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To: Commissioner Robert Goldstein, MD and Members of the Public Health Council

From: Elizabeth Kelley, Bureau Director, Bureau of Health Care Safety and Quality

Date: July 12, 2023

RE: Informational Briefing on Proposed Amendments to Health Care Facility Licensing and  
Emergency Medical Services Regulations

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## I. Introduction

The purpose of this memorandum is to provide the Public Health Council (PHC) with information about proposed amendments to health care facility and Emergency Medical Services licensing regulations.

The Department of Public Health (“Department”) proposes revisions to the following regulations:

1. 105 CMR 130.000, *Hospital Licensure*
2. 105 CMR 140.000, *Licensure of Clinics*
3. 105 CMR 141.000, *Licensure of Hospice Programs*
4. 105 CMR 150.000, *Standards for Long-Term Care Facilities*
5. 105 CMR 158.000, *Licensure of Adult Day Health Programs*
6. 105 CMR 170.000, *Emergency Medical Services System*

These regulations set forth standards governing health care facilities and the emergency medical services system, to provide high quality of care, industry standardization, and strong consumer protection to the residents of Massachusetts. Because all six regulations are being updated to include similar amendments to align their standards around personnel vaccination, they are being presented together.

## II. Background

### *CMS COVID-19 Vaccination Requirements – Primary Series*

Beginning in February 2022, the Centers for Medicare & Medicaid Services (CMS) required all CMS-certified providers (including staff in healthcare facilities) to have completed the COVID-19 primary series vaccine (which currently means either having received two doses of a monovalent mRNA vaccine, a single dose of a protein-based vaccine (e.g., J&J), or a single dose of a bivalent mRNA vaccine) and does not require booster doses. On May 31, 2023, CMS rescinded this requirement effective July 2023, and communicated that it will not be enforced in the interim.

### *Department COVID-19 Vaccination Requirements – Primary Series*

Currently, Department regulations require certain licensees, specifically hospice and long-term care facilities, to confirm all personnel have received COVID-19 vaccination.

- Staff may be exempted from this requirement if vaccination is medically contraindicated or against an individual’s sincerely held religious belief. In these instances, an individual subject to an exemption must be able to perform their essential job functions with a reasonable accommodation that does not place undue burden on the facility.
- These facilities must report to the Department, documenting their compliance, in accordance with guidelines.
- Guidance implementing this vaccination requirement requires personnel to receive the “primary series” of vaccines; it does not require that personnel receive boosters. Per Centers for Disease Control and Prevention guidance, primary series vaccination no longer provides adequate protection against COVID-19 and staying up-to-date with bivalent doses and boosters is recommended.

### *Department Influenza Vaccine Requirements - Seasonal*

- Most Department-licensed healthcare facilities (hospitals, long-term care facilities, clinics, and adult day health) have had longstanding requirements to confirm that all personnel are vaccinated with the seasonal influenza vaccine and other pandemic or novel influenza viruses, unless the individual is exempt for medical or religious reasons or declines vaccination.
- Staff may be exempt, including the ability to decline for any reason (not limited to medical or religious reasons). In the long-term care facility regulation, which was updated more recently than the other regulations, an exempt individual must be able to perform their essential job functions with a reasonable accommodation that does not place undue burden on the facility. This standard is not included in licensure regulations for the other licensed settings noted above.
- Facilities must maintain a system to track personnel vaccination status, including proof of current vaccination against influenza virus (which may be an attestation) or an individual’s exemption statement.
- Facilities must report seasonal personnel vaccination rates annually to the Department, in accordance with guidelines.

## *Requirements for Emergency Medical Services*

There are currently no COVID-19 or influenza vaccination requirements for EMS personnel, either by the Department or by CMS.

### **III. Summary of Proposed Changes**

The Department proposes amendments to all six regulations listed above, to standardize COVID-19 and influenza vaccination requirements across all licensed health care facility settings, and Emergency Medical Service (EMS) providers. With these proposed amendments, personnel will need to be vaccinated with both COVID-19 and influenza vaccines, unless an individual is subject to an exemption.

- Staff may be exempt if they decline for any reason (medical contraindication, religious beliefs, personal reasons, or other).
- Individuals who decline may be required by their employer to take mitigation measures to prevent viral infection and transmission, in accordance with guidance from the Department. Staff in hospice and long-term care facilities who decline vaccination must take mitigation measures.
- Licensees must maintain a system to track personnel vaccination status, including proof of current vaccination against COVID-19 or influenza virus (which may be an attestation) or an individual's exemption statement.
- Licensees must report personnel COVID-19 and influenza vaccination rates to the Department, in accordance with guidelines.

The clinic licensure regulations related to COVID-19 and influenza vaccination requirements are also applicable to out-of-hospital dialysis units, by reference.

### **IV. Rationale**

On May 11, 2023, both the federal and Massachusetts COVID-19 public health emergencies ended. With this change, the Department is moving to incorporate COVID-19 response and management into its broader respiratory illness prevention and mitigation strategy. Part of this change includes aligning our COVID-19 vaccination and influenza vaccination requirements for personnel across licensed healthcare settings. Vaccination is the best method of preventing influenza and COVID-19 and potentially serious complications.

The Department approached these amendments with the following goals:

- Emphasize the importance of both influenza and COVID-19 vaccination among this workforce, due to higher risk of exposure, to prevent missed days of work due to illness, and to safeguard availability to care for patients
- Maximize vaccination while providing flexibility to personnel to be exempt from vaccination by declining
- Reduce risk to patients from COVID-19 and influenza infection and potential serious complications

- Update outdated language which currently only addresses the “primary series” of COVID-19 vaccine
- Close pre-existing gaps and inconsistencies in vaccine requirements, by including all health care facilities and Emergency Medical Service providers in this process, as all serve vulnerable and immunocompromised patients

This approach also builds upon longstanding regulatory standards around influenza vaccination, so will be familiar to both licensees and their employees.

## **V. Next Steps**

The Department intends to conduct a public comment hearing and will then return to the PHC to report on testimony and any recommended changes to the proposed amendments. Following final action by the PHC at a future meeting, the Department will be able to file the final amendments with the Secretary of the Commonwealth.

The proposed amendments are attached to this memorandum.