American Hospital Association™
Advancing Health in America

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September 27, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd
Baltimore, MD 21244

RE: Forthcoming Interim Final Rule Implementing a Mandatory COVID-19 Vaccination Policy for Hospitals and Other Health Care Providers Participating in Medicare and Medicaid

Dear Administrator Brooks-LaSure:

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) writes to offer our recommendations on how the Centers for Medicare & Medicaid Services (CMS) should implement its mandatory COVID-19 vaccination policy.

On Sept. 9, CMS announced it would issue an interim final rule (IFR) in October 2021 requiring COVID-19 vaccinations for workers in most health care settings receiving Medicare or Medicaid reimbursement, likely by using Medicare/Medicaid Conditions of Participation (CoPs). CMS has indicated that a wide range of health care personnel would be subject to the policy, including clinical staff, volunteers, staff not directly involved in patient care and individuals providing services under arrangements.

The AHA strongly supports the stated goal of CMS' mandatory vaccination policy – that is, to ensure all health care workers are vaccinated for COVID-19 as safely and expeditiously as possible. The AHA has repeatedly urged the vaccination of all health care workers, and has supported hospitals and health systems that choose to mandate vaccination. In fact, as of the date of this letter, 2,549 hospitals and health systems have publicly announced their own mandatory vaccination policies.

However, these mandate decisions were informed by hospitals' evaluation of the local circumstances in their own facilities and communities. Many hospitals believed it was the right time to implement a vaccine mandate, but others have continued to work diligently with their unvaccinated colleagues to convince them to take the vaccine

voluntarily. In implementing a national regulatory mandate for health care facilities to vaccinate their personnel, CMS should ensure its policy is feasible, transparent and fair for all health care providers that are subject to it.

In addition, it is vital that CMS issue the IFR and associated interpretive guidance as expeditiously as possible to help create stability for the health care field. While knowing CMS' general intention to implement a mandatory vaccination policy is helpful, the agency's announcement also has introduced some uncertainty and confusion. Those hospitals that do not yet have mandatory vaccination policies are eager to know how CMS will assess and enforce compliance so that they can plan accordingly. Furthermore, those hospitals that already have mandatory vaccination policies want to know to what extent their existing policies may need modification. A few states and municipalities also have implemented or are in the process of implementing vaccination mandates for health care workers. Hospitals in these areas are concerned about ensuring their policies align with all regulatory requirements. Lastly, some unvaccinated health care workers have indicated to our members that they are unwilling to start the process of obtaining the vaccines until there is an official CMS policy in place. At a time when hospitals remained strained by ongoing surges in COVID-19 hospitalizations, issuing the IFR and interpretive guidance quickly will help minimize disruptions to the field, and provide hospitals with the clarity and stability they need to implement the policy.

The AHA urges CMS to ensure its mandatory vaccination policy includes appropriate safeguards to preserve access to care in all communities. We believe CMS can achieve a balance between high vaccination rates and access to care by:

- **Ensuring a level playing field across health care** by applying mandatory vaccination policies to all Medicare-regulated health care providers;
- Providing an **adequate amount of time** for hospitals to come into compliance;
- Using a **progressive enforcement approach** that gives hospitals adequate notice if they are not in compliance, as well as multiple opportunities to come into compliance; and
- Providing **enforcement flexibility in the event of vaccine supply shortages.**

In addition, the AHA urges CMS to provide clear, specific information about how hospitals can demonstrate their compliance and how CMS will conduct enforcement by:

- Issuing **interpretive guidance** concurrently; and
- Allowing **exceptions from the mandate for medical reasons and sincerely held religious beliefs,** and providing guidance for all providers on how to apply these exceptions consistently.

Lastly, the AHA urges CMS to minimize the potential for misalignment and duplication with existing federal vaccine-related policies by:

- Using the reporting of the recently adopted CMS **health care personnel vaccination quality measure** to measure hospital compliance; and
- **Coordinating with other federal agencies** such as the Occupational Safety and Health Administration (OSHA), the Equal Employment Opportunity Commission (EEOC), and others to ensure hospitals are subject to only one consistent mandatory vaccination policy.

Below we provide additional details on each of these recommendations.

PRESERVING ACCESS TO CARE

Ensuring a Level Playing Field Across Health Care. **The AHA urges CMS to apply its mandatory vaccination policy to all Medicare-regulated health care providers.** CMS' initial public announcement made it clear that the requirement would apply to hospitals, ambulatory surgery centers, end-stage renal disease providers and post-acute care settings like home health agencies and nursing homes. However, it is vital that CMS fosters a consistent vaccination expectation across all types of health care providers. CMS should ensure its mandate applies to other types of entities that may receive Medicare or Medicaid reimbursement, such as federally-qualified health centers (FQHCs), community health centers (CHC) and non-hospital based physician practices.

We recognize that not all of these entities have CoPs or conditions of coverage like hospitals so the precise regulatory mechanism to implement a vaccination mandate could vary. Nevertheless, making the mandate as broad based as possible would ensure that health care providers do not compete for a limited labor pool based on whether particular types of entities are required to have vaccination mandates. A consistent approach applicable to as many health care providers as possible would help minimize this possibility.

