Federation of American Hospitals®

Charles N. Kahn III
President and CEO

October 1, 2021

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

The Honorable James Frederick
Acting Assistant Secretary of Labor
Occupational Safety and Health Administration
200 Constitution Ave NW
Washington, DC 20210

Re: Federal COVID-19 Vaccine Mandate

Dear Administrator Brooks-LaSure and Acting Assistant Secretary Frederick:

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. FAH members provide patients and communities with access to high-quality, affordable care in both urban and rural areas across 46 states, plus Washington, D.C 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 understand that the Centers for Medicare & Medicaid Services (CMS) and the Occupational Safety & Health Administration (OSHA) are developing policy regarding implementation of the recent federally mandated COVID-19 vaccine requirement. As such, we wanted to provide you with key recommendations and considerations, as discussed below, based on our hospital and health system member experience in serving patients and their communities during the COVID-19 public health emergency (PHE).

Hospitals' and health systems' primary responsibility is to treat patients while at the same time ensuring the safety of their employees. This requires ensuring there are sufficient health care workers (HCWs) available to serve patients and the community, as well as sufficient non-HCW employees to support hospital and health system operations. To achieve this goal, there are a number of factors that we urge you to consider to ensure that hospitals have the resources, including availability of sufficient staffing, to continue to treat their patients, while also ensuring that the regulations do not present obstacles for hospitals in serving their patients.

As an overall matter, the FAH urges CMS and OSHA to minimize operational burdens and promote efficiency by exempting those hospitals that are already subject to state or locally ordered COVID-19 vaccine mandates from the corresponding federal requirement. Our members' hospitals and health systems operate nationally, and many are already subject to state and local vaccination requirements for HCWs. Such an exemption would avoid an unnecessary patchwork of competing vaccination requirements, definitions, and compliance burdens that risk hindering operations and patient care. In addition, the FAH offers the following critical recommendations for facilitating hospitals' and health systems' compliance efforts with the mandate.

IMPLEMENTING THE FEDERAL VACCINE MANDATE: KEY RECOMMENDATIONS

Time/Flexibility

Implementing the mandate successfully will require providing hospitals with a reasonable timeframe within which to operationalize the implementing regulations consistent with hospital workflow, and **we urge CMS and OSHA to allow hospitals at least 90 days to achieve compliance once the vaccine mandate requirement becomes effective.**

Impact of Vaccine Mandate on Testing Capacity

As our members ramp up efforts to vaccinate and periodically test their unvaccinated HCWs and other employees, this will significantly increase the number of COVID-19 test kits that will need to be available, especially as other covered employers begin regular testing of non-vaccinated employees. In addition to a shortage of test kits, this influx of new testing likely will result in delays in processing and receiving test results, and these dynamics will be intensified in geographic areas across the country that currently have limited access to testing facilities and/or experience longer waits for testing results.

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 HCWs. These requirements, while important to contain the spread of COVID-19, have a material impact on, and limit, the testing supply chain. If this trend continues, symptomatic patients will be considered Patient Under Investigation (PUI) positive until tests and results are available. This will increase use of personal protective equipment (PPE) and hospital staffing ratios – two other areas where shortages currently exist.

CMS and OSHA implementing regulations should be developed in a manner that averts a national shortage of COVID-19 test kits and prolonged wait times for test results. For example, the regulations should:

- **Allow flexibility in the frequency of testing of non-vaccinated employees;**
- **Allow staggered testing of non-vaccinated employees;**
- **Provide an exemption or a pause from testing for asymptomatic HCWs (who have an approved religious or medical exemption) when certain criteria are met (e.g., HCWs wear safe and appropriate PPE, including a fitted respirator), particularly when testing shortages arise; and**
- **Direct federal resources toward increased test kit and lab processing availability, including establishing and funding state testing facilities.**

Further, the FAH urges that diagnostic testing be prioritized over surveillance testing in order to minimize the risk that patients who actually are symptomatic for COVID-19 experience testing and result delays due to testing of asymptomatic, non-vaccinated employees, who must test weekly as part of the federal strategy. Regulations should ensure that symptomatic patients are prioritized so that these individuals can rapidly know their test results and take appropriate action so as not to spread the disease further.

Sufficiency/Availability of Health Care Workers

The success of the vaccine mandate will be amplified if the regulations allow compliance time and flexibility to address HCW shortages, including nursing and other staff shortages. The regulations should anticipate that a number of caregivers may choose to leave their employment rather than receive a vaccine. This will exacerbate the existing HCW shortages that hospitals currently face. For example, our members are experiencing shortages of medical technicians and laboratory assistants, and in some instances, hospitals do not have enough staff to be able to operate at full capacity. In addition, they also are experiencing nursing shortages, which certainly will increase the already substantial cost of travel nurses.

Further, the regulations should recognize and provide hospitals with the flexibility to address the fact that some HCWs will experience short-term side effects of the vaccine and may miss a day or two of work while waiting for these effects to subside. **Staggering implementation of the vaccine mandate could help avoid significant loss of staff at the same time.**

Minimum and Flexible Reporting Requirements

While hospitals understand the need to ensure reporting compliance with the vaccine mandate regulatory requirements, many hospitals continue to be at or beyond maximum capacity due to the current surge of COVID-19 patients as the country experiences another phase of the multiple surges that have occurred since the beginning of the PHE in 2020. Also, as discussed above, hospitals are experiencing shortages in HCWs and other employees, many of whom would be responsible for documentation efforts. In this environment, hospital workers' time and

resources should be focused as much as possible on helping patients fight for their lives and sustaining hospital operations.

