



AMERICA'S ESSENTIAL HOSPITALS

December 21, 2021

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue SW
Washington, DC 20201

CMS-3415-IFC: Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination

Dear Administrator Brooks-LaSure:

America's Essential Hospitals appreciates the opportunity to submit comments on the above-captioned interim final rule establishing COVID-19 vaccination requirements for staff at covered Medicare-and Medicaid-certified providers and suppliers. Keeping America's health care workforce, and the patients they serve, healthy and safe is of utmost importance to America's Essential Hospitals. Our members understand the critical role their staff and health care providers play in our nation's response to the COVID-19 public health emergency (PHE).

The Centers for Medicare & Medicaid Services (CMS) vaccination mandate comes at a time when hospitals are already working determinedly to urge staff and the broader community to get vaccinated and, when appropriate, receive booster shots. In fact, America's Essential Hospitals urged its member hospitals to require their employees be vaccinated.¹ Essential hospitals continue to educate staff and their communities about the importance of vaccination in the fight against COVID-19, particularly given the rise of cases tied to the delta variant and emergence of the new, highly transmissible omicron variant. However, we are concerned about CMS' timeline for implementation of its vaccination requirements, given the ongoing stress to our health care system, and seek clarification on certain requirements in the rule.

America's Essential Hospitals is the leading champion for hospitals and health systems dedicated to high-quality care for all. Our more than 300 member hospitals provide a disproportionate share of the nation's uncompensated care, and three-quarters of their patients are uninsured or covered by Medicare or Medicaid. Essential hospitals provide state-of-the-art, patient-centered care while operating on margins one-third that of other hospitals—2.9 percent on average compared with 8.8 percent for all hospitals nationwide.² These narrow operating

¹ America's Essential Hospitals Urges Members to Require Employee Vaccination. America's Essential Hospitals. July 21, 2021. <https://essentialhospitals.org/general/americas-essential-hospitals-urges-members-require-employee-vaccination/>. Accessed December 14, 2021.

² Clark D, Roberson B, Ramiah K. *Essential Data: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2019 Annual Member Characteristics Survey*. America's Essential Hospitals. May 2021. <https://essentialdata.info>. Accessed December 14, 2021.

margins result in minimal reserves and low cash on hand, circumstances which have been exacerbated by the financial pressures of COVID-19.

As the pandemic continues and hospitals dedicate additional resources to vaccination efforts, essential hospitals face an uncertain financial future. We urge the agency to provide hospitals more time to comply with the vaccination requirements. Further, we urge CMS to issue guidance on types of staff subject to the requirements—particularly related to vendors—and the ability of staff to provide services before completing their primary vaccination series or while awaiting determination of an exemption request.

- 1. CMS should delay implementation at least one month to allow hospitals time to fully design policies and procedures aimed at improving vaccination rates and ensuring the health and safety of individuals providing and receiving care.**

CMS outlines a phased implementation for its vaccination requirements. Phase 1, effective 30 day after publication of the rule (i.e., December 6) includes the requirement that staff receive the first dose, or only dose as applicable, of a COVID-19 vaccine, or request an exemption. Phase 2 requires that by January 4, 2022, the primary vaccination series has been completed, except for those staff that are exempt.

Because COVID-19 prevalence is not consistent across the country, hospitals in different areas have been affected differently at various times throughout the pandemic. Some members, like those in Indiana and Missouri, are experiencing a surge with hospitals filled to capacity with both COVID-19 and other patients, compounded by the increase in prevalence of coronavirus variants. In some instances, the National Guard has been deployed to provide teams to support the over-stretched health care workforce. Given the ongoing stress to our health care system, including essential hospitals in many parts of the country responding to surges of the delta variant and preparing for a potential wave of omicron-related cases, **we urge CMS to delay compliance with Phase 2 (fully vaccinated) at least one month.**

Throughout the COVID-19 pandemic, essential hospitals have served as valued partners, working with the federal government to respond to our nation's needs through swift action to protect patients and staff. Our members are committed to these efforts and will continue to provide a safe environment for all staff and patients. However, contingency planning described by CMS—such as using staffing agencies to supply vaccinated workers if some of the facility's staff are unable to work—require time and resources. Additionally, preliminary injunctions in select states and ongoing litigation, along with CMS' December 2 memorandum suspending all implementation and enforcement of this rule pending the legal proceedings, has created an atmosphere of uncertainty for essential hospitals. It is unclear how this rule and its compliance deadlines might be affected by future developments in the litigation. This uncertainty makes implementation of a vaccination policy challenging for hospitals and staff. If the rule is ultimately upheld and CMS resumes implementation, **we urge the agency to allow an additional month for compliance.**

- 2. CMS should issue interpretive guidance as soon as possible to improve hospitals' ability to comply with the vaccination requirements and maintain appropriate staffing levels.**

Hospitals look to guidance from CMS, as well as materials issued by the Centers for Disease Control and Prevention (CDC), when crafting policies and procedures to protect their staff. Hospitals need immediate compliance assistance in interpreting the CMS vaccination requirements. Further, as the COVID-19 pandemic continues to evolve, so too does our knowledge about vaccines, their efficacy over time, and the impact of new variants. Given the

changing landscape, it is critical CMS issue interpretive guidance and update its FAQs in response to the most current evidence.

