

Massachusetts Department of Public Health

Public Health Council Meeting January 15, 2025

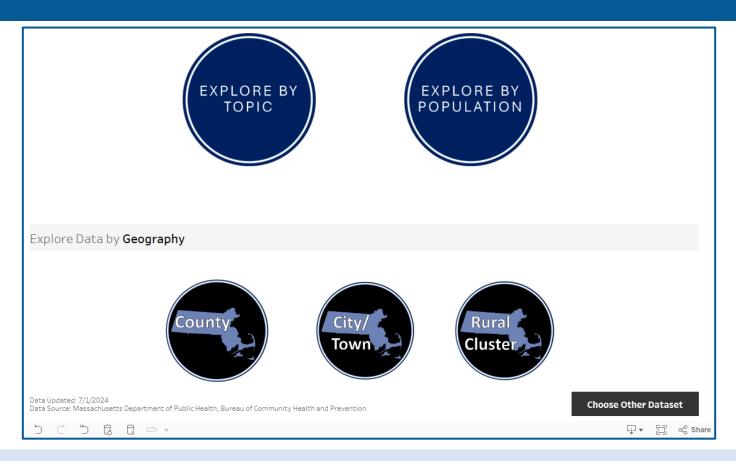
Robert Goldstein, Commissioner

Today's presentation is available on mass.gov/dph under "Upcoming Events" by clicking on the December 11 Public Health Council listing.

Martin Luther King Jr. Day



Community Health Equity Initiative updates



- Dashboard: mass.gov/info-details/community-health-equity-initiative-data-dashboard
- Community partner data request form: <u>forms.office.com/g/7pxW24Yc5K</u>
- Mental health report: mass.gov/info-details/ches-2023-mental-health

Barriers to Entry Project



Photo: DPH staff take part in workshop for the Reducing Barriers to Entry project.

As of December 2024:



87 solutions implemented

35 solutions in process

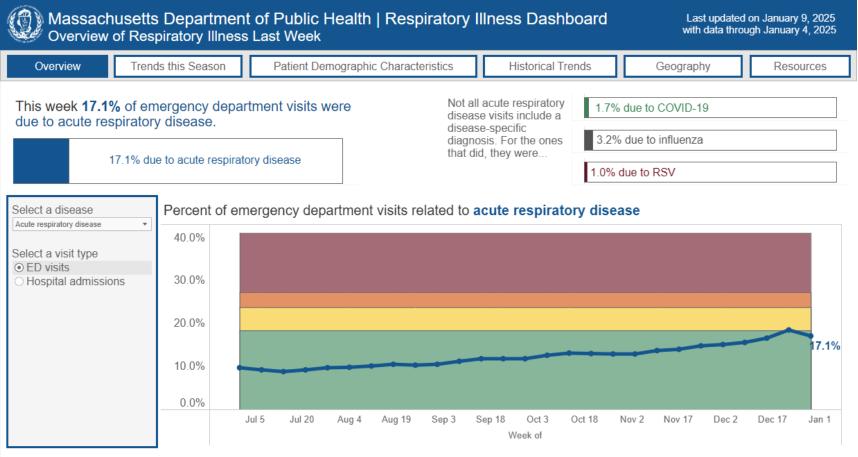
Emergency Regulations — Shield Law



<u>mass.gov/news/healey-driscoll-administration-adopts-</u> <u>emergency-regulations-protecting-reproductive-health-care</u>

Respiratory Illness





All data are preliminary and subject to change. Source: Bureau of Infectious Disease and Laboratory Sciences, Syndromic Surveillance program. Created by the Massachusetts Department of Public Health, Bureau of Infectious Disease and Laboratory Sciences, Division of Surveillance, Analytics and Informatics.

mass.gov/info-details/respiratory-illness-reporting

Avian Flu

cdc.gov/bird-flu



Current Situation

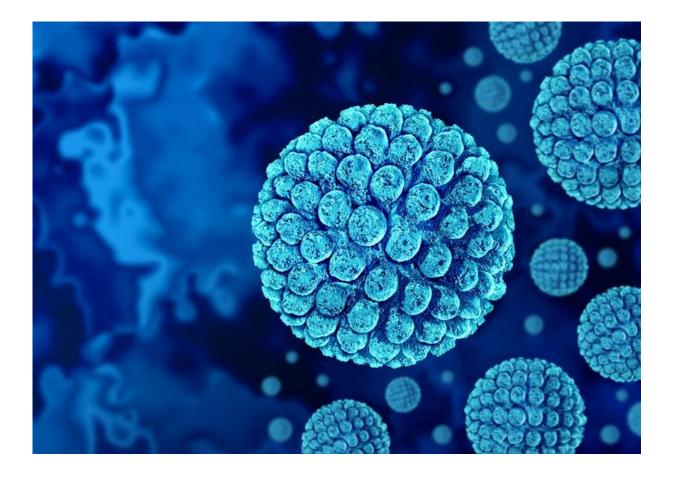
H5 bird flu is causing outbreaks in wild birds and poultry, other animals and sporadic human cases.



