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To: Commissioner Monica Bharel, MD 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: September 11, 2019

RE: Informational Briefing on Proposed Amendments to 105 CMR 721.000 (*Standards for Prescription Format and Security in Massachusetts*)

I. Introduction

The purpose of this memorandum is to provide the Public Health Council (PHC) with information on proposed amendments to 105 CMR 721.000, *Standards for Prescription Format and Security in Massachusetts*. This regulation sets forth standards governing prescription format and security.

The Bureau of Health Professions Licensure's (BHPL) Drug Control Program (DCP), within the Department of Public Health (Department), drafted these amendments to implement provisions of chapter 208 of the acts of 2018 (chapter 208 or CARE Act) establishing a new requirement that most Schedule II through Schedule VI and device prescriptions be issued in a federally-compliant, secure electronic format (ePrescribing) rather than orally, on paper or through an electronic system that does not meet federal security requirements. Proposed amendments also implement CARE Act updates to the partial fill law, while improving the efficiency and consistency of the regulation for both the Department and the regulated community.

Summary of the Amendments

Like other states which have implemented ePrescribing requirements, the primary purpose of Massachusetts' ePrescribing legislation is to improve controlled substance safety and security by reducing prescription forgery and drug diversion. However, the breadth of the Massachusetts law exceeds the ePrescribing requirements of other states in that it includes prescriptions for Schedule VI medications (i.e., prescription drugs that are not federally controlled, such as antibiotics, blood thinners, and chemotherapy) and prescriptions for devices, including insulin pumps; pacemakers, intraocular lenses, and crutches.

The Massachusetts ePrescribing law includes several exceptions to the requirement to prescribe electronically:

- prescriptions issued by veterinarians;
- prescriptions issued or dispensed in circumstances where electronic prescribing is not available due to temporary technological or electrical failure;
- prescriptions issued by practitioners who have been granted a time-limited waiver after demonstrating economic hardship or technological limitations that are not reasonably within the control of the practitioner, or other exceptional circumstance;
- prescriptions issued or dispensed in emergency situations as defined by the Commissioner, including situations where the electronic prescription requirement would result in a delay that would adversely impact the patient's medical condition;
- prescriptions that cannot be issued electronically under federal or state law or regulations; and
- prescriptions issued outside the jurisdiction of the Commonwealth.

The law also authorizes the Commissioner to establish additional exceptions determined necessary, provided the legislature receive at least 90 days' notice before any additional exceptions take effect.

The Department put forth for public comment four additional exceptions deemed necessary for the implementation process that align with other states' implementation of ePrescribing requirements:

- Compounded drug preparations;
- Expedited Partner Therapy;
- Individuals with a Massachusetts Controlled Substances Registration (MCSR) for Schedule VI only; and
- Durable Medical Equipment

II. Public Comment

A public hearing was held on June 27, 2019, and the public comment period closed July 2, 2019. The comments received are summarized in the attached chart and below in this memo. Upon review of all public comments received and further review of other states' experience implementing required ePrescribing, DPH recommends additional changes to the regulation that:

- Delay full implementation of the ePrescribing mandate until January 1, 2021;
- Clarify pharmacists' role related to filling prescriptions submitted under an ePrescribing exception or waiver;
- Expand the Schedule VI exception from individuals with a MCSR for Schedule VI only to all Schedule VI medications;
- Clarify prescriptions that cannot be issued electronically under federal or state law or regulations, including those prescriptions the FDA requires contain elements, such as an attachment, that are not supported through current ePrescribing systems; and
- Add two additional ePrescribing exceptions as follows:
 - Prescriptions for residents of nursing homes through January 1, 2023, or such later date as determined by the Department; and

- Prescriptions issued in response to a declared public health emergency, diseases dangerous to public health, or other urgent public health matter.

