# Massachusetts Department of Public Health

# PUBLIC HEALTH COUNCIL

## November 9, 2022

***Please standby – the meeting will begin shortly***

***Today's presentation is available on the mass.gov/dph website under "Upcoming Events" by clicking on the November 9th Public Health Council listing***

Massachusetts Department of Public Health

# PUBLIC HEALTH COUNCIL MEETING NOVEMBER 9, 2022

Margret R. Cooke, Commissioner

# DPH at APHA Meeting


*Image: APHA.org*

# DPH at Massachusetts Health Officers Meeting


*DPH Office of Local and Regional Health at MHOA*

# Association for Behavioral Health Meeting


*Commissioner Margret Cooke (right) with BSAS Director Dee Calvert at the ABH Annual Meeting*

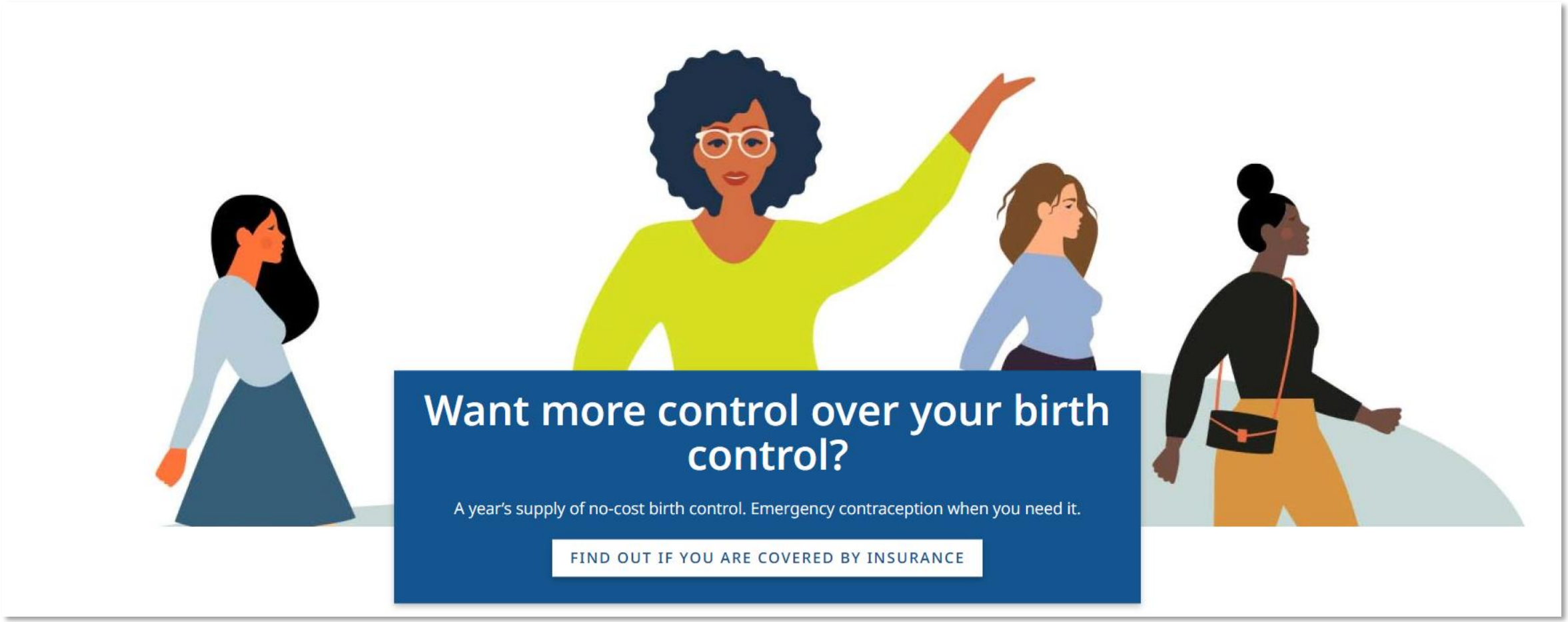
# Fall COVID-19 Booster Campaign


**Mass.gov/GetBoosted**

# Flu Season


**Mass.gov/FluShot**

# ACCESS Law Campaign




**Mass.gov/BirthControl**

# $15M from Community Health and Healthy Aging Funds

PRESS RELEASE

## Baker-Polito Administration announces awards of $15.9 million for community health

**Latest group of awardees to focus on increasing awareness of structural racism's impact on population health and addressing disparities**