Current H5N1 Bird Flu Situation in Dairy Cows

A multi-state outbreak of HPAI A(H5N1) bird flu in dairy cows was first reported on March 25, 2024. Milk collected from all 95 dairy cattle herds in Massachusetts and tested monthly, remains negative.

Norovirus



Prevention tips

- Wash hands frequently hand with soap and water.
- Cook shellfish thoroughly and wash fruits and vegetables.
- Clean and disinfect potentially contaminated surfaces.
- ✓ Stay home when sick.



Massachusetts Department of Public Health

Determination of Need: *Atrius Health, Inc. Ambulatory Surgery Center*

Dennis Renaud Director - Determination of Need Program Bureau of Health Care Safety and Quality

Background Information

Atrius Health

- Physician led non-profit, multi-specialty group practice
- Health Policy Commission ("HPC") Certified Accountable Care Organization
- Member of the Fallon-Health-Atrius Health Care Collaborative, a MassHealth Accountable Care Organization ("MassHealth ACO")

Proposed Project Description

- Licensed freestanding ambulatory surgery center ("ASC") with six (6) operating rooms and associated support space located in Waltham, Massachusetts.
- Multi-specialty clinic offering otorhinolaryngology ("ENT"), general surgery, obstetrics and gynecology ("OB/GYN"), orthopedics, and podiatry.
- Value-based care model for surgical care to the Atrius patient panel.
- The capital expenditure for the Proposed Project is \$20,777,721. The Community Health Initiatives (CHI) contribution is \$1,038,886.05.

Six Factors of a Determination of Need (DoN) Application

Factor 1	Patient Need, Public Health Value and Operational Objectives
Factor 2	Health Priorities
Factor 3	Compliance
Factor 4	Financial Feasibility and Reasonableness of Expenditures and Costs
Factor 5	Relative Merit
Factor 6	Community Health Initiatives

Factor 1: Patient Need, Public Health Value and Operational Objectives - Requirements

In Factor 1, the Applicant must demonstrate the project will positively impact three areas:

1. Patient Panel Need

2. Public Health Value

3. Operational Objectives

The Applicant attributes need for the Proposed Project to the following:

- 1. Need to Expand Upon the Limited ASC Supply in Massachusetts
- 2. Need for Surgical Services Due to Growth in Population Requiring Outpatient Procedures (Including the Aging Population)
- 3. Need to Integrate ASC services into Atrius Health Continuum of Care

Factor 1: Patient Panel Need Analysis-cont.

1. Need to Expand Upon the Limited ASC Supply in Massachusetts

- Health Policy Commission's reports from June 2023 and February 2024
- Atrius Panel current surgical location
- ASC capacity by specialty
- Atrius surgical access at ASC's
- Lower the cost of care for the patient panel

Factor 1: Patient Panel Need Analysis-cont.

Proposed, Current and Approved ASCs in Waltham

	Surgical Offerings				
Proposed Atrius ASC	ENT, OB/GYN, General Surgery, Orthopedics, Podiatry				
	Center 1: Ophthalmology				
	Center 2: Ophthalmology				
Current ASCs in Waltham	Center 3: Fertility Services				
	Center 4: Pain Management				
	Center 5: Orthopedics and Podiatry				
Approved ASC in Waltham	Center 6: Orthopedic, Spine, Podiatry, and General Surgery				
Approved HOPD in Waltham	HOPD: Burn, Endoscopy, Oncology, Gynecology, Urology, Oral Maxillofacial, Orthopedic, Podiatry, Radiology, Reconstructive, and Neurosurgery				

Factor 1: Patient Panel Need Analysis- cont

2. Need for Surgical Services Due to Growth in Population Requiring Outpatient Procedures- Including the Aging Population

	Total	Under 50	Over 50	50+ % of Total
CY 2020	12,573	4,611	7,962	63.3%
CY 2023	15,396	5,783	9,613	62.4%
Change CY 2020 - 2023	2,823	1,172	1,651	-

Factor 1: Patient Panel Need Analysis- cont

3. Need to Integrate ASC services into the Atrius Health Continuum of Care

- Navigate a different set of providers where they have a time-bound limited, relationship
- Coordinate medical records sharing among outside providers and their Atrius Health team
- Undergo repeat diagnostic testing due to inefficient or lack of medical record-sharing
- Ensure follow-up with their Atrius Health primary care provider on their own

Factor 1: Patient Panel Need Analysis- cont

Utilization Rates for Each Year Based on Projections

	CY 2026	CY 2027	CY 2028	CY 2029	CY 2030
Projected Cases	3,428	6,233	6,358	6,485	6,615
Projected Hours	5,485	9,973	10,173	10,376	10,584
Utilization Rate	46%	83%	84%	86%	88%

Factor 1: Patient Panel Need Analysis-cont.