Proposed Post-Comment Section by Section Changes

105 CMR 721.010 (Definitions)

- To bring greater clarity and consistency to the regulation, definitions were added for Compounded Drug Preparation, Electronic Prescribing System, Electronic Prescription, Electronic Transmission, ePrescribing, Prescription, and Written Prescription. In addition, clarifications were made to the existing definitions of Electronic Signature and Registration Number.
- By amending the regulation to provide an ePrescribing exception for all Schedule VI prescriptions (*see* 105 CMR 721.070 (ePrescribing Exceptions)), the terms Confidentiality, Content Integrity and Technical Non-repudiation are no longer used in the regulation and have been removed. In addition to removing these definitions, DPH has updated the definition of Written Prescription by removing language classifying prescriptions issued through Schedule VI-only prescribing systems as “Written Prescriptions”; the ePrescribing exception for all Schedule VI prescriptions makes the reference unnecessary.
- For ease of reference, the definition of Emergency Situations has been moved from 105 CMR 721.060, the Emergency Situations section, to 105 CMR 721.020, the Definitions section.
- Definitions were added for the terms Failover and Oral Prescription to coincide with a new provision providing a process by which a Schedule VI prescription, which begins as an ePrescription and is received as a computer-generated facsimile (i.e., a “Failover”), may be considered a valid oral prescription (*see* 105 CMR 721.020 (Prescription Formats) for additional information).

105 CMR 721.020 (Prescription Formats):

Delayed Implementation:

Amendments to 105 CMR 721.000 put forth for public comment indicate that all prescriptions must be electronic prescriptions, except for those issued under one of the exceptions included at 104 CMR 721.070, and outlines the required format of prescriptions. Commenters emphasized that prescribers need additional time to implement this new-to-many technology. This view is consistent with implementation of electronic prescription legislation in other states, where delays were experienced.

In response to this feedback, DPH has amended the regulation to provide a one-year grace period, allowing all electronic, written and oral prescriptions meeting the format requirements of 105 CMR 721.020 to remain valid during calendar year 2020. As of January 1, 2021, only those written and oral prescriptions issued under one of the e-prescribing exceptions or a waiver will be valid.

This delay will also allow time for the CMS mandated switch to the National Council for Prescription Programs' (NCPDP) electronic prescribing standards contained within NCPDP's SCRIPT Version 2017071, which contains important new features such as an expansion of the "directions for use" field from 140 to 1,000 characters, a Compounding Module for electronically prescribing compounded medications, pharmacy to pharmacy e-transfer, and others. This switch will occur in early 2020 and while it will address numerous issues prescribers and pharmacies currently face when ePrescribing, this one year grace period provides time for the updated SCRIPT version to be fully vetted and operationalized by electronic health record (EHR) and electronic prescriptions for controlled substances (EPCS) vendors.

Facsimile Prescriptions:

Commenters requested a broad exception for any prescription issued or dispensed under circumstances where electronic prescribing is unavailable or impracticable due to unforeseen circumstances outside a practitioner's or health care facility's control. While many of these technological challenges or other circumstance where ePrescribing is unavailable or impractical are addressed through statutory exceptions for instances where electronic prescribing isn't available due to temporary technological or electrical failure and Emergency Situations, the major prescription transmission vendor noted that the network engine, due to temporary technological or electrical failure, converts and transmits Schedule VI ePrescriptions to a pharmacy as computer-generated fax prescriptions.

In light of this information, DPH has included a definition for "Failover" and amended this section to include criteria for when a Failover can be considered a valid oral prescription. This authorized format only applies to a Schedule VI prescription, but excludes those Schedule VI medications determined by the Commissioner to carry a bona fide potential for abuse (currently, this determination applies to gabapentin only).

105 CMR 721.030 (Security Standards for Prescriptions Issued by Prescribers Registered to Prescribe Schedule VI Controlled Substances Only):

In the draft regulations put forward for public comment, security requirements for Schedule VI-only prescribing systems were included for those prescribers who are registered to prescribe Schedule VI medications only, in accordance with an exception in 105 CMR 721.070(A)(9).