Providing Time to Come Into Compliance. **The AHA believes that providing adequate time to come into compliance with CMS' vaccination mandate is vital to maintaining access to care.** This is especially true given that the maximum penalty for non-compliance with a CoP – removal from the Medicare and Medicaid programs – is severe enough to jeopardize most hospitals' financial viability, and threaten their ability to care for their communities. Furthermore, many hospitals are experiencing severe workforce shortages. While the challenges of sustaining the health care workforce predate COVID-19, the pandemic has only served to exacerbate them. Hospitals report that some workers have chosen to leave the health care field altogether due to the emotional toll.

Among the remaining workforce, the reality is that, as is the case in the general population, some hospital workers remain hesitant to receive the vaccine, and some hospitals have more of such workers than others. To be clear, all hospitals have redoubled their efforts convince the remainder of their workforce to obtain the vaccines. However, these efforts take time, and some hospitals are fearful that a hasty implementation of CMS' policy could prompt abrupt resignations of some staff. Given the national scale of staffing shortages, replacing staff could be extremely challenging for some hospitals. This could force difficult choices about suspending or eliminating services. As has been reported in the media, a hospital in New York state was recently forced to suspend labor and delivery services following the implementation of a vaccination mandate due to a lack of sufficient staffing. Simply put, maintaining adequate staffing is foundational to assuring access to quality care.

In addition, while CMS has announced its intention to write an IFR at least one month before it is issued, many details of how hospitals will be expected to demonstrate their compliance are still unclear. Hospitals will need time to familiarize themselves with CMS' expectations and ensure they are compliant with them. **For these reasons, we urge CMS to ensure there is sufficient time between when the requirement takes effect and when compliance would begin to be enforced.** For example, many hospitals that have implemented their own mandatory vaccination policies announced them at least 60-90 days before employees were to comply. CMS could use a similar timeframe for its policy. By way of illustration, if CMS were to issue the final rule and associated interpretive guidance on or about Oct. 15, its first assessment of whether hospitals were complying with the mandate could take place on Dec. 15. This would allow as yet unvaccinated employees time to get any remaining questions answered, schedule themselves to receive the vaccine doses, and get inoculated.

Progressive Enforcement Approach. Even with the above "grace period," it is possible that some hospitals – even those with high vaccination rates – could have portions of their workforce that are not yet vaccinated by the time they must come into compliance. As noted above, these remaining employees could be among the most challenging to convince to get the vaccine. Yet, we do not believe that a precipitous removal of these hospitals from Medicare and Medicaid participation would serve the interests of CMS, communities or hospitals, especially given the ongoing work to manage COVID-19 patients, as well as an increase in care for non-COVID-19 patients.

For this reason, the AHA urges CMS to adopt a progressive enforcement approach that gives hospitals opportunities to demonstrate progress in coming into compliance with the mandate. CMS could consider emulating the multi-step corrective action process it uses to enforce the COVID-19 daily data reporting CoP. This approach gives hospitals time to demonstrate compliance, and only escalates consequences when hospitals fail to engage with CMS to seek guidance and assistance related to actions that can be taken to come into compliance. Furthermore, hospitals have demonstrated extremely high levels of compliance with reporting COVID-19 data

from the outset. As a result, we believe using a similar approach for the vaccination mandate CoP would be similarly successful.

Flexibility in the Event of Vaccine Supply Shortages. **The AHA urges CMS to include enforcement flexibility in its mandatory vaccination policy in the event of unexpected vaccine supply shortages.** The nation has been fortunate that since May 2021, there has been an adequate supply of vaccines for all who want them. However, as with any vital medical supply, it is possible that disruptions to manufacturing or distribution could cause unexpected shortages in vaccine supply. Furthermore, as the science around vaccination continues to evolve, it is possible that there would be a mismatch between the vaccines that are available and the vaccines needed to complete a regimen. For example, if future booster shot dosages differed from those used in an initial series, a shortage of the booster doses would make it hard to ensure health care workers were fully vaccinated.

To be clear, we anticipate that the supply of vaccine will remain adequate to vaccinate all who need it. However, we urge CMS to include contingencies in its policy (e.g., temporary suspension of requirements, grace periods, etc.) to ensure that hospitals are not considered out of compliance in the event that vaccine supplies are inadequate.

TRANSPARENT AND CONSISTENT IMPLEMENTATION

Timely Issuance of Interpretive Guidance. **The AHA urges CMS to issue any interpretive guidance associated with its mandatory vaccination policy as close to concurrently with the IFR as possible.** If CMS adheres to its usual process for promulgating CoPs, we would expect that many enforcement details would be specified in sub-regulatory interpretive guidance issued either concurrently with the regulation or shortly after it. Hospitals are eager to have as much detailed information as possible about how they can demonstrate their compliance and how CMS will conduct enforcement. The sooner CMS can issue any associated interpretive guidance, the greater the certainty for hospitals.

