Massachusetts Department of Public Health

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Final Regulatory Amendment Presentation
105 CMR 721.000
Standards for Prescription Format and Security in Massachusetts

Public Health Council
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Summary of Regulation

105 CMR 721.000, *Standards for Prescription Format and Security in Massachusetts*:

- Outlines Drug Control Program (DCP) format and security requirements for valid prescriptions in Massachusetts;
- Provides special procedures for emergency prescription of Schedule II controlled substances; and
- Establishes requirements for issuing and dispensing partial prescriptions.

Summary of Proposed Amendments

The proposed amendments to this regulation implement provisions of Chapter 208 of the Acts of 2018 (the CARE Act), which:

- Update partial fill requirements for Schedule II prescriptions, consistent with federal opioid legislation (The SUPPORT Act).
- Require all prescriptions for controlled substances and devices to be generated and transmitted through federally compliant electronic prescribing systems.
- Set forth several exceptions to allow written and oral prescriptions.
- Specifically authorize the Commissioner to establish additional exceptions as necessary.

Summary of Post-Comment Changes

Upon review of all public comments and other states' experience implementing required ePrescribing, DPH has made additional changes to the regulation that:

- Extend a grace period on implementation of mandated ePrescribing until January 1, 2021;
- Clarify pharmacists' role in filling prescriptions submitted under an exception or waiver;
- Expand exception for Schedule VI-only prescribers to exclude all Schedule VI medications;
- Clarify exception for prescriptions that cannot be issued electronically under federal or state law or regulations to include those for which the FDA requires certain elements, such as an attachment, that are not supported by ePrescribing systems; and
- Add the following two ePrescribing exceptions:
  - Prescriptions for residents of nursing homes through January 1, 2023; and
  - Prescriptions issued in response to a declared public health emergency, diseases dangerous to public health, or other urgent public health matter.

Controlled Substance Schedules

- Controlled Substances are placed in a Federal schedule based on
  - currently accepted medical use in treatment in the United States,
  - relative abuse potential, and
  - likelihood of causing dependence when abused.

- **Schedule I Controlled Substances** have no currently accepted medical use in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse. Examples: heroin, LSD, peyote, & Ecstasy.
- **Schedule II Controlled Substances** have a high potential for abuse which may lead to severe psychological or physical dependence. Examples: most opioids and stimulants like Adderall® & Ritalin®.
- **Schedule III Controlled Substances** have a lesser potential for abuse than Schedules I or II, and abuse may lead to moderate or low physical dependence or high psychological dependence. Examples: buprenorphine, ketamine & anabolic steroids
- **Schedule IV Controlled Substances** have a lower potential for abuse than Schedule III. Examples: Xanax®, Valium® & Ativan®
- **Schedule V Controlled Substances** have a lower potential for abuse than Schedule IV and consist primarily of preparations containing limited quantities of certain narcotics. Examples: Robitussin AC®, and Phenergan with Codeine®.

- **Schedule VI Controlled Substances (in Massachusetts)** include all other prescription drugs that are not included in Schedules I-V. Examples: antibiotics , naloxone, sterile saline, chemotherapy treatments, oxygen and epi-pens.

Post-Comment Changes: Definitions

SUMMARY OF PRE-COMMENT CHANGES

- Definitions added for clarity and consistency: Compounded Drug Preparation, Electronic Prescribing System, Electronic Prescription, Electronic Transmission, ePrescribing, Prescription, and Written Prescription; and
- Definitions clarified: Electronic Signature and Registration Number.

SUMMARY OF PROPOSED FINAL AMENDMENT

- As a result of amending the regulation to provide an ePrescribing exception for all Schedule VI prescriptions:
  - Definitions removed as no longer used in regulation: Confidentiality, Content Integrity and Technical Non-repudiation; and
  - Definition of Written Prescription amended to remove reference to prescriptions issued through Schedule VI-only prescribing systems as unnecessary.
- Definition of Emergency Situation moved from 105 CMR 721.060, *Emergency Situations*, to 105 CMR 721.010, *Definitions,* for ease of reference; and
- Definitions added for Failover and Oral Prescription to coincide with a new provision in 105 CMR 721.020, *Prescription Formats,* allowing a Schedule VI prescription received as a computer-generated facsimile (i.e., a "Failover") to be considered a valid oral prescription.

These changes are necessary to implement ePrescribing requirements.

Post-Comment Changes: Prescription Formats – One-Year Grace Period

SUMMARY OF PRE-COMMENT CHANGES

- Outlined the required format of prescriptions, including requirement that all prescriptions must be electronic as of January 1, 2020, unless issued under an exception.