Commenters requested a broad exception for all Schedule VI medications, as these medications have been determined to have a low potential for abuse, misuse or diversion, and systems have evolved separately from those developed for federally controlled substances and solve issues unrelated to prescribing. For example, one such system for radiopharmaceuticals includes an electronic ordering module meeting the stringent nuclear requirements 21 CFR 1311 Subpart C.

In response to these comments, DPH has included an exception to ePrescribing for all Schedule VI medications (*see* 105 CMR 721.070 (ePrescribing Exceptions)). By adding this exception, this section is no longer necessary and has been removed.

105 CMR 721.040 (Invalid Prescription):

This section was originally amended to clarify when an electronic prescription is invalid.

Language has been added confirming Failovers, as defined, are valid prescriptions provided the Failover prescription meets the criteria set forth at 105 CMR 721.020(G).

105 CMR 721.060 (ePrescribing in Emergency Situations) and 105 CMR 721.065 (Special Procedures for Emergency Prescribing of Schedule II Controlled Substances):

105 CMR 721.060 was originally amended to define emergency situations during which a prescriber is not required to issue an electronic prescription. The draft regulation put forward for comment moved requirements for prescribing and dispensing Schedule II medications in emergency situations to a new section, 105 CMR 721.065.

Commenters expressed confusion about the distinction between 105 CMR 721.060 and 105 CMR 721.065, and indicated reporting non-compliance with follow-up prescription requirements to the Department of Justice is duplicative of additional reporting requirements to DEA and DPH. Commenters also questioned the two-day electronic follow-up requirement for Schedule II prescriptions.

- In response to these comments, the definition of “Emergency Situation” was moved to the Definitions section and the requirements for prescribing and dispensing Schedule II medications in emergency situations were restored to 105 CMR 721.060, which had been moved to a now deleted section, 105 CMR 721.065.
- Pursuant to comments received, DPH amended the provision requiring notice of prescriber non-compliance with prescription follow-up requirements to align with federal law, which only requires notification to the DEA if the prescribing practitioner fails to follow-up an emergency oral schedule II prescription with delivery of a written prescription to the pharmacist within seven business days.
- The two-day electronic follow-up prescription requirement has been removed, as Schedule II oral prescriptions fall within the emergency situation exception in 721.070, which requires a seven-day written follow-up prescription.
- In response to comments and to reduce stakeholder confusion, 105 CMR 721.065 has been removed and its provisions restored within 105 CMR 721.060.

105 CMR 721.070 (ePrescribing Exceptions):

New or Modified Exceptions:

The draft regulation includes a new section, to implement M.G.L. c. 94C, § 23(h), as amended by the CARE Act, that outlines the statutory exceptions to electronic prescribing, namely prescriptions for expedited partner therapy, compounded drug preparations, Schedule VI prescriptions issued by prescribers holding Schedule VI-only MCSRs, and durable medical equipment. In response to comments, four additional exceptions were added pursuant to M.G.L. c. 94C, § 23(h)(vii), as they were determined necessary to implement the ePrescribing law while maintaining its intent to reduce diversion and fraud. These additional exceptions are as follows:

- **Exception- All Schedule VI prescriptions:** Public comments emphasized the need to exclude all Schedule VI medications, rather than only providing an exception for

prescribers registered to prescribe only Schedule VI medications, as Schedule VI medications are unlikely to be abused or diverted.

DPH has amended the exception for prescriptions issued by prescribers who hold Schedule VI-only MCSRs to provide an ePrescribing exception for all Schedule VI prescriptions in response to technological and financial concerns ranging from prescribing radiopharmaceuticals, hospice and cancer infusions, and routine treatments provided by small pediatric and dermatologic practices. This is consistent with other states that have implemented ePrescribing laws, and will improve implementation in Massachusetts while preserving drug security and minimizing fraud.

