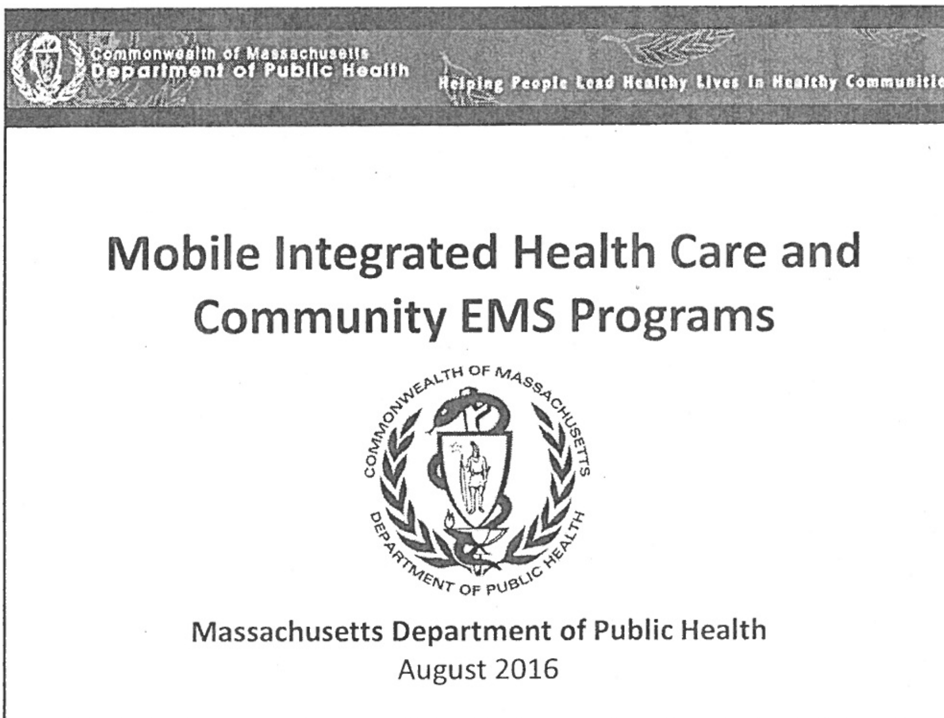


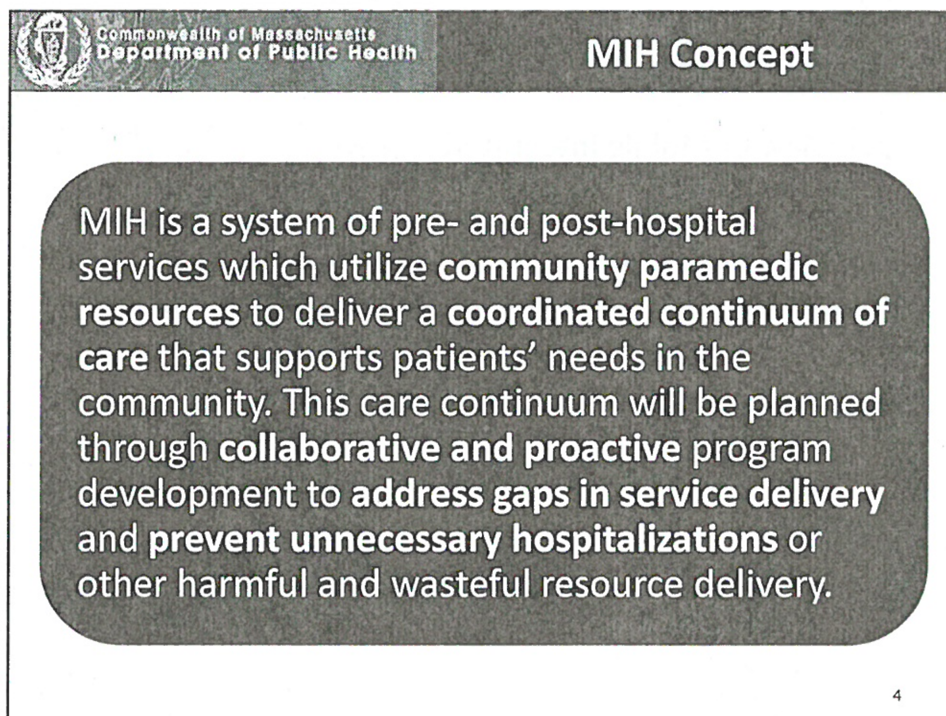
Commonwealth of Massachusetts Department of Public Health