FOR IMMEDIATE RELEASE:
10/24/2022

Department of Public Health

MEDIA CONTACT

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**BOSTON** — The Baker-Polito Administration today announced $15.9 million in grants to 24 nonprofit community-based organizations, cities and towns, and regional planning commissions to fund community health efforts in the Commonwealth.

These funds come from the Massachusetts Community Health and Healthy Aging Funds, administered by Health Resources in Action, Inc. (HRiA) in partnership with the Massachusetts Department of Public Health (DPH) and the Executive Office of Elder Affairs (EOEA). The 24 newly funded organizations are in addition to 32 organizations funded in 2020, bringing the total funding to $30.6 million for community health efforts statewide. These funds are made available to the Commonwealth for community health improvement initiatives from health care entities that engage in the Determination of Need process.

# ASTHO Interview – CDC Genomics Grant


Full segment: **newscast.astho.org**

Massachusetts Department of Public Health

# PUBLIC HEALTH COUNCIL MEETING NOVEMBER 9, 2022

Margret R. Cooke, Commissioner

# Determination of Need:

*Request by **UMass Memorial Health Care, Inc**. for a substantial capital expenditure and substantial change in service*

# Determination of Need:

*Request by **New England Baptist Surgery Center, LLC** for a freestanding ambulatory surgery center- transfer from an existing Hospital Based Department*

# Determination of Need:

*Request by **Mass General Brigham, Inc.** for an amendment for a significant change*

Massachusetts Department of Public Health

# Proposed Revisions to 105 CMR 700.000:

*Implementation of M.G.L. c. 94C*

**Lauren B. Nelson**
Acting Deputy Director, Bureau of Health Professions Licensure

**David E. Johnson**
Director, Drug Control Program

# Regulation Overview

**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 requirements for practitioners and facilities to receive a Massachusetts Controlled Substances Registration (MCSR); and
- Manages oversight of the Prescription Monitoring Program (PMP) and the Medication Administration (MAP).

- Amendments are needed to implement new state and federal controlled substances and health professions licensure laws enacted since the last version of this regulation and to clarify current requirements and available flexibilities.

# Proposed Amendment – 700.0001
*Electronic Prescribing*

## Summary of Current Standard

- Since this regulation was last amended, electronic prescribing  was mandated
- However, this regulation still has references to oral and written prescriptions

## Summary of Proposed Change

- Deletes the definitions of “written prescription” and “oral prescription” and deletes those terms throughout the regulation to recognize that prescriptions must be issued and transmitted electronically (ePrescribing)
- ePrescribing is the only permissible prescription format, unless otherwise noted in 105 CMR 721: *Standards for Prescription Format and Security*

# Proposed Amendment – 700.004(A) & (E)
*Prescriptive Practice*

## Summary of Current Standard

- An advanced practice registered nurse's prescriptive practice had to be supervised by a physician;
- An optometrist was limited to prescribing schedule VI controlled substances only; and
- The MCSR term was one year for all professions

## Summary of Proposed Change

- Authorizes registration of APRNs with newly independent prescriptive practice authority
- Expands optometrists' prescriptive practice authority to include all controlled substances schedules
- Adds provision to synchronize a registrant's controlled substances registration term with their underlying license term, allowing registrants to renew both authorizations at the same time