In addition, we recommend that there be a sufficient amount of time in between when guidance becomes effective, and when CMS begins to conduct enforcement. We suggest a minimum period of 60-90 days. In the event that the interpretive guidance is not released concurrently, we ask that the agency provide additional flexibility, leniency and judgment in the enforcement of the CoP until such time as the interpretive guidance is released.

Exceptions for Medical and Religious Reasons. **The AHA urges CMS to include in its mandatory vaccination policy exceptions for medical reasons and for sincerely held religious beliefs, practices or observances. Furthermore, we urge CMS to provide interpretive guidance on how to apply these exceptions consistently.** Based on the experience of hospitals that have already implemented their own

mandatory vaccination policies, we believe the number of individuals who actually require these exceptions is relatively small. However, we anticipate that health care personnel's demand for these exceptions could grow as hospitals work with those staff who remain unvaccinated. Hospitals are eager to ensure that there is a consistent approach to applying such exceptions, one that strikes a balance between rigor and administrative burden to hospitals and health care personnel.

For medical exemptions, it would be important for CMS' guidance to have enough detail to promote standardized approaches among hospitals. We encourage CMS to consult with both the Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA) to provide hospitals with a list of common contraindications for the vaccinations. We appreciate that no list of contraindications is exhaustive, but it would give hospitals a starting point. In addition, CMS could ask that hospitals have a process in place for their workers to attest to having a medical contraindication to the vaccination, along with a policy that permits hospitals to ask employees for substantiation of their medical contraindication. This "proof" could be, for example, a signed letter from a physician, or a hospital-issued form that the hospital produces for physicians to sign.

For religious exemptions, we urge CMS to ensure its approach is consistent with other government guidance from OSHA as well as the EEOC guidance issued on May 28, 2021. The EEOC guidance indicates that employees can ask for accommodations from vaccination requirements based on sincerely held religious beliefs, practices or observances. CMS' interpretive guidance should describe what documentation is required to substantiate a religious exemption.

ALIGNMENT WITH OTHER FEDERAL VACCINATION-RELATED POLICIES

Measuring Compliance Using CMS Health Care Personnel Vaccination Measure. **To minimize duplicative efforts and promote alignment, CMS should consider measuring hospital compliance with its vaccination mandate by using the recently adopted COVID-19 vaccination coverage among health care personnel (HCP) measure.** Beginning on Oct. 1, CMS will require hospitals and several other provider types to report a measure reflecting the proportion of health care personnel in their facilities that are vaccinated for COVID-19. Hospitals and other providers will report a "snapshot" of their vaccination coverage rates into the CDC's National Healthcare Safety Network (NHSN) portal at least once per month. We believe using this mechanism to measure hospital progress and compliance with the vaccination mandate would ensure a consistent approach to assessing HCP vaccination rates across the agency. In addition, the HCP measure's definition of included personnel types aligns quite closely with what CMS has indicated it intends to include in its mandatory vaccination policy. Lastly, we believe using HCP measure reporting to assess compliance would reduce the amount of administrative burden for hospitals and other health care providers subject to the mandate.

Coordination with Other Federal Vaccination-Related Policies. As noted above, the AHA strongly supports the vaccination of all HCP for COVID-19. However, CMS' vaccination mandate is not the only vaccination mandate policy that could apply to hospitals and health systems. The Biden Administration's Sept. 9 COVID-19 Action Plan indicates that OSHA soon will issue an emergency temporary standard (ETS) requiring all employers with 100 or more employees to either fully vaccinate their staff or implement weekly COVID-19 testing. Most hospitals in America employ at least 100 people. Furthermore, the Administration announced its intent to require federal contractors to vaccinate their staff. By means of their significant research work, it is possible that some hospitals also could be considered federal contractors.

The AHA urges CMS to work with other federal agencies to minimize inconsistency and redundancy between these mandates. For example, we would encourage CMS to engage OSHA to either carve out hospitals from the pending ETS, or to develop an information sharing mechanism with OSHA so that hospitals' Medicare CoP compliance can "count" as meeting the OHSA ETS requirements. Similarly, for those hospitals that may be undertaking research activity as a federal contractor, we would encourage CMS to develop information sharing mechanisms to enable hospitals to count their CoP compliance as meeting the federal contracting vaccination rules**. In short, we believe that hospitals should have a single set of federal rules and regulations to which they are held accountable**. This would ensure that hospitals can spend their finite resources on achieving as high a level of vaccination among their workforce as possible, rather than on deciphering federal rules that could differ from one another.

We appreciate your consideration of these issues, and welcome the opportunity to work with CMS to ensure this new policy is implemented and enforced in a transparent, feasible and fair manner. Please contact me if you have questions or feel free to have a member of your team contact Akin Demehin, AHA's director of policy ademehin@aha.org, or Mark Howell, AHA's senior associate director of policy at mhowell@aha.org.

Sincerely,

/s/

Stacey Hughes
Executive Vice President

Cc: Jonathan Blum, CMS Principal Deputy Administrator
Lee Fleisher, M.D., CMS Chief Medical Officer