SUMMARY OF PROPOSED FINAL AMENDMENT

- Provides 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 a waiver or one of the e-prescribing exceptions will be valid.
- Allows testing and operability of CMS-mandated switch to the National Council for Prescription Programs' (NCPDP) electronic prescribing standards (NCPDP's SCRIPT Version 2017071) by electronic health record (EHR) and electronic prescriptions for controlled substances (EPCS) vendors.
  - NCPDP's SCRIPT Version 2017071 contains important new features, including:
    - Expansion of "directions for use" field from 140 to 1,000 characters;
    - A Compounding Module for electronically prescribing compounded medications; and
    - Pharmacy to pharmacy e-transfer.

This change will ease prescriber burdens and allow a more manageable time frame to comply.

Post-Comment Changes: Prescription Formats – Failovers

SUMMARY OF PRE-COMMENT CHANGES

- Outlined the required format of prescriptions and indicated that all prescriptions must be electronic, unless issued under one of the exceptions included at 105 CMR 721.070.

SUMMARY OF PROPOSED FINAL AMENDMENT

- Amends this section to include criteria for considering a Failover as a valid oral prescription.
  - only applies to a Schedule VI prescription, but excludes those determined by the Commissioner to carry a bona fide potential for abuse (currently, this determination applies to gabapentin only).
  - arises when a prescriber issues a Schedule VI ePrescription, and, due to a defect in transmission, it is converted and transmitted to a pharmacy as a computer-generated fax.
- Addition of this authorized format recognizes commenter concerns about situations when electronic prescribing is unavailable or impracticable due to unforeseen circumstances outside a prescriber's or health care facility's control.

This change allows Schedule VI computer-generated fax prescriptions to be valid oral prescriptions.

Post-Comment Changes: Schedule VI Prescriptions

SUMMARY OF PRE-COMMENT CHANGES

- Included security requirements for Schedule VI-only prescribing systems used by prescribers, under an exception in 105 CMR 721.070, who are registered to prescribe Schedule VI medications only
- Added exception for Schedule VI prescriptions issued by prescribers holding Schedule VI-only MCSRs.

SUMMARY OF PROPOSED FINAL AMENDMENT

- Includes an ePrescribing exception in 105 CMR 721.070 for all Schedule VI medications.
- By adding this exception, the security requirements of 105 CMR 721.030 are no longer necessary and have been removed.

This change eliminates an unnecessary provision.

Post-Comment Changes: ePrescribing in Emergency Situations

SUMMARY OF PRE-COMMENT CHANGES

- Revised to define emergency situation, when prescriber is not required to issue an ePrescription.
- Moved requirements for prescribing and dispensing Schedule II medications in emergency situations to a new section, 105 CMR 721.065, *Special Procedures for Emergency Prescribing and Dispensing of Schedule II Controlled Substances*.

SUMMARY OF PROPOSED FINAL AMENDMENT

- Moved definition of "Emergency Situation" to 105 CMR 721.010, *Definitions*.
- Restored requirements for prescribing and dispensing Schedule II medications in emergency situations within 105 CMR 721.060, *ePrescribing in Emergency Situations.*
- Deleted 105 CMR 721.065 to reduce stakeholder confusion.
- Amended provision requiring duplicative notice that a prescriber did not provide written follow-up within seven business days to align with federal law, which only requires notification to the DEA.
- Removed two-day electronic follow-up prescription requirement, as Schedule II oral prescriptions fall within the emergency situation exception in 721.070, which requires a seven-day written follow-up.

This change recognizes situations when ePrescribing could delay or adversely impact a patient's medical care

Post-Comment Changes: ePrescribing Exceptions

SUMMARY OF PRE-COMMENT CHANGES

- Added new section, 105 CMR 721.070, *ePrescribing Exceptions*, outlining statutory exceptions to electronic prescribing, pursuant to M.G.L. c. 94C, § 23(h)(vii), including prescriptions for expedited partner therapy, compounded drug preparations, Schedule VI prescriptions issued by prescribers holding Schedule VI-only MCSRs, and durable medical equipment.

SUMMARY OF PROPOSED FINAL AMENDMENT

- Adds four additional exceptions that were determined necessary to implement the ePrescribing law while maintaining its intent to reduce diversion and fraud.
  - All Schedule VI prescriptions;
  - Prescriptions with FDA-required elements;
  - Prescriptions for residents of nursing homes; and
  - Prescriptions issued pursuant to a public health emergency, disease response and prevention, and urgent public health matters.