Therefore, we urge that the implementing regulations minimize any reporting requirements related to the vaccine mandate. Some states require hospitals to report to the state twice monthly regarding the total number of vaccinated individuals, exemptions granted, and other related factors. This is unduly burdensome.

Hospitals should be able to attest that they are implementing the mandate. In this case, hospitals would internally document, monitor, and ensure that staff are vaccinated, rather than being required to affirmatively report to federal agencies.

Definitions

We also urge that the implementing regulations reasonably define the scope of the vaccine mandate.

Fully vaccinated

"Fully vaccinated" should be defined as when an individual completes the full course of the vaccine dosing (whether two shots or one), rather than the full course of the vaccine dosing plus 14 days. Some states, define "fully vaccinated" as the moment the full course of the dosing occurs, which provides flexibility to meet deadlines and ensure availability of HCWs.

Further, the implementing regulations should address which international COVID-19 vaccines for foreign HCWs are permissible even though they may be vaccinated with a non-US/FDA approved vaccine. In addition, the regulations should address booster shots and how they factor into the definition of "fully vaccinated," with flexible timelines for compliance to assure availability of HCWs. These timelines should recognize that:

- Booster shots can have greater short-term side effects and thus HCWs may need extra time for the side effects to subside; and
- Some HCWs may need a booster shot while others are getting their initial vaccine dosing, which will affect availability of HCWs.

Finally, the regulations should allow flexibility for HCWs who have had COVID-19 within the previous 90 days, as early data indicates that these individuals often have greater immunity than vaccinated individuals. This is particularly important for those treated with monoclonal antibodies, as they often are medically advised not to be immunized for at least 90 days due to residual effects of the treatment.

Health Care Worker

Further, flexibility also should apply in defining an HCW, which should exclude individuals who are:

- Not directly employed by the hospital, but verifiably employed by another entity subject to the vaccine mandate;
- Employed by the hospital, but work remotely; and
- Only transiently on the hospital campus, such as contractors and vendors.

COVID-19 Approved Tests

The determination of what constitutes an approved COVID-19 test should be flexible and should include all tests with a high level of reliability, including molecular tests, as well as rapid antigen tests.

Proof of Vaccination

Hospitals should be permitted to attest that their employees have provided proof of vaccination and should have flexibility in determining how their HCWs and employees demonstrate proof of their vaccination. States have varying standards for hospitals to demonstrate that their HCWs are vaccinated and a specific federal standard on top of the state standards would be unduly burdensome.

Further, hospitals and employers should not be put in a position to confirm the authenticity of proof of vaccination – which may vary depending on the state or, in the case of foreign workers, the country in which the individual was vaccinated – and should not be liable if and when an individual defrauds a hospital or other employer with a fake proof of vaccination.

Exemptions from Vaccination

Existing law and standards for required medical and religious exemptions from the vaccine mandate should continue. However, there is little guidance for hospitals and employers to determine whether the standard for an exemption – particularly an exemption for religious reasons – is met, and states have varying standards as well. **Thus, we urge development of federal criteria with clear and actionable standards on whether an exemption can be approved.** These standards should be minimally burdensome on hospitals and employers, who should not be put in the position of assessing employees' religious beliefs.

With respect to HCWs who remain unvaccinated due to an approved health or religious exemption, hospitals should have flexibility to determine whether these HCWs should be required to be tested on a regular basis and/or wear a certain type of mask while at the hospital.

Consistency of Federal Regulatory Requirements

We are concerned about the complexity of varying requirements applicable to hospital employees and **urge CMS and OSHA to coordinate to ensure that the agencies' respective regulations are consistent with each other and do not overlay conflicting requirements on hospitals.**

Some hospital employees who are not HCWs may be covered by OSHA requirements while certain hospital clinical staff would be covered under CMS' conditions of participation (COPs), or both. Consistency among these appliable regulations will be critical for ensuring seamless compliance.

Cost of Testing

The federal vaccine mandate will require a great amount of testing – whether for HCWs who receive an approved exemption or employees of businesses who opt not to receive a vaccine. Testing may not be covered (or fully covered) by an individual's insurance, and even if insurance covers the cost of testing, this places a significant cost on businesses, especially those that are self-insured, and individuals, including the cost of increased premiums due to the mandate. **Due to these substantial costs, we urge that the costs of testing due to the vaccine mandate be covered by the federal government.**

Enforcement

The FAH urges CMS and OSHA to provide hospitals with as much flexibility as possible in the implementing regulations regarding enforcement. Hospitals currently are experiencing unprecedented times and need to be able to direct all of their resources, which already are limited due to the length and ongoing surge of the COVID-19 PHE, toward patient care.

In addition, we urge a progressive enforcement approach that allows hospitals adequate notice of any non-compliance issues with multiple opportunities to develop an action plan to come into compliance, as well as enforcement flexibility if limitations in the vaccine supply develop.

****

The FAH commends CMS and OSHA for your leadership and dedication toward ending the COVID-19 PHE and appreciates your consideration of these comments. If you have any questions, please contact me at 202-624-1534, or any member of my staff at 202-624-1500.

Sincerely,