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January 4, 2022

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Blvd.
Baltimore, MD 21244-1850

Re: Docket # CMS-3415-IFC: Medicare and Medicaid Omnibus COVID-19 Health Care Staff Vaccination

Dear Ms. Brooks-LaSure:

The Association for Professionals in Infection Control and Epidemiology (APIC) wishes to thank the Centers for Medicare and Medicaid Services (CMS) for the opportunity to provide input to the Medicare/Medicaid Omnibus COVID-19 Health Care Staff Vaccination interim final rule. APIC is a nonprofit, multidisciplinary organization representing 16,000 infection preventionists whose mission is to advance the science and practice of infection prevention and control. We are pleased that CMS continues to demonstrate its commitment to improving the quality of patient care and healthcare personnel (HCP) safety across the healthcare continuum.

APIC supports efforts to improve employee safety, especially during the public health emergency (PHE) that has had a severe impact on HCP. APIC applauds CMS for developing the interim final rule to require COVID-19 vaccination for staff at Medicare- and Medicaid-certified providers and suppliers. Vaccination is the most effective way to protect employees and prevent transmission,[1] which in turn, protects patients and visitors in CMS-certified facilities. For this reason, APIC has joined with other infection control and epidemiology organizations in a Multisociety Statement supporting COVID-19 vaccination as a condition of employment for HCP.[2] According to the statement, full vaccination not only provides individual protection, but also provides further protection for patients and HCP who are unable to receive COVID-19 vaccination or are not able to mount an adequate immune response. It also helps to reduce transmission from HCP who are exposed to COVID-19 in the workplace to their families and communities.

In August, 2021, the Biden Administration took action to mandate COVID-19 vaccination for nursing home personnel.[3] While nursing homes care for many of the highest risk individuals, those same individuals receive care and treatment in other healthcare continuum settings. Without a similar mandate for HCP in other care settings, there is a discrepancy between vaccine mandates and vaccination status of HCP in various settings. APIC is pleased that CMS is expanding the nursing home mandate to other settings in the healthcare continuum.

APIC also appreciates that CMS has chosen not to be prescriptive as to how hospitals and other covered entities within the Interim Final Rule choose to manage 'additional precautions' for those that have approved exemptions and are unvaccinated, yet still working. With the continued uncertainty of the spread of the virus and the emergence of variants the most effective approach at control continues to be dynamic. In addition, there is a continued high demand for testing supplies and personal protective equipment, including N95s; therefore, the flexibility to adjust this approach at the local level is essential. For example, serial testing of unvaccinated HCP may be warranted in certain high-risk clinical environments, but not all. Or, availability of testing supplies may only allow for a limited approach.

APIC also appreciates that CMS is taking into consideration the administrative and data reporting requirements of any new rule, as well as cross-walking to other requirements to avoid redundancy. Infection preventionists' time is best spent in the field with the frontline workers ensuring best practices through observation, education, and compliance checking.

APIC appreciates CMS providing clarity and the definition of 'Fully Vaccinated'; however, we would recommend adding in a cushion to this definition to allow for booster doses, as we predict those to be an essential part of the future definition of fully vaccinated, especially as variants continue to emerge and the initial two-dose mRNA series, or single-dose vaccines, are proving to not be as effective against Omicron as past variants. We would recommend continuing to defer to the Centers for Disease Control and Prevention (CDC) to define 'Fully Vaccinated' in the HCP population.

APIC appreciates that CMS allows for flexibility in the exemption from vaccination process for employees and provided specifications around what is expected in an approved medical exemption provider letter. We also appreciate that 'prior infection with COVID-19 infection' and/or evidence of COVID-19 antibodies does NOT constitute evidence of immunity and therefore exemption from vaccination.

Responsibility of Healthcare Personnel

APIC has long supported mandating certain vaccines as a condition of employment for HCP. In our 2011 Position Paper supporting mandating influenza vaccination as a condition of employment, APIC noted that "This is not only a patient safety imperative but is a moral and ethical obligation to those who place their trust in our care."[4] HCP play a special role in our (and any) society. The nature of their chosen work often includes putting their own interests aside to care for their patients. This includes working in settings where exposure to disease is common. Healthcare facilities must provide employees with the means to keep them protected, but it is also incumbent on employees to take whatever actions are available to protect themselves and their patients. The Multisociety Statement noted that prior experience and current information suggest that a sufficient vaccination rate is unlikely to be achieved without making COVID-19 vaccination a condition of employment.[5]

Public Health Precedent

Although we can understand the hesitancy some people might have about such new vaccines, they have proven to be highly safe and effective against COVID-19 severity of illness and hospitalization. Vaccine mandates are not a new concept; they have been part of American public health efforts since the 18th century when General George Washington required American troops to be immunized against smallpox during the Revolutionary War. Of the 16 immunizations the CDC recommends for children and teens, all

50 states and the District of Columbia mandate vaccination against diphtheria, tetanus, pertussis (whooping cough), polio, measles, rubella and chickenpox.[6] In fact, all public health measures, by definition, require individuals to sacrifice their own interests for the public good. This can be seen in such now-common measures as regulating personal and industry disposal of wastewater to prevent epidemics of cholera and other waterborne illnesses and banning smoking on airlines to prevent tobacco-related illnesses due to secondhand smoke.