This change recognizes situations where ePrescription requirements are inconsistent with clinical practice and system capabilities.

Post-Comment Changes: ePrescribing Exceptions – All Schedule VI Prescriptions

SUMMARY OF PRE-COMMENT CHANGES

- Added exception for Schedule VI prescriptions issued by prescribers holding Schedule VI-only MCSRs.

SUMMARY OF PROPOSED FINAL AMENDMENT

- Expanded ePrescribing exception in 105 CMR 721.070 to apply to all Schedule VI medications.
- This change recognizes commenter concerns over applying ePrescribing requirements to Schedule VI medications, including:
  - Medications have been determined to have a low potential for abuse, misuse or diversion.
  - ePrescribing will disrupt practices and systems that have evolved separately from those developed for federally controlled substances and may solve issues unrelated to prescribing.

This change allows dispensing of electronic, written and oral Schedule VI prescriptions.

Post-Comment Changes: ePrescribing Exceptions – Prescriptions with FDA-required elements

SUMMARY OF PRE-COMMENT CHANGES

- Included statutory exception for prescriptions that cannot be issued electronically under federal or state law or regulations.

SUMMARY OF PROPOSED FINAL AMENDMENT

- Clarifies this exception to include prescriptions for which the federal Food and Drug Administration (FDA) requires certain elements, such as an attachment, that are not supported by ePrescribing systems.

This change recognizes situations where ePrescription requirements are incompatible with FDA requirements.

Post-Comment Changes: ePrescribing Exceptions – Prescriptions for Residents of Nursing Homes

SUMMARY OF PRE-COMMENT CHANGES

- Added new section outlining statutory and additional exceptions to electronic prescribing, including prescriptions issued under a waiver.

SUMMARY OF PROPOSED FINAL AMENDMENT

- Adds an exception for prescriptions for residents of nursing homes through January 1, 2023.
- A closed relationship between prescriber, facility and long term pharmacy provides sufficient security for prescriptions that never end up in the resident's possessions.
- A three-year exception will allow sufficient time for nursing homes to implement compliant systems.

This change recognizes that these facilities are not currently capable of compliance due to a lack of electronic prescribing systems.

Post-Comment Changes: ePrescribing Exceptions –
Public Health Emergency, Disease Response and Prevention, and Urgent Public Health Matters

SUMMARY OF PRE-COMMENT CHANGES

- Added new section outlining statutory and additional exceptions to electronic prescribing, including prescriptions issued under a waiver.

SUMMARY OF PROPOSED FINAL AMENDMENT

- Adds exception for prescriptions issued pursuant to a public health emergency, disease response and prevention, and urgent public health matters.
- The department could authorize prescribers to provide oral and written prescriptions and orders directly to patients for dispensing and administration in instances determined necessary for the public health.
- This exception will cover
  - instances where close contact prophylaxis must occur within 48 hours;
  - dispensing by standing order, like naloxone;
  - dispensing by non-patient specific prescriptions for unidentified patients; and
  - other emergent instances that may not yet be anticipated.

This change recognizes situations where ePrescription requirements could delay or prevent emergency response.

Post-Comment Changes: Pharmacists' Role and Responsibility

SUMMARY OF PRE-COMMENT CHANGES

- Added new section outlining statutory and additional exceptions to electronic prescribing, including prescriptions issued under a waiver.

SUMMARY OF PROPOSED FINAL AMENDMENT

- Includes language indicating that pharmacists are not required to verify whether a prescription falls under an ePrescribing exception or waiver, provided the prescription is an otherwise valid written or oral prescription.

This change recognizes that pharmacists must be able to rely on the apparent validity of prescriptions.

Post-Comment Changes: Waivers

SUMMARY OF PRE-COMMENT CHANGES

- 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.

SUMMARY OF PROPOSED FINAL AMENDMENT

- Consistent with statute, adds the clause “or other exceptional circumstances,” which was not included in the original proposal.

This change recognizes that waivers are available in circumstances other than economic hardship, or technological limitations that are not reasonably within a prescriber’s control.

Next Steps

- We request approval of the proposed amendments.
- Following approval, we will seek promulgation from the Secretary of the Commonwealth, after a notice period.
- Beginning in October 2019 and continuing throughout 2020, we will provide sub-regulatory guidance and extensive in-person and web-based outreach and education to prescribers, pharmacists and other stakeholders.

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Thank you for the opportunity to present this information today.

For more information regarding prescription format and security, please find the relevant statutory language and the full current regulation here:

https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXV/Chapter94C

https://www.mass.gov/files/documents/2017/09/11/105cmr721.pdf

Please direct any questions to:

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