American Hospital Association™
Advancing Health in America

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January 4, 2022

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

RE: Comments on the Interim Final Rule Implementing a Mandatory COVID-19 Vaccination Policy for Hospitals and Other Health Care Providers Participating in Medicare and Medicaid (CMS-3415-IFC)

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) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) interim final rule (IFR) requiring vaccination of health care personnel.

The AHA repeatedly has urged the vaccination of all health care workers, and supports hospitals and health systems that chose to implement vaccination requirements. Prior to CMS' publication of the IFR, a number of hospitals and health systems implemented vaccination requirements for their staff with decisions made on an organization-by-organization basis. Now, with the IFR's publication, CMS has made the decision to implement a national mandate for health care facilities to vaccinate their personnel. That decision now places the responsibility on CMS to ensure the policy's stated goal – the vaccination of all health care staff for their safety and the safety of the patients they treat – is met through a thoughtful, transparent, consistent and meaningful compliance process that appropriately balances maintaining access to care with the decision to use enforcement action.

We appreciate that CMS on Dec. 28 released interpretive guidance for the IFR along with an updated Frequently Asked Questions (FAQs) document. Together, these documents describe CMS' intent to survey for and enforce this rule where

possible, while providing additional flexibility to enable hospitals and other Medicare-participating organizations to come into full compliance. Our members rely upon such guidance to ensure they are implementing the right processes in the right way to meet regulatory expectations. This guidance's release provides greater clarity for hospitals and other providers across the country as they seek to better understand what is expected of them and how much discretion they have in establishing policies that will be applicable to their respective organizations.

Also, we are pleased that CMS in the interpretive guidance announced that it will push back the two implementation dates for compliance with the IFR. Organization will now have until Jan. 27, 2022 (rather than Dec. 6, 2021) to establish policies mandating COVID-19 vaccines for health care workers and achieve a high level of compliance for the workers to have received their first vaccine doses. Additionally, workers will have until Feb. 28 (instead of Jan. 4) to complete their primary vaccination series.

In accompanying FAQs, CMS further indicates the use of enforcement discretion to not cite hospitals or other organizations with established policies that are achieving high vaccination levels among health care workers in the first few months of implementation. As the virus continues to mutate, resulting in new variants with different characteristics, the care delivery system must deal with ever evolving challenges at an unpredictable rate. Given these challenges, **we are pleased to see CMS indicate in the interpretive guidance that it would exercise enforcement discretion for hospitals and other health care delivery organizations. We strongly encourage CMS to continue to monitor both the new variants of the virus and the state of stress on our health care delivery system so to employ appropriate enforcement discretion as the rule becomes effective.**

Finally, we want to acknowledge the current legal challenges to the IFR. As of Dec. 31, there is a temporary injunction to the rule in 25 states, with a decision by the U.S. Supreme Court on the injunction expected within the month. This puts hospitals and health systems in a difficult position, as some health care workers will be required to become vaccinated and others will not, based on where their employer is located.

It is critical that CMS use its enforcement discretion to assure that the revised compliance deadlines of Jan. 27, 2022 (for receipt of a first dose), and Feb. 28, 2022 (for completion of the primary vaccine course), do not adversely impact care**. To that end, if the Supreme Court lifts the injunction, we urge CMS to provide facilities in the states where the rule is currently enjoined additional time to put in place their policies and come into compliance. This approach would positively support hospitals' and health systems' vaccination efforts and bolster their progress in achieving compliance while helping to minimize any adverse impacts on care.**

Our complete comments follow.

Further Clarification of Interpretive Guidance

While the language of the IFR and the newly released interpretive guidance establishes parameters for CMS' vaccination requirements, our members have additional questions that remain unanswered.

Given the IFR's complexity and broad-sweeping implications, hospitals are eager to receive as many details as possible about how they can demonstrate compliance, along with how CMS intends to conduct enforcement. Even with the release of interpretive guidance, it is difficult for our membership to ensure they know how to meet the agency's expectations. **We therefore urge CMS to provide for hospitals and health systems the opportunity to submit questions and receive rapid feedback to ensure that the policies they put in place are compliant with the rule.**

The recently released interpretive guidance also is critical for surveyors; while it is necessary for our members to understand what is required of them from CMS, it is equally important that surveyors have a comprehensive grasp on what is required and expected of them during a survey. Surveyors play a vital role in the regulatory compliance process and their work informs CMS and its decisions. Given the importance of surveyors' work and the complexities of the IFR, **the AHA strongly recommends that CMS provide in-depth education and training on the IFR's requirements to ensure that compliance is assessed objectively and consistently across the provider field.**

Recognizing Processes Already In Place

Many hospitals and health systems implemented staff vaccination requirements prior to the IFR's release and thus established processes for organization-specific vaccination requirements. In addition, once the IFR was released, many of those who had not yet established formal vaccination processes and requirements for staff immediately did so to ensure compliance with CMS' new requirement. While the goal of these efforts are in lockstep with CMS' stated intentions, the lack of detailed information from the agency prior to the interpretive guidance's Dec. 28 release forced our members to make their own determinations as to what is appropriate and acceptable.

