August 1, 2023

William Anderson

Office of the General Counsel

Department of Public Health

250 Washington Street

Boston, MA 02108

Dear Mr. Anderson,

The Massachusetts Health & Hospital Association (MHA), on behalf of its member hospitals, health systems, physician organizations, and allied healthcare providers, is grateful for the opportunity to comment on the proposed amendments to 105 CMR 130.000, Hospital Licensure. MHA and its members appreciate the intent of the draft language to balance infection control and workforce issues. Several health systems have raised concerns that several provisions of the draft regulations are ambiguous and may pose potential problems if promulgated as currently written. Two concerns addressed below include (1) ambiguous language about the ability for hospitals/health systems to mandate influenza (flu) and COVID-19 vaccines, while allowing for exemptions for any declination reason, and (2) data and reporting challenges in the proposed language. MHA asks the Department of Public Health (DPH) to kindly consider these comments to address the areas of concern prior to promulgation.

*Exemption Language*

The proposed regulations state that hospitals shall require flu and COVID-19 vaccinations for all healthcare personnel. We appreciate the proposed language and want to ensure the intent of the regulation allows each hospital to enforce flu and COVID vaccination policies based on the individual facility’s unique patient population, clinical determinations, and workforce dynamics. The way the regulation is currently written is concerning because it may be misinterpreted as a limiting policy instead of baseline requirement for vaccinations. Many hospitals currently have flu vaccination programs that only allow medical or religious exemptions. If the ability to limit exemptions is not explicitly stated in the regulation, it could lead to uncertainty regarding the implementation and enforcement of such policies, and could also lead to unnecessary and costly litigation over these issues. It should be up to the individual organization to decide whether a flu or COVID-19 vaccine mandate is appropriate at their facility, based on their own patient population, infectious disease protocols, workforce considerations, and clinical evidence as it relates to their specific facility. We ask that the regulation directly states that hospitals have the ability to create a facility-based vaccination policy that includes, but can go beyond, the DPH provisions if the individual hospital chooses.

Sections 130.325 (F) & 130.326 (E) Exemptions allow healthcare personnel to be exempt from flu and/or COVID-19 vaccine if the individual declines the vaccine(s). The proposed exemption language for flu and COVID-19 vaccines is ambiguous as written. Hospitals have raised concern that the plain language reading of these amendments indicates that hospitals must provide an exemption to any member of their workforce that “declines the vaccination,” which should not be the intent of regulation. The proposed language could be interpreted as prohibiting hospitals from imposing mandatory vaccination programs that do not allow individuals to receive an exemption other than for medical or religious reasons.

There is concern that these proposed regulations may lead to a decline in overall vaccination rates at hospitals that have vaccination rates as a pay-for-performance measure. This could lead to hospitals not hitting their target benchmark for vaccination rates and missing out on the opportunity for additional funding. These pay-for-performance targets were chosen prior to this proposed regulation, and hospitals should not be penalized for the potential effect this new policy could have on vaccination rate compliance.

DPH announced that along with the regulations, it will also publish recommended mitigation procedures for personnel who decline either vaccination and that mitigation measures would ultimately be up to the individual facility based on its unique patient and workforce populations. MHA appreciates the agency’s flexibility and recommendations during the current challenging workforce environment. Ultimately, it should be up to the hospital to decide what mitigation measures to enforce for employees who do not vaccinate. While some hospitals have indicated they have concerns about maintaining staff if they mandate the COVID-19 vaccine in particular, others are contemplating mandating COVID-19 vaccinations to keep staff healthy and able to provide patient care during future upticks in COVID-19 prevalence. As such, flexibility for facilities in determining whether to mandate the vaccination among their specific workforce is critical to meeting their own unique workforce and patient needs.

*Declination for Any Reason*

Another area of concern with the proposed regulation is the ability for healthcare personnel to decline flu or COVID-19 vaccines for any reason. There is concern that allowing declination of these two vaccines for any reason would then translate to declinations of other vaccinations across the workforce. This could potentially result in an immediate decline in vaccinated personnel. Previously, regulations for flu vaccinations laid out the minimum vaccine requirements that hospitals had to have in place, and hospitals could allow for a broader pathway for exemptions if they chose. Under the existing regulations, for example, facilities in Massachusetts experience high flu vaccine rates – some as high as 98% of their workforce, while those without mandates see rates 10-15% lower. It’s suspected that with the new regulation allowing for declination of flu vaccination for any reason, vaccination rates of healthcare personnel could significantly decrease, increasing infection risk for patients and staff. Hospitals recommend that the choice to allow for personal vaccine declination beyond medical and religious exemptions should be the choice of the individual facility based on its unique patient population and workforce needs, instead of allowing for declination of flu vaccination for any reason.

*Documentation, Reporting and Data Collection*

We appreciate the department’s intent on data tracking and reporting of COVID-19 vaccines in the proposed regulations to monitor compliance and increase patient and staff safety. However, the additional data collection, tracking, and reporting of COVID-19 vaccinations among employees is a large administrative burden for facilities to manage. Since the end of the Public Health Emergency, there has been no easy way for occupational health departments to monitor employee vaccinations, making tracking COVID-19 vaccination rates for hospitals and healthcare facilities more challenging. COVID-19 vaccinations are either self-reported or updated by occupational health departments after an internal vaccination clinic. Hospitals are concerned that verifying self-reported vaccinations may be challenging and onerous. MHA requests alignment with National Health Safety Network (NHSN) Healthcare Personnel Safety Component requirements to avoid imposing unnecessary and significant burdens on healthcare facilities when reporting COVID-19 vaccination rates.

Another concern is the ambiguity of being “up to date” with COVID-19 vaccination based on the CDC guideline. The guidance from CDC may change at any time, and hospitals would have to pivot quickly, either preparing additional vaccine clinics for employees, and updating their internal records to comply with the data tracking and reporting requirements. Hospitals spend months planning and preparing for the upcoming flu seasons every year, so placing such a burden on hospitals at the last minute would be extremely challenging. If guidance for COVID-19 vaccinations were to change, MHA requests that DPH consider ample time for hospitals and healthcare facilities to be able to properly prepare and operationalize additional vaccine clinics and updating of records systems to comply with the proposed regulations.

Additionally, the tracking requirements for flu and COVID-19 vaccinations require documentation for declining either or both vaccines. The language around the exemption options is unclear as currently written. MHA requests that DPH’s requirements also clearly specify whether “personal or other” constitutes a single reporting category, or two separate categories of “personal” or “other reasons.” This is important as health systems are currently building their IT/reporting mechanisms for fall flu clinics. Another point to clarify is how to categorize employees that may have had the initial COVID-19 vaccines but are not currently up to date based on the CDC definition.

MHA appreciates DPH’s commitment to keeping the commonwealth healthy and safe for the upcoming flu and COVID-19 season. When reviewing the proposed language for 105 CMR 130.000, Hospital Licensure we encourage DPH to leave the flu and COVID-19 mandates up to the individual facility policy. Each hospital has its own unique needs, and a blanket vaccination mandate is not feasible for all facilities. We kindly ask the DPH to consider clarifying the exemption language, stating that hospitals have the ability to go beyond the current flu and covid vaccination guidance if it is best suited for their clinical situation, and to align documentation and reporting requirements with NHSN requirements. Thank you for considering MHA’s comments. If you have any questions please contact Leigh Simons, senior director of Healthcare Policy, at [lsimons@mhalink.org](mailto:lsimons@mhalink.org).

