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# Massachusetts Department of Public Health

## **Draft Proposed Amendments to 105 CMR 700.000 Implementation of M.G.L. c. 94C**

**Public Health Council  
February 13, 2019**

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# Summary of Regulation

105 CMR 700.000, *Implementation of M.G.L. c. 94C:*

- Sets forth consistent standards for the safety, security and storage of controlled substances;
- Outlines Drug Control Program (DCP) requirements for practitioners and facilities to receive a Massachusetts Controlled Substances Registration (MCSR); and
- Manages oversight of the Massachusetts Prescription Awareness Tool (MassPAT) through the Prescription Monitoring Program (PMP).

# Summary of Amendments

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

- Authorize first responders or state or municipal emergency preparedness agencies to convey or exchange excess naloxone with another such agency prior to expiration. (Section 32)
- Require a warrant for most law enforcement personnel prior to receiving PMP data in connection with a bona fide specific controlled substance investigation. (sections 42-44)
- Authorize PMP data use agreements with prescribers and healthcare facilities to facilitate Electronic Medical Record (EMR) integration. (section 45 and 46)
  - To allow prescriber access to PMP data directly through EMRs to include patient-specific PMP data as a clinical note in a patient's EMR.
  - To allow healthcare facilities to perform PMP data compilation, analysis or visualization for patient diagnostic, treatment or care coordination purposes.
- Require prescribers to utilize the PMP every time a benzodiazepine is prescribed, rather than only the first time. (section 41)

# Regulation Changes: Naloxone Exchange

Amendments to 105 CMR 700.004(B), *Exemptions from Requirement to Register*, are proposed to implement section 32 of the CARE Act, which allows municipalities and non-municipal public agencies registered under M.G.L. c. 94C §7(g) to convey or exchange naloxone between one another to ensure availability of unexpired naloxone.

Proposed changes:

- Exempt these entities from registration as distributors for purposes of exchanging or conveying naloxone;
- Require all naloxone exchanges or conveyances to be recorded in a memorandum between the agencies, as required by the CARE Act.
  - *DPH guidance will communicate requirements for recording each exchange in the memo, such as date of exchange and the drug lot number*

*This change will allow for the preservation of the naloxone supply in the community.*

# Regulation Changes: PMP Warrants

Sections 42-44 of the CARE Act require most law enforcement agencies obtain a warrant prior to receiving PMP data in connection with a bona fide specific controlled substance investigation.

- Proposed changes to 105 CMR 700.012(C), *Prescription Monitoring Program – Privacy, Confidentiality and Disclosure* codify this requirement by referencing the applicable section of the PMP law, M.G.L. c. 94C, §24A(f).

*This change improves security and ensures the appropriate use of the PMP.*

# Regulation Changes: PMP Data Use Agreements

Amendments to 105 CMR 700.012(C), *Prescription Monitoring Program – Privacy, Confidentiality and Disclosure*, are proposed to implement section 45 of the CARE Act, which amends the PMP law, M.G.L. c. 94C, §24A, to allow prescribers to access PMP data directly through MassPAT or an Electronic Medical Record (EMR) and include patient-specific PMP data in a patient’s EMR, in accordance with a data use agreement with the Department.

Proposed changes:

- Add a definition for MassPAT to clarify this new provision.
- Insert a subsection authorizing PMP data provided to prescribers to be accessed directly through MassPAT, in compliance with state and federal health care privacy regulations, and in accordance DPH guidance and a data use agreement.
  - Allows such data to be used to create and maintain summary , patient-specific, data as a clinical note of the specific clinical encounter;
  - Limits use of data to diagnostic, treatment or care coordination purposes; and
  - Prohibits the data to be retained separately from the clinical note.

*This amendment improves the ability of health care systems to fully integrate the PMP with EMRs.*

# Regulation Changes: PMP Data Use Agreements (continued)

Amendments to 105 CMR 700.012(E), *Prescription Monitoring Program –Electronic Transmission of PMP Information*, are proposed to implement section 46 of the CARE Act, which amends the PMP law to allow healthcare facilities to integrate secure software systems with EMRs in order to perform PMP data compilation, analysis or visualization for specific patient diagnostic, treatment or care coordination purposes only and in accordance with a data use agreement with the Department.

- Proposed changes insert a subsection authorizing data use agreements between the Department and health care facilities to integrate secure software with EMRs which:
  - Allows such data to be used to perform compilation, data analysis or visualization; and
  - Limits use of the data only for the purpose of diagnosis, treatment or coordinating care.

*This amendment improves data analytics and patient care capacity of health care systems.*

# Regulation Changes: Benzodiazepines

Amendments to 105 CMR 700.012(G), *Requirement to Utilize the Prescription Monitoring Program*, are proposed to implement section 41 of the CARE Act, which amends the PMP law to require prescribers to utilize the PMP every time a benzodiazepine is prescribed, rather than the first time only.

- Proposed changes add benzodiazepines to the list of controlled substances for which a prescriber must utilize the PMP every time.
  - This list was formerly limited to any narcotic drug in Schedule II or III.

*Department data has demonstrated that the combination of benzodiazepines and Schedule II and III narcotics contributes to the increased risk of opioid overdose death.*

# Next Steps

- Following this initial presentation, a public hearing and comment period will be held.
- Approval of the proposed amendments, along with a review of public comments, will be requested at a subsequent meeting of the Public Health Council.



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# Massachusetts Department of Public Health

Thank you for the opportunity to present this information today.

For more information regarding Drug Control, including the Prescription Monitoring Program, please find the relevant statutory language and the full current regulation here:

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

<https://www.mass.gov/regulations/105-CMR-70000-implementation-of-mgl-c94c>

Please direct any questions to:

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