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To: Commissioner Robert Goldstein and Members of the Public Health Council From: James G. Lavery, Director, Bureau of Health Professions Licensure

David E. Johnson, Director, Drug Control Program

Date: October 11, 2023

RE: Request of the Public Health Council to Approve Proposed Emergency Amendments to Regulation 105 CMR 700.000 (*Implementation of M.G.L. c. 94C*)

# Introduction

The purpose of this memorandum is to request that the Public Health Council (PHC) approve emergency amendments to 105 CMR 700.000, *Implementation of M.G.L. c. 94C*.

The amendments require emergency approval in order to ensure an accessible, expedited process for patients to obtain a hormonal contraceptive patch or self-administered oral hormonal contraceptive from pharmacists in the Commonwealth, which is necessary to remove barriers individuals currently face in accessing this important component of reproductive health. A summary of proposed changes is set out below.

# Background

The proposed amendment implements M.G.L. c. 94C, §19F, as inserted by section 42 of chapter 28 of the acts of 2023 (the FY2024 general appropriations act), which authorizes pharmacists to prescribe and dispense hormonal contraceptive patches and self-administered oral hormonal contraceptives to any person, irrespective of evidence of a previous prescription for a hormonal contraceptive patch or self-administered oral hormonal contraceptive, subject to certain requirements under the statute.

The proposed amendments were drafted in consultation with the Board of Registration in Medicine, Board of Registration in Pharmacy, and MassHealth, and in consideration of American College of Obstetricians and Gynecologists (ACOG) guidelines when considering a

timeframe for a patient to have had a provider visit prior to subsequent pharmacists’ prescription of a hormonal contraceptive.

# Proposed Emergency Amendments

The addition of section 105 CMR 700.004(B)(15) creates an exemption for registered pharmacists who are prescribing and dispensing hormonal contraceptive patches and self- administered oral hormonal contraceptives from the requirement to have a Massachusetts Controlled Substance Registration for this prescriptive practice.

Based upon consultation with the groups mentioned above and consideration of ACOG guidelines, the amendment does not include an interval, after a pharmacist prescribes and dispenses, within which to provide evidence of a visit with a clinical provider, as no evidence of a follow-up is needed for a pharmacist to perform this activity safely and independently.

These amendments ensure pharmacists and patients can realize the advantages of this more accessible, expedited process for obtaining a hormonal contraceptive patch or self-administered oral hormonal contraceptive in the Commonwealth.

Additional information and implementation guidance on the statute and regulation will be issued upon promulgation.

# Next Steps

The Department respectfully requests that the Public Health Council vote to approve the proposed amendments to the regulation, 105 CMR 700.000, on an emergency basis, which

allows the amendments to take effect upon filing with the Secretary of State’s office for a 90-day period while the regulatory process continues, as provided for in the state’s administrative procedure laws, outlined in M.G.L. c. 30A.

The proposed amendments to 105 CMR 700.000 are attached to this memorandum.