The Commonwealth of Massachusetts

Executive Office of Health and Human Services

Department of Public Health

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To: Commissioner Robert Goldstein, MD, PhD

Members of the Public Health Council

From: James G. Lavery, Director, Bureau of Health Professions Licensure

David E. Johnson, Director, Drug Control Program

Date: February 14, 2024

RE: Overview of Proposed Amendments to Regulation 105 CMR 722.000: *Dispensing Procedures for Clinic and Hospital Pharmacies*

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1. **Introduction**

The purpose of this memorandum is to provide the Public Health Council (PHC) with information about proposed amendments to 105 CMR 722.000: *Dispensing Procedures for Clinic and Hospital Pharmacies,* for public comment*.* This regulation sets forth standards governing dispensing procedures for clinic and hospital pharmacies. This regulation was last updated in May 2017 as part of regulatory review, pursuant to former Governor Baker’s Executive Order 562, which required review of all existing regulations.

1. **Summary of Proposed Changes**

These new proposed amendments update the regulation to better align with other Department regulations and with updated state law:

105 CMR 722.020 (Definitions)

* A definition was added for “Hospital,” in alignment with the statutory definition.

105 CMR 722.091 (Clinic Pharmacies)

* This section was amended to align with the Bureau of Health Care Safety and Quality (BHCSQ) regulatory requirement that clinics must have pharmacy services listed on their facility license in order to dispense controlled substances. This language is being added here to eliminate existing confusion among clinics about the relationship between the clinic regulation (105 CMR 140) and the Massachusetts Controlled Substances Registration (MCSR) process.
* This section was further amended to note an exception to the on-site pharmacy rule for clinics dispensing naloxone only, and for family planning clinics, as recently recognized in [M.G.L c. 94C, § 9(e)](https://www.mass.gov/info-details/mass-general-laws-c94c-ss-9#(e)-:~:text=administration%20or%20dispensing.-,(e),-Notwithstanding%20subsection%20(b), as amended in 2021.

1. **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 approval by the PHC at a future meeting, the Department will file the final amendments with the Secretary of the Commonwealth.

The proposed amendments to 105 CMR 722.000 are attached to this memorandum.