Even though our members are making good faith efforts to ensure their vaccination activities line up with CMS' intent, it was impossible for them to fully and accurately predict CMS' expectations of providers. Given the immediacy of the new implementation deadlines, **we urge CMS to consider grandfathering already-established hospital and health system processes that seek to achieve the agency's vaccination objectives.**

For example, CMS could permit medical and religious exemptions granted under mandatory vaccination policies that were established prior to the IFR's issuance to remain in place. This should be permitted even if these policies differ from the examples CMS points to of the CDC's Summary Document for Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States and the Equal

Employment Opportunity Commission's (EEOC) Compliance Manual on Religious Discrimination guidance for religious exemptions. Alternatively, CMS could provide a phase-out period for previously established exemptions that do not align with the agency's interpretive guidance.

Providing Time to Come Into Compliance

The AHA continues to stress that providing adequate time to come into compliance with CMS' vaccination mandate is vital to maintaining access to care. Given the unique circumstances surrounding this IFR, we urge the agency to employ maximum enforcement discretion in the early stages of implementation, coupled with a longer-term, progressive enforcement approach focused on achieving increased vaccination without penalizing hospitals and health systems in the midst of their ongoing pandemic response work. Even in light of changes to the implementation dates made through the interpretive guidance, we expect that now, more than ever, a continued discretionary approach to enforcement will be necessary to allow hospitals to come into compliance.

This is especially important given that the maximum penalty for non-compliance with a condition of participation is a hospital or health system's termination from the Medicare and Medicaid programs. This is severe enough to endanger most hospitals' financial viability, and therefore threatens their ability to care for their communities.

Many hospitals are further challenged by severe workforce shortages. While the difficulties of sustaining the health care workforce predate COVID-19, the pandemic has exacerbated these challenges and created an unprecedented need. Simply put, maintaining adequate staffing is foundational to ensuring access to quality care.

Even with robust efforts to vaccinate staff, many hospitals could have portions of their workforce that are not yet vaccinated in time to meet the compliance deadlines; given the national staffing shortages, these health care workers may not be easily replaced. In these instances, the agency must recognize that these remaining unvaccinated employees could be among the most challenging to convince to get the vaccine and that even the best plans for replacing those staff or convincing them to get vaccinated will require time to implement. Thus, hospitals may be forced to balance having sufficient, appropriately trained staff to provide needed care with ensuring all of their staff are vaccinated.

We urge CMS to develop a balanced and thoughtful approach in making its enforcement determinations for now and into the future for this requirement. Many of the staffing issues are unlikely to be quickly resolved. An enforcement approach that presses forward too aggressively has the potential to create disruptions in patient care. CMS should continue to employ significant enforcement discretion in an effort to mitigate any potential disruptions in care while our members work to come into compliance.

Flexibility in the Event of Vaccine Supply Shortages

The AHA urges that CMS' mandatory vaccination policy include enforcement flexibility to account for unexpected vaccine supply shortages. The nation has been fortunate that, since May 2021, there has been adequate supplies of COVID-19 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, in the event that vaccine supplies are inadequate, hospitals are not considered out of compliance.

The Use of an Interim Final Rule

Finally, CMS implemented the mandate by means of a condition of participation (CoP), promulgated in an IFR. This expedient action deprived the agency of the benefit of input prior to implementation from Congress and those most impacted by the rule, including rural providers. We believe CMS' rules always benefit from the input of all those impacted by its rules.

Assuring the integrity of CoPs is particularly important to the hospital field as they set the standard for essential elements of operating a hospital safely and carry the potential penalty of exclusion from in the Medicare and Medicaid programs for lack of compliance.

For these reasons, CMS should resort to establishing CoPs through an IFR only under extraordinary circumstances. Even under those circumstances, the agency should seek input from congressional leaders and other key stakeholders through other, less formal means. Using this critical information, CMS should then exercise exceptional diligence in assessing the rule's impact on rural providers, hospitals that serve a disproportionate share of the poor and other hospitals that may struggle to come into compliance for a host of particular reasons.

We thank you for the opportunity to comment on this important topic. As our members continue to work to vaccinate their staff, we ask CMS to remain flexible in its approach so that we can work together to achieve the goal of vaccinating all health care staff for their safety and for the safety of the patients they treat.

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, at 202-626-2326 or ademehin@aha.org, or Mark Howell, AHA's senior associate director of policy, at 202-626-2317 or mhowell@aha.org.

Sincerely,

/s/

Stacey Hughes
Executive Vice President
Government Relations and Public Policy