Presentation Overview

- Overview of Mobile Integrated Health
- Proposed Regulation: 105 CMR 173.000 – Mobile Integrated Health Care and Community EMS Programs
- Next Steps
- Questions

2

Commonwealth of Massachusetts
Department of Public Health
MIH in Massachusetts
Massachusetts' Mobile Integrated Health (MIH) law was passed in 2015 (FY16 Budget), known as Chapter 111O
Designates DPH as the lead MIH agency
Charges DPH with reviewing and approving MIH programs and Community EMS programs
What does Ch. 111O do?
1. Formally establishes Mobile Integrated Health or "MIH" in Massachusetts
2. Creates "Community EMS" programs, opportunities for municipalities to partner with their EMS agencies
3. Establishes the Mobile Integrated Health Advisory Council (MIHAC) to support and advise DPH's implementation of the statute
3


Commonwealth of Massachusetts
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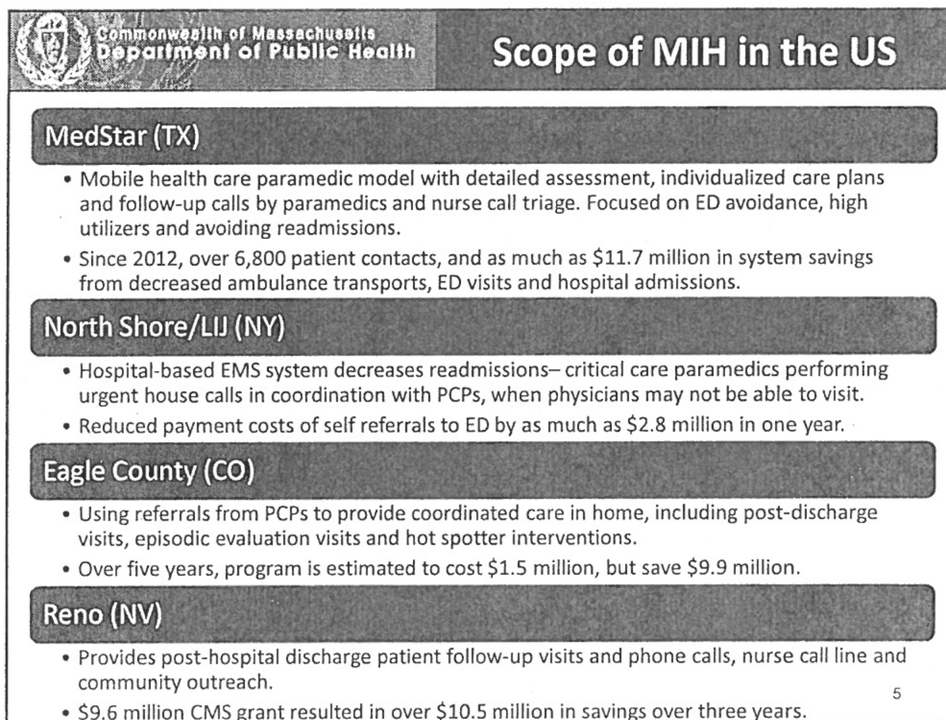
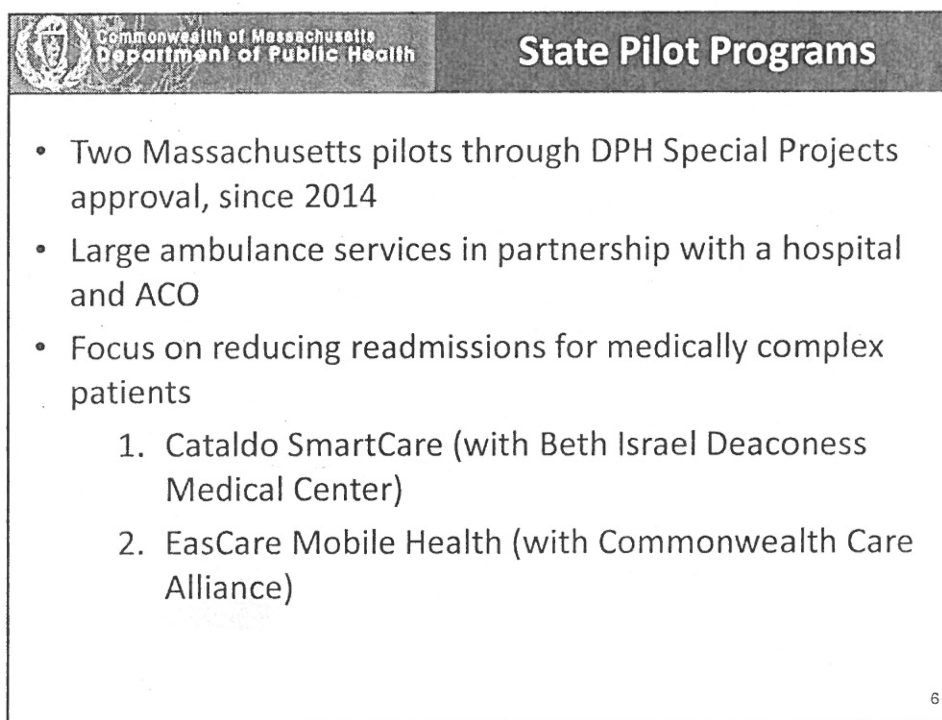
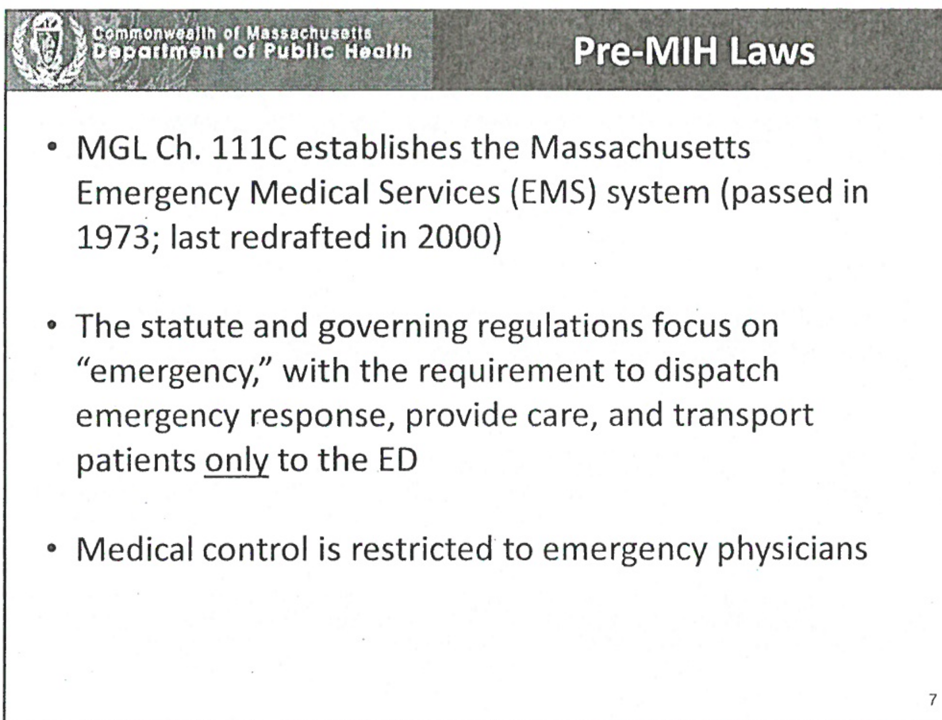
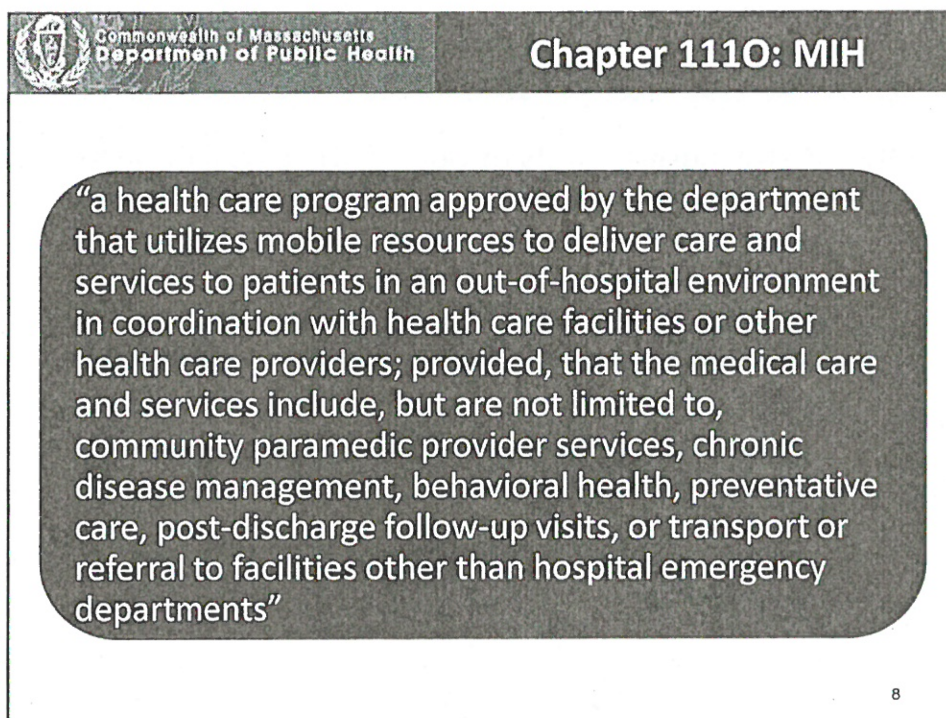
MIH Concept
MIH is a system of pre- and post-hospital services which utilize community paramedic resources to deliver a coordinated continuum of care that supports patients' needs in the community. This care continuum will be planned through collaborative and proactive program development to address gaps in service delivery and prevent unnecessary hospitalizations or other harmful and wasteful resource delivery.
4