Factor 1: b) Public health value, improved health outcomes and quality of life; assurances of health equity

- Quality benefits
- Shorter surgical procedures and faster recovery times
- Less of an impact related to schedule disruptions

Factor 1: Patient Panel Need Analysis-cont.

Public Health Value: Health Equity

- High MassHealth population
- Health Equity Steering Committee
- Pride + Care

Factor 1: c) Efficiency, Continuity of Care, Coordination of Care

- 1. Benefits of a limited scope of care
- 2. Improved scheduling and shorter wait times
- 3. Management Agreement with Surgical Associates Inc.
- 4. Integrated Electronic Medical Record (EMR)

The expectation is that, using objective data, Applicants will address how the Proposed Project supports Commonwealth cost containment goals, improved public health outcomes, and delivery system transformation.

Factor 2: Cost Containment - Analysis

- "Foundational Element" to control costs
- Alternative Payment Arrangements "APMs"
- Anticipated Costs Savings in Year 2 = \$15.9 million

Factor 2: Improved Public Health Outcomes Analysis

Coordination of Care

Improved Patient Experience

Benefit the Aging Population

- 1. Culturally Competent Care
- 2. Training and DEI Resources
- 3. Screening for Health-Related Social Needs

The Determination of Need Program staff has determined that the Applicant has provided evidence of compliance and good standing with federal, state, and local laws and regulations.

Factor 4: Financial Feasibility and Reasonableness of Expenditures and Costs - Requirements

CPA Review

To assess Financial Feasibility in compliance with this Factor, the Applicant must provide evidence that it has sufficient funds available for capital and ongoing operating costs necessary to support the Proposed Project without negative impacts or consequences to the Applicant's existing Patient Panel. The report is certified by an Independent CPA. As a result of the CPA's analysis, the CPA concluded the following:

"Based upon our review, the Atrius Waltham Prospective Financial Schedules are based upon reasonable and feasible assumptions. Accordingly, we determined that the Atrius Waltham Prospective Financial Schedules (associated with the Proposed Project) are a reasonable expectation and based on feasible and sustainable financial projections which are not likely to have a negative impact on the Atrius patient panel or result in a liquidation of assets of the Applicant." When conducting an evaluation and articulating the relative merit determination, Applicants shall take into account, at a minimum, the quality, efficiency, and capital and operating costs of the Proposed Project relative to potential alternatives or substitutes, including alternative evidence-based strategies and public health interventions. <u>Alternative #1</u>: Maintain the status quo and continue providing outpatient surgeries at local hospitals and/or other ASCs.

- Applicant would not meet Patient Panel need for low-cost and highquality outpatient surgical services in the community.
- The anticipated positive impact the project would have on patient health outcomes and quality of life would not be achieved.
- This alternative would not result in integration of medical records and therefore, clinical and operational inefficiencies would persist.

<u>Alternative #2</u>: Alternative Sites Evaluation

- Not ideally located for the patient population
- Not appropriately sized for 6 operating rooms
- Greater implementation costs

This is a DoN project for a freestanding ASC that is not affiliated with a hospital, and therefore does not require the submission of CHI forms. Atrius Health, Inc. will fulfill Factor 6 requirements by directing their full CHI contribution to the Statewide Community Health and Healthy Aging Funds (CHHAF).

Conditions

In addition to the measures provided in Appendix 1, commencing with the approval of this DoN, and continuing for a period of five years after the Proposed Project is complete, the Holder shall provide the following information as part of the annual report.

a. Surgical procedure volume by Specialty

b.Payer-mix by specialty for surgical cases

Outcome Measures

- Clinical Quality Surgical Site Infection Rate
- Clinical Quality On-Time Starts
- Clinical Quality Hospital Transfer Rate
- Patient Satisfaction

Thank you for the opportunity to present this information today.

Please direct any questions to:

Dennis Renaud

Director, Determination of Need Program

Bureau of Health Care Safety and Quality

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Massachusetts Department of Public Health

Proposed Revisions to 105 CMR 210:

The Administration of Prescription Medications in Public and Private Schools

Karen Robitaille Director, School Health Program, Bureau of Community Health and Prevention 105 CMR 210: *The Administration of Prescription Medications in Public and Private Schools*, provides minimum standards for the safe and proper storage and administration of medications to students in the Commonwealth's public and non-public primary and secondary schools. It also permits school nurses to delegate responsibility for administration of medications to trained, nursing-supervised, unlicensed school personnel. The regulation addresses:

- The role of the medication program manager in overseeing and managing the medication program, beginning with registering with the Department of Public Health
- Training of unlicensed school personnel who may administer medication under the school nurse's supervision
- Procedures for students who administer their own medication
- Handling, storage, and disposal of medications
- A carve-out specific to administration of epinephrine for life-threatening allergic reactions

Medical practice and medication prescribing has advanced significantly since this regulation was last amended. There have also been increases in students with chronic conditions and medical complexity attending school. Key changes which we will discuss today are:

- Language updates and updated definitions
- Requirement for a Massachusetts Controlled Substance Registration (MCSR)
- Expanded access to emergency rescue medications
- Adding a carve-out for emergency rescue opioid antagonist (e.g., naloxone)
- Adding procedures for self-carry
- Outlining the authority in these regulations to conduct investigations

Proposed Revisions: Language Updates

Current regulation

- Title and content of the regulation refers to "prescription" medication
- Language is out of date
- Common terms are used inconsistently

Summary of proposed revisions

- The Department proposes to clarify that, because the Department's statutory authority is more expansive, this regulation applies to all medications, including over-the-counter medications as well as medical devices that deliver medications.
- The Department proposes changes to update the names of state agencies and make the language of the regulation gender neutral.
- The Department proposes changes to improve consistency of common terms throughout the regulation, such as caregiver, student, etc.

Proposed Revisions: Updated Definitions

Current regulation

- Some definitions are unnecessarily complex or unclear
- Key definitions are missing

Summary of proposed revisions

- The Department proposes removing an unnecessary hierarchy of school staff and instead refers to a new defined term, <u>Unlicensed School Personnel</u>.
- The Department proposes adding a definition of <u>Medication</u> which is specifically inclusive of over-the-counter medications.
- The Department proposes adding a definition of <u>Regular School Activities</u> which has been challenging to define for residential schools.

Proposed Revisions: Requirement for MCSR

Current regulation

 Unclear on whether or under what circumstances registration with the Department was required

Summary of proposed revisions

 The Department proposes changes to affirmatively require that all schools that store or administer medications must register with the DPH Drug Control Program for a Massachusetts Controlled Substances Registration (MCSR).

Current regulation

- Allows training on administration of epinephrine
- Does not address the current availability of pre-dosed, layperson-appropriate emergency rescue medications

Summary of proposed revisions

- The Department proposes changes that will allow training on, or delegation of, additional emergency
 rescue medications to unlicensed staff under certain circumstances. These may include, but are not
 limited to:
 - Naloxone or other FDA-approved opioid antagonists
 - Rescue inhalers
 - Glucagon (nasally administered)
 - Seizure rescue medications (nasally administered)
 - Nerve agent or nuclear fallout antidotes (e.g., atropine and pralidoxime chloride)

Proposed Revisions: Naloxone

Current regulation

• No specific section on emergency rescue opioid antagonists

Summary of proposed revisions

• The Department proposes adding a new section 210.011: Administration of *Emergency Rescue Opioid Antagonist* that is similar to the existing carve-out for epinephrine and allows unlicensed staff to administer undesignated emergency rescue opioid antagonists (e.g., from naloxboxes). This will increase access to emergency rescue opioid antagonists in school settings.

Proposed Revisions: Self-Carry

Current regulation

 Provisions related to self-administration of medications do not allow for students to self-carry medication, making self-administration impractical

Summary of proposed revisions

 The Department proposes changes to provide clear guidance for students to selfcarry medication.

Proposed Revisions: Investigations

Current regulation

• The Department provided minimal detail on its ability to conduct investigations

Summary of proposed revisions

• The Department proposes to add 210.017: Inspection and Investigation which clarifies the Department's ability to inspect school records and issue plans of correction to schools found to be out of compliance with the regulation.

Next Steps

- Following this presentation, DPH will hold a public hearing and will provide a public comment period.
- After the close of the public comment period, DPH will review comments, revise as necessary to reflect comments received, and then request approval of the final regulation at a subsequent meeting of the Public Health Council.

Thank you for the opportunity to present this information today.

For more information regarding the administration of medications in primary and secondary schools, please find the relevant statutory language and the full current regulation here:

Massachusetts Law:

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

https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXII/Chapter71/Section54B

Current Regulation:

https://www.mass.gov/regulations/105-CMR-21000-the-administration-of-prescription-medications-in-public-and-private-schools

Proposed Amendment:

mass.gov/dph/proposed-regulations

Please direct any questions to:

Karen.Robitaille3@mass.gov



Massachusetts Department of Public Health

Next Meeting: February 12, 2025