# Proposed Amendment – 700.004(K)
## *Medication Administration at Medical Specialty Camps*

### Summary of Current Standard

- DPH was authorized to promulgate regulations allowing medication administration to campers at medical specialty camps by:
  - student nurses (enrolled and recently graduated);
  - certified diabetes care and education specialists; and
  - trained medical specialty camp staff

### Summary of Proposed Change

- Establishes requirements for non-licensed staff at registered medical specialty camps to administer diabetes medications to campers
- In alignment with anticipated updates to 105 CMR 430: *Minimum standards for recreational camps for children: State sanitary code chapter IV*

# Proposed Amendment – 700.001; 700.004
*Controlled Substances Registration*

## Summary of Current Standard

- Facility definitions limited eligibility for an MCSR largely to traditional medical settings
- MCSRs authorized all controlled substances activities, regardless of facility type, population or need

## Summary of Proposed Change

- Clarifies registration requirements and limitations for practitioners and facilities by amending “Health Facility” and “Health Care Entity” definitions to:
  - Expand health facility MCSR eligibility to many facilities approved by the Bureau of Substance Addiction Services;
  - Permit custom authorization for MCSR-eligible non-“health facilities”; and
  - Clarify the particular activities permitted under each health care entity’s MCSR

# Proposed Amendment – 700.0001; 700.003(C)
*Administration of Rescue Medication*

## Summary of Current Standard

- Naloxone is the only "rescue medication" mentioned in the regulation, despite requests for an emergency administration process for inhalers and epinephrine auto-injectors
- Federal law prohibits administration of these prescription medications without a prescription or medication order

## Summary of Proposed Change

- Outlines process, within the bounds of federal law, to make it easier to respond to life-threatening emergencies in congregate care and other facilities by non-licensed staff;
- Specifies who is authorized to administer rescue medications; and
- Outlines requirements for entities, including municipalities, to acquire and handle rescue medications
  - Clarifies that municipalities and state agencies may purchase or acquire naloxone without an MCSR

# Proposed Amendment – 700.003(F)
*Medication Administration Program*

## Summary of Current Standard

- The MAP section is detailed and prescriptive, which may present a barrier to participation

## Summary of Proposed Change

- Clarifies and simplifies the MAP regulation
- Adds flexibility for MAP Certified staff by highlighting that other permissible routes of administration are permitted with additional training
- Codifies COVID-19 emergency order relative to rescue medication administration by trained, unlicensed direct care staff

# Proposed Amendment –700.003(M)
*Medication Administration – DOC/HOC Nurse Delegation*

## Summary of Current Standard

- Section 700.003 sets forth programs and requirements pursuant to the commissioner's authority under M.G.L. c. 94C, § 7(g)
- To ensure HOCs and DOCs had sufficient capacity to administer medication to inmates, COVID-19 Order No. 2022-08, was issued on 1/21/22

## Summary of Proposed Change

- Codifies current authorization under Commissioner's COVID-19 Order No. 2022-08, issued on 1/21/22 pursuant to the commissioner's authority under M.G.L. c. 94C, § 7(g)
- Authorizes licensed nurses employed at Massachusetts Houses of Correction and Department of Correction facilities to delegate medication administration, to trained but unlicensed personnel, pursuant to existing patient prescriptions and administration orders

# Proposed Amendment – 700.004(B)(6)
*Medication Administration – Pharmacy Technician Vaccine*

## Summary of Current Standard

- Pharmacists and pharmacy interns are authorized to administer vaccines and mental health and substance use disorder medications, pursuant to a prescription

## Summary of Proposed Change

- Clarifies authority for pharmacy staff to administer vaccine and mental health and substance use disorder medications
  - Includes pharmacy technician as pharmacy personnel authorized to administer vaccines
  - Lowers minimum patient age for administration from 9 to 5 years old, by agreement of the Pharmacy Board and the Bureau of Infectious Disease and Laboratory Sciences