Commonwealth of Massachusetts
Department of Public Health
Scope of MIH in the US
MedStar (TX)
• Mobile health care paramedic model with detailed assessment, individualized care plans and follow-up calls by paramedics and nurse call triage. Focused on ED avoidance, high utilizers and avoiding readmissions.
• Since 2012, over 6,800 patient contacts, and as much as $11.7 million in system savings from decreased ambulance transports, ED visits and hospital admissions.
North Shore/LIJ (NY)
• Hospital-based EMS system decreases readmissions– critical care paramedics performing urgent house calls in coordination with PCPs, when physicians may not be able to visit.
• Reduced payment costs of self referrals to ED by as much as $2.8 million in one year.
Eagle County (CO)
• Using referrals from PCPs to provide coordinated care in home, including post-discharge visits, episodic evaluation visits and hot spotter interventions.
• Over five years, program is estimated to cost $1.5 million, but save $9.9 million.
Reno (NV)
• Provides post-hospital discharge patient follow-up visits and phone calls, nurse call line and community outreach.
• $9.6 million CMS grant resulted in over $10.5 million in savings over three years.
5


Commonwealth of Massachusetts
Department of Public Health
State Pilot Programs
• Two Massachusetts pilots through DPH Special Projects approval, since 2014
• Large ambulance services in partnership with a hospital and ACO
• Focus on reducing readmissions for medically complex patients
1. Cataldo SmartCare (with Beth Israel Deaconess Medical Center)
2. EasCare Mobile Health (with Commonwealth Care Alliance)
6


