacity. This is also resulting in increased costs to the health care system to operate, as some health care staffing companies are charging exorbitantly higher rates during the PHE, including for vaccine-required positions.

The FAH acknowledges CMS' statement in the IFC preamble that, "there is insufficient evidence to quantify and compare adverse impacts on patient and resident care associated with temporary staffing losses due to mandates and absences due to quarantine for known COVID-19 exposures and illnesses."⁵ However, the FAH urges CMS to monitor these staffing shortages

⁴ 86 Fed. Reg. at 61,607 ("currently there are endemic staff shortages for almost all categories of employees at almost all kinds of health care providers and suppliers and these may be made worse if any substantial number of unvaccinated employees leave health care employment altogether").

⁵ See 86 Fed Reg. at 61,569.

and related considerations and provide appropriate remedies or enforcement discretion in light of the shortages.

In the meantime, our members are engaging in outreach efforts to maximize the vaccination status of their staff. These efforts take time to implement and achieve results. Providing enforcement discretion in light of good faith efforts to comply with the mandate will allow hospitals to continue to educate staff on vaccinations, which in turn, may increase overall vaccination rates and assist hospitals in coming into compliance with the IFC.

Vaccine Supply Considerations

Should limitations in the vaccine supply develop, additional flexibility may be appropriate. The FAH urges CMS to remain attuned to vaccine supply and distribution and adjust enforcement and/or related requirements, when appropriate.

Testing

We also urge CMS to monitor the testing supply chain, especially if testing becomes a significant part of large employers' approach to ensuring safety for its workforce (with or without the OSHA mandate). If so, shortages of test kits, along with delays in processing and receiving test results could affect hospitals' ability to diagnose and treat patients. Our members report that hospitals' ability to test actual symptomatic patients is already being impacted by testing shortages. For example, some states require increased testing in areas of high transmission of COVID-19, e.g., require testing twice a week, with a rapid test prior to the beginning of each shift for health care workers. These requirements, while important to contain the spread of COVID-19, have a material impact on, and limit, the testing supply chain.

Request for Remedial Action for State Enforcement

Lastly, we urge CMS to take remedial action in support of hospitals meeting the requirements of the IFC if any state were to move forward with an enforcement action against a hospital that complies with requirements of the IFC that may conflict with state law.

The FAH appreciates CMS' continued leadership and dedication toward ending the COVID-19 PHE and your consideration of our comments. We look forward to continued collaboration with CMS to implement effective policies that assist the hospital industry in meeting the challenges of the PHE. If you have any questions, please contact me at 202-624-1534, or any member of my staff at 202-624-1500.

Sincerely,