- **Exception- FDA-required elements:** Consistent with section 40 of Chapter 208 of the Acts of 2018, the regulation put forward for public comment included an exception from mandatory ePrescribing when a prescription cannot be issued electronically under federal or state law or regulations.

Commenters requested an exception for prescriptions issued for drugs in which the federal Food and Drug Administration (FDA) requires the prescription to contain certain elements, such as attachments and attestations, that are not able to be accomplished with electronic prescribing which are not likely to be addressed by CMS-required system upgrades set to go into effect in 2020.

In response, DPH has amended the regulation by clarifying that the ePrescribing exception for prescriptions that cannot be issued electronically under federal or state law or regulations to also include prescriptions that are not able to be transmitted through electronic prescriptions systems due to FDA required elements that cannot be accomplished with electronic prescribing. This is consistent with mandatory ePrescribing implementation in other states (15 out of 28 states with ePrescribing laws include this exception).

- **Exception- Public health emergency, disease response and prevention; and urgent public health matters:** Commenters outlined a need for either an explicit exception for prescriptions for close contact prophylaxis or broader, more inclusive language so that local outbreaks of communicable diseases, such as pertussis or meningitis, may be quelled at the outset before they become widespread emergency situations.

In response, DPH has amended the regulation to provide an exception that will broadly cover instances where close contact prophylaxis must occur within 48 hours and other emergent instances that may not yet be anticipated. This exception also covers dispensing by standing order, such as the statewide naloxone standing order, or dispensing by non-patient specific prescriptions for unidentified patients. Under this exception, the Department would be able to direct prescribers to provide oral and written prescriptions and orders directly to patients for dispensing and administration in instances determined necessary for the public health.

- **Temporary Exception- Residents of nursing homes:** Commenters requested a broad-based exception for skilled nursing facilities until such time as the Commonwealth’s eHighway allows for seamless interoperability of health systems. It was stated that no long term care facilities currently have ePrescribing capability and that nursing homes are “closed systems” that function more like hospitals with medication orders than outpatient settings where patients receive and fill prescriptions independently.

In response to these comments, DPH has amended the regulation to provide a three-year exception for prescriptions issued to residents of nursing homes, as none of these facilities is currently capable of compliance due to a lack of electronic prescribing systems. In the interim, a closed relationship between prescriber, facility and long term care pharmacy provides security safeguards. Providing a three-year exception will allow sufficient time for nursing homes to implement compliant systems. A majority of states with mandatory ePrescribing laws include similar exceptions.

Clarifying pharmacists’ role related to prescriber exceptions and waivers:

Commenters requested language indicating pharmacists are not responsible to verify whether an otherwise valid written, oral, or faxed prescription was issued pursuant to an exception or waiver.

As has been done in New York, Maine, and Connecticut, DPH included language indicating pharmacists are not required to verify whether a prescription falls under an e-prescribing exception or practitioner waiver, provided the prescription is otherwise a valid written or oral prescription.

105 CMR 721.075 (Time Limited Waivers of Electronic Prescribing Requirements):

DPH’s draft regulation included a new section to implement M.G.L. c. 94C, § 23(h)(iii) that establishes a time-limited waiver process for prescribers and health care facilities who demonstrate economic hardship, or technological limitations that are not reasonably within their control.

Commenters requested the regulation be amended to include “other exceptional circumstance” as allowed for in chapter 94C section 23 (h) (iii) of the General Laws, as amended by section 40 of Chapter 208 of the Acts of 2018.

DPH has amended the regulation consistent with statute to also include the clause “or other exceptional circumstances” which was inadvertently omitted from the original proposal.

III. Summary/Requested Action

DCP requests that the Public Health Council approve these amendments today for final promulgation on December 27, 2019, upon the completion of the 90-day notice period to the legislature, in accordance with section 40 of chapter 208 of the acts of 2018.