# Proposed Amendment – 700.004(B)(9)

*Medication Administration – Pharmacist Medication Assisted Treatment*

## Summary of Current Standard

- Methadone was not included in the authorization for pharmacists to administer substance use disorder medications, because administration for maintenance at an Opioid Treatment Programs is conducted pursuant to medication orders, rather than prescriptions

## Summary of Proposed Change

- Authorizes pharmacists to administer Medication Assisted Treatment (MAT), including methadone, in registered Opioid Treatment Programs pursuant to medication orders

# Proposed Amendment – 700.004(G) & 700.009
## *Controlled Substance Research Registration*

### Summary of Current Standard

- Provisions governing registration of drug researchers are overly detailed and include several requirements to submit paper that the Drug Control Program investigators do not use to determine initial eligibility for a research MCSR

### Summary of Proposed Change

- Clarifies the purpose of research MCSRs to ensure drug security, under prerequisite federal authorization of the research itself
- Emphasizes that multiple research studies of the same category can be included on a single application
- Simplifies registration by requiring fewer paper copies
- Replaces requirement to submit research protocol, including protocol for Schedule I research, with availability only

# Proposed Amendment – 700.007
*Inspection Process*

## Summary of Current Standard

- Internal conflicts and overly detailed inspection requirements created confusion among practitioners and facilities subject to inspection
- This confusion led to registrants pushing back against unscheduled inspection requirements and access to inspectors

## Summary of Proposed Change

- Simplifies and clarifies inspection process to
  - make it more predictable and efficient
  - align with boards' investigatory procedures
  - support inspectors' work
- Clarifies that registrants must provide a disposition plan and records access
  - when going out of business with remaining controlled substances, or
  - upon MCSR suspension or revocation
- Underscores DPH's access during inspections and enforcement and states "failure to cooperate with an inspection" as grounds for revocation, suspension, or refusal to renew

# Proposed Amendment – 700.008
*Drug Incident Reporting*

## Summary of Current Standard

- Immediate reporting of drug incidents, including loss, theft and tampering, is required in a provision of the routine reporting section, potentially hiding this urgent, even life-threatening, reporting requirement

## Summary of Proposed Change

- Recognizes the urgency of reporting drug theft, loss or tampering by relocating immediate Drug Incident Report requirements out of the routine records section, 105 CMR 700.005(D), to its own section, 105 CMR 700.008, to increase visibility and priority of this reporting to registrants

# Proposed Amendment – 700.010
## *Dispensing Schedule VI Samples by Practitioners*

### Summary of Current Standard

- Procedures for practitioners to dispense schedule VI samples is outlined in this section
- In light of common questions about this section, amendments are necessary to emphasize this as the only way to dispense without a pharmacy

### Summary of Proposed Change

- Highlights the limited conditions under which practitioners may currently dispense medication from their place of business, permitting sample medication in schedule VI only
- Clarifies process for dispensing sample medication in schedule VI

# Proposed Amendment – 700.012
*Prescription Monitoring Program*

## Summary of Current Standard

- The PMP section ensures complete, accurate data collection from practitioners and facilities prescribing opioids and other drugs of abuse
- Many exemptions from the requirement to check the PMP before prescribing opioids or benzodiazepines are irrelevant, duplicative, or no longer needed for technical reasons

## Summary of Proposed Change

- Allows a clinical supervisor, as indicated in PMP, to review prescriptions issued by their supervisees
- Removes some exemptions from the requirement to check the PMP before prescribing opioids and benzodiazepines:
  - utilization requirement does not apply to some of the exempted activity
  - technological advances make other exemptions unnecessary

# Next Steps

- DPH will put forth the proposed amendments for posting for public hearing/public comment
- After the conclusion of the public comment period, DPH will review all comments and determine if any further substantive revisions to the regulation are needed

# Massachusetts Department of Public Health

**Thank you for the opportunity to present this information today.**

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

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

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

**Please direct any questions to:**
DCP.DPH@mass.gov

*Next Meeting:*

**December 14, 2022**