- a. CMS should provide additional detail about factors to consider when determining whether to require vaccination of an individual who does not fall into the categories established in the rule, as well as how to verify vaccination status for such individuals.

We agree with CMS that vaccination policies and procedures must apply to all staff regardless of frequency of patient contact. Additionally, CMS includes administrative staff, facility leadership, housekeeping, food services, and others under the category of “staff” for whom COVID-19 vaccination is now required as a condition of continued provision of services.

However, when determining whether to require vaccination of an individual who does not fall into these categories, further clarification is needed. In particular, to assist hospitals when developing vaccination policies for vendors and those under contract that infrequently provide services. CMS provides the example of a plumber making an emergency repair in an empty restroom, who wears a mask, as someone for which proof of vaccination would not be required. Whereas, a construction crew working on a project and making use of shared facilities (restrooms, cafeteria, etc.) during their breaks, would be subject to the vaccination requirement. In the case of the construction crew, it is unclear whether a facility would be able to provide a copy of its vaccination policies and procedures and require that the vendor or contractor acknowledge and agree to those policies prior to performing any work. **We urge CMS to provide further detail on how facilities might operationalize a process for verifying vaccination status among vendors that does not add administrative burden to hospitals.**

- b. CMS should clarify work restrictions for providers making plans in consideration of staff that are not fully vaccinated, with a goal of preserving workforce levels.

CMS acknowledges that “the course of the COVID-19 pandemic remains unpredictable” and is requiring that hospitals make contingency plans in consideration of staff that are not fully vaccinated. The agency notes these individuals should not provide care, treatment, or other services “until they have completed the primary vaccination series and are considered fully vaccinated, or, at minimum, have received a single-dose COVID-19 vaccine, or the first dose of the primary vaccination series.” Given ongoing workforce concerns and the need to maintain sufficient levels of care at our hospitals nationwide, we ask that CMS clarify when staff is eligible to provide services under the rule. Further, **we urge CMS to allow staff that has received one dose to provide services, in accordance with policies that ensure they minimize the risk of transmission (e.g., mask wearing, testing), while they await their second dose.**

Essential hospitals have borne the brunt of pandemic-related hospitalizations, with a significant impact on staffing. Essential hospitals have incurred considerable costs in hiring and maintaining staff to respond to the continued spread and reverberating effects of the pandemic. It is critical that vaccination mandates support hospital staffing, particularly for essential hospitals that provide vital services to their communities.

- c. CMS should further examine the impact of booster shot recommendations on the vaccination requirements under the rule and monitor for potential changes to the “fully vaccinated” definition.

The Food and Drug Administration December 9 amended its emergency use authorization for the Pfizer COVID-19 vaccine to include a booster shot for 16- and 17-year-old individuals at

least six months after completing their primary dose series.³ Further, CDC strengthened its booster recommendations and is encouraging everyone 16 and older to receive a booster shot. As noted by CDC Director Rochelle Walensky, MD, “Although we don’t have all the answers on the omicron variant, initial data suggests that COVID-19 boosters help broaden and strengthen the protection against omicron and other variants.”⁴

In the rule, CMS notes providers are required to have a process for tracking and securely documenting the COVID-19 vaccination status of staff that have obtained a booster dose. We support collecting the most current vaccination data for staff; however, **it should be made clear that the definition of “fully vaccinated” for purposes of compliance does not include boosters.** Further, we encourage CMS to monitor the use of boosters, along with CDC guidance, and provide hospitals reasonable notice if there is a change in the definition of “fully vaccinated” under this rule.

3. We urge CMS to be thoughtful in its enforcement of the vaccination requirements, take a flexible approach to surveying, and allow providers to show they are working to achieve compliance.

The new CMS vaccination requirements likely will lead to more surveys and surveyors deployed to hospitals nationwide. This is in addition to the return of regular surveys from CMS, after those surveys were suspended for a period of time during the COVID-19 PHE. **We urge CMS to take a flexible approach to its survey process if a hospital is experiencing a COVID-19 surge or workforce shortages.**

Essential hospitals value the partnership developed with CMS over the course of the COVID-19 pandemic and ask that the agency work with facilities to achieve higher vaccination rates and full compliance with this rule. If a surveyor identifies noncompliance, we ask that CMS first provide a warning letter to the facility and the opportunity to work with CMS on a corrective plan, during which time the agency ceases further enforcement action.

America’s Essential Hospitals appreciates the opportunity to submit these comments. If you have questions, please contact Senior Director of Policy Erin O’Malley at 202-585-0127 or eomalley@essentialhospitals.org.

Sincerely,

Bruce Siegel, MD, MPH
President and CEO

³ Coronavirus (COVID-19) Update: FDA Expands Eligibility for Pfizer-BioNTech COVID-19 Booster Dose to 16- and 17-Year-Olds. FDA News Release. December 9, 2021. <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-expands-eligibility-pfizer-biontech-covid-19-booster-dose-16-and-17>. Accessed December 14, 2021.

⁴ CDC Expands COVID-19 Booster Recommendations to 16-and-17-year-olds. December 9, 2021. <https://www.cdc.gov/media/releases/2021/s1208-16-17-booster.html>. Accessed December 14, 2021.