In 1905, the U.S. Supreme Court upheld a Massachusetts law requiring smallpox vaccination in *Jacobson V. Massachusetts*. In its decision, the Court held that "in every well ordered society charged with the duty of conserving the safety of its members the rights of the individual in respect of his liberty may at times, under the pressure of great dangers, be subjected to such restraint, to be enforced by reasonable regulations, as the safety of the general public may demand" and that "[r]eal liberty for all could not exist under the operation of a principle which recognizes the right of each individual person to use his own [liberty], whether in respect of his person or his property, regardless of the injury that may be done to others."[7] The Court also noted, "The liberty secured by the Constitution of the United States to every person within its jurisdiction does not import an absolute right in each person to be, at all times and in all circumstances, wholly freed from restraint. There are manifold restraints to which every person is necessarily subject for the common good. On any other basis organized society could not exist with safety to its members."

CMS Mission and Vision

The CMS mission is to serve Medicare and Medicaid beneficiaries. Its vision includes strengthening the healthcare services and information available to beneficiaries **and the healthcare providers who serve them**. Long-standing childhood vaccination mandates and the Supreme Court decision in *Jacobson* refer to state law. However, APIC believes that, as a federal agency, CMS also has both the authority and the responsibility to mandate COVID-19 vaccination of healthcare personnel in the facilities it regulates. Although CMS is the largest provider of healthcare funding in the U.S., participation in the Medicare program is voluntary for healthcare facilities. Facilities that choose to accept Medicare funding also agree to comply with Medicare Conditions of Participation, Conditions for Coverage, and regulatory requirements that CMS may impose to protect the safety of its beneficiaries and staff.

The COVID-19 pandemic has already claimed over 825,000 American lives. Further, in an October 20, 2021 newsletter, the World Health Organization estimated that between 80,000 and 180,000 healthcare workers had died from COVID-19 between January 2020 and May 2021. In a public health emergency such as this one, everyone has a responsibility to do their part to prevent further transmission, especially those tasked with providing healthcare.

APIC congratulates CMS for implementing the COVID-19 vaccination mandate for healthcare staff in facilities governed by its conditions as the most effective action to protect all who enter these facilities in order to reduce transmission of COVID-19. We look forward to continuing to work with CMS and other federal agencies to bring an end to this pandemic.

Sincerely,

Linda L. Dickey, RN, MPH, CIC, FAPIC
2022 APIC President

[1] Morbidity and Mortality Weekly Report /April 2, 2021/70(13);495-500

[2] Weber, D., Al-Tawfiq, J., Babcock, H., Bryant, K., Drees, M., Elshaboury, R., . . . Young, H. (2021). Multisociety Statement on COVID-19 Vaccination as a Condition of Employment for Healthcare Personnel. *Infection Control & Hospital Epidemiology,* 1-46. doi:10.1017/ice.2021.322.

[3] Centers for Medicare & Medicaid Services. Biden-Harris Administration Takes Additional Action to Protect America's Nursing Home Residents from COVID-19. August 18, 2021. Available at: https://www.cms.gov/newsroom/press-releases/biden-harris-administration-takes-additional-action-protect-americas-nursing-home-residents-covid-19 Accessed August 19, 2021.

[4] APIC Position Paper: Influenza Vaccination Should be a Condition of Employment for Healthcare Personnel, Unless Medically Contraindicated" https://apic.org/wp-content/uploads/2019/07/APIC_Influenza_Immunization_of_HCP_12711.pdf/ , January 27, 2011.

[5] Weber, D, et.al, Multisociety Statement.

[6] DeSilver, D. "States Have Mandated Vaccinations Since Long Before COVID-19", Pew Research Center October 8, 2021. Accessed 1/2/22 at https://www.pewresearch.org/fact-tank/2021/10/08/states-have-mandated-vaccinations-since-long-before-covid-19/.

[7] U.S. Supreme Court, *Jacobson v. Massachusetts*, 197 U.S. 11 (1905).