Commonwealth of Massachusetts
Department of Public Health
Pre-MIH Laws
• MGL Ch. 111C establishes the Massachusetts Emergency Medical Services (EMS) system (passed in 1973; last redrafted in 2000)
• The statute and governing regulations focus on "emergency," with the requirement to dispatch emergency response, provide care, and transport patients only to the ED
• Medical control is restricted to emergency physicians
7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Chapter 111O: MIH
"a health care program approved by the department that utilizes mobile resources to deliver care and services to patients in an out-of-hospital environment in coordination with health care facilities or other health care providers; provided, that the medical care and services include, but are not limited to, community paramedic provider services, chronic disease management, behavioral health, preventative care, post-discharge follow-up visits, or transport or referral to facilities other than hospital emergency departments"
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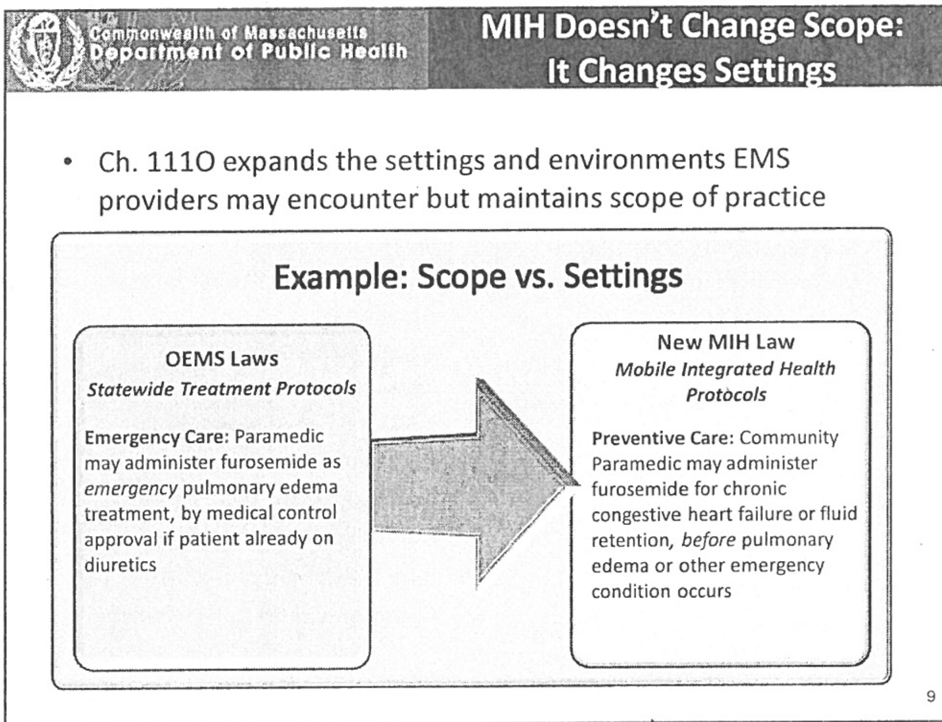

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Department of Public Health

- Provide coordinated continuum of care
- Address gaps in service delivery and prevent unnecessary hospitalizations
- Focus on partnerships
- Adhere to clinical standards and protocols; ensure appropriate training and competency in protocols
- Access qualified medical control and medical direction, including secure communication system
- Appropriately activate the 911 system
- Comply with privacy laws
- Appropriately collect and analyze data

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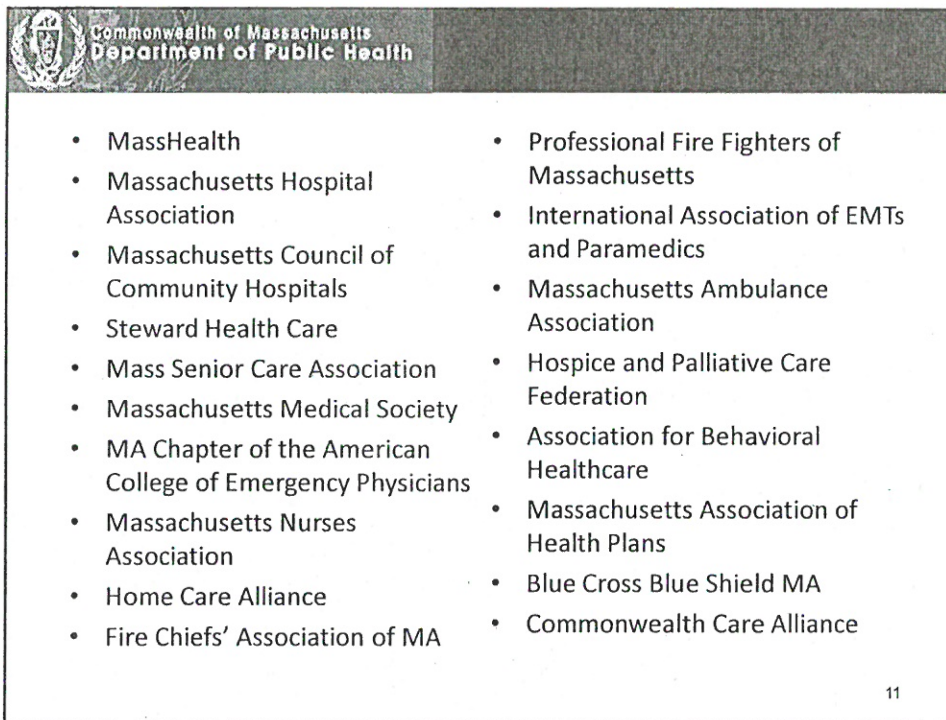
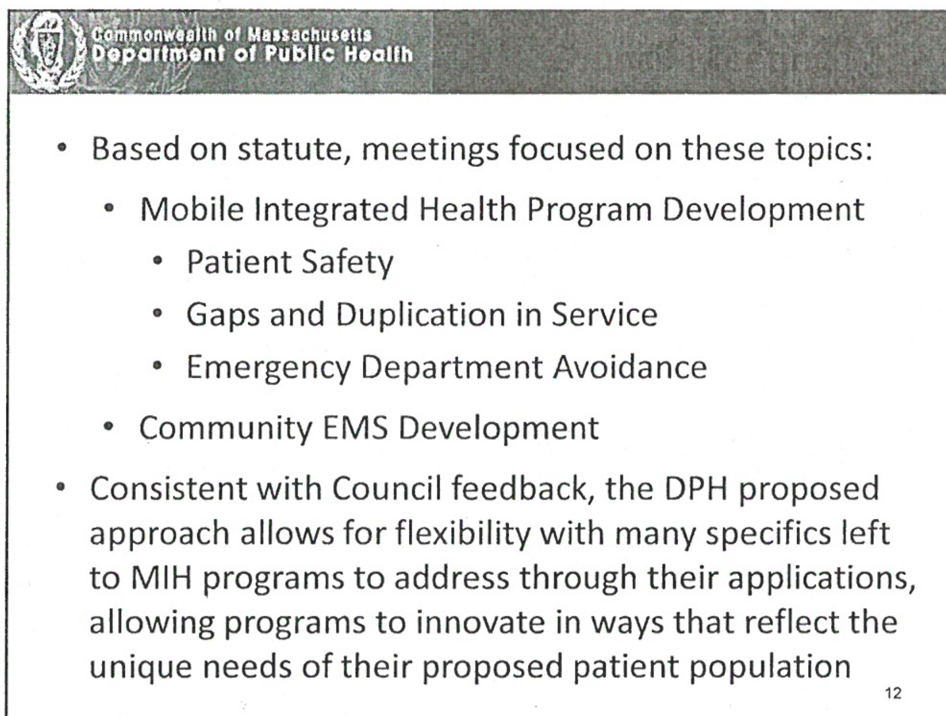

Commonwealth of Massachusetts
Department of Public Health
MassHealth
Massachusetts Hospital Association
Massachusetts Council of Community Hospitals
Steward Health Care
Mass Senior Care Association
Massachusetts Medical Society
MA Chapter of the American College of Emergency Physicians
Massachusetts Nurses Association
Home Care Alliance
Fire Chiefs' Association of MA
Professional Fire Fighters of Massachusetts
International Association of EMTs and Paramedics
Massachusetts Ambulance Association
Hospice and Palliative Care Federation
Association for Behavioral Healthcare
Massachusetts Association of Health Plans
Blue Cross Blue Shield MA
Commonwealth Care Alliance
11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Based on statute, meetings focused on these topics:
Mobile Integrated Health Program Development
Patient Safety
Gaps and Duplication in Service
Emergency Department Avoidance
Community EMS Development
Consistent with Council feedback, the DPH proposed approach allows for flexibility with many specifics left to MIH programs to address through their applications, allowing programs to innovate in ways that reflect the unique needs of their proposed patient population
12

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- Primary focus on Care/Patient Safety
  - Training
  - Treatment Protocols
  - Care Coordination
  - Complaints/Investigations
  - Informed Consent
  - Interoperability/Data Systems
  - Medical Direction
  - Patient Education
  - Program Renewal Frequency

13

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Department of Public Health

- MIH programs must:
  - **Address gaps in service delivery** and prevent unnecessary hospitalizations, or other harmful and wasteful resource delivery
  - Focus on partnerships, through contracts or otherwise, between health care providers and health care entities that promote coordination and utilization of existing personnel and resources **without duplication of services**

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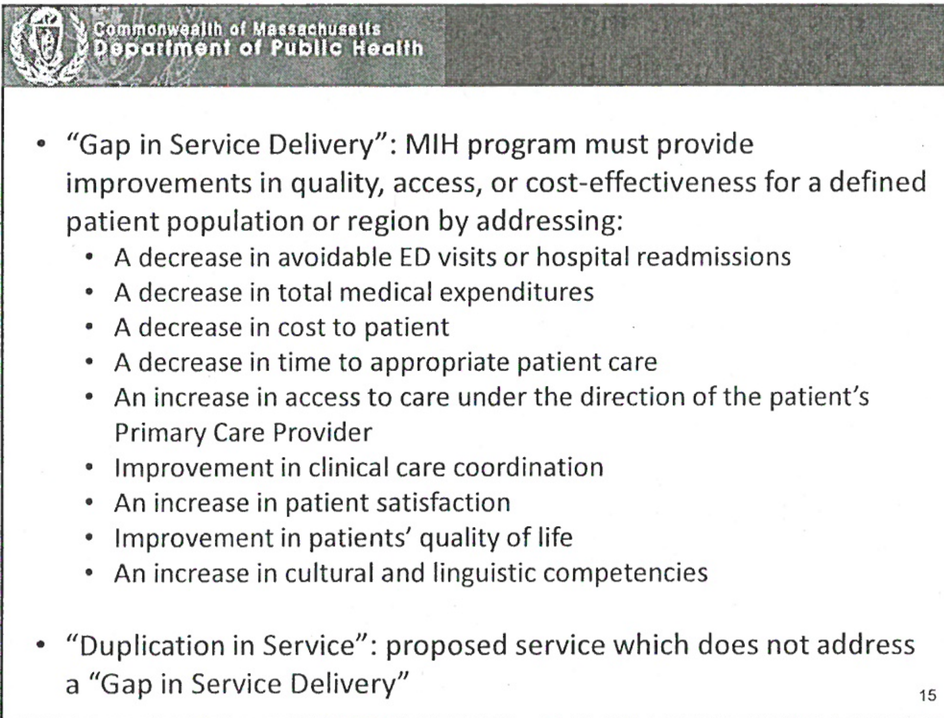
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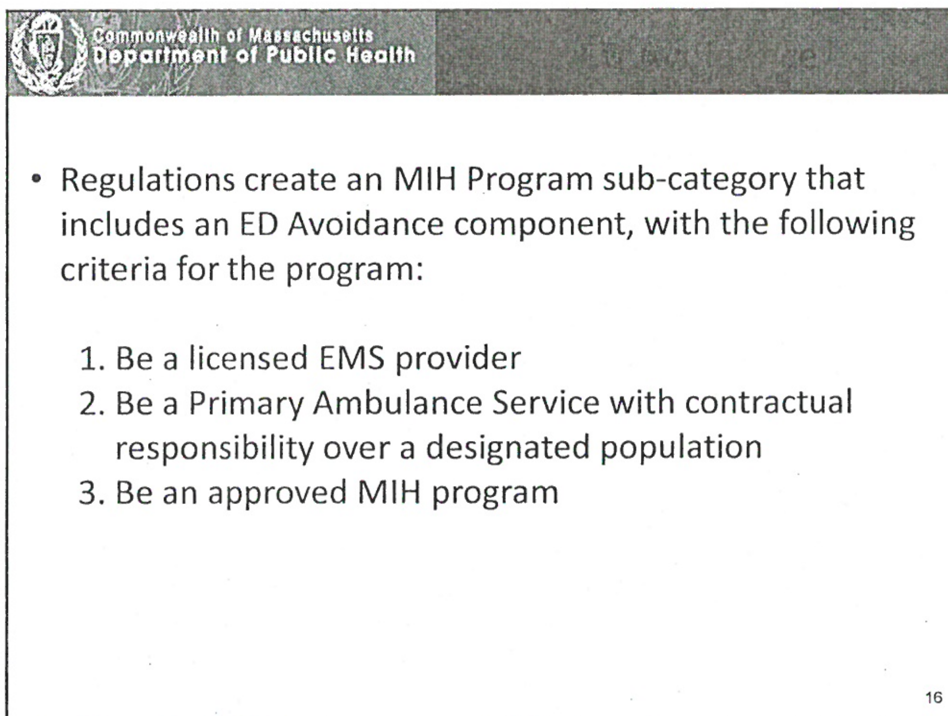
Department of Public Health
• "Gap in Service Delivery": MIH program must provide improvements in quality, access, or cost-effectiveness for a defined patient population or region by addressing:
• A decrease in avoidable ED visits or hospital readmissions
• A decrease in total medical expenditures
• A decrease in cost to patient
• A decrease in time to appropriate patient care
• An increase in access to care under the direction of the patient's Primary Care Provider
• Improvement in clinical care coordination
• An increase in patient satisfaction
• Improvement in patients' quality of life
• An increase in cultural and linguistic competencies
• "Duplication in Service": proposed service which does not address a "Gap in Service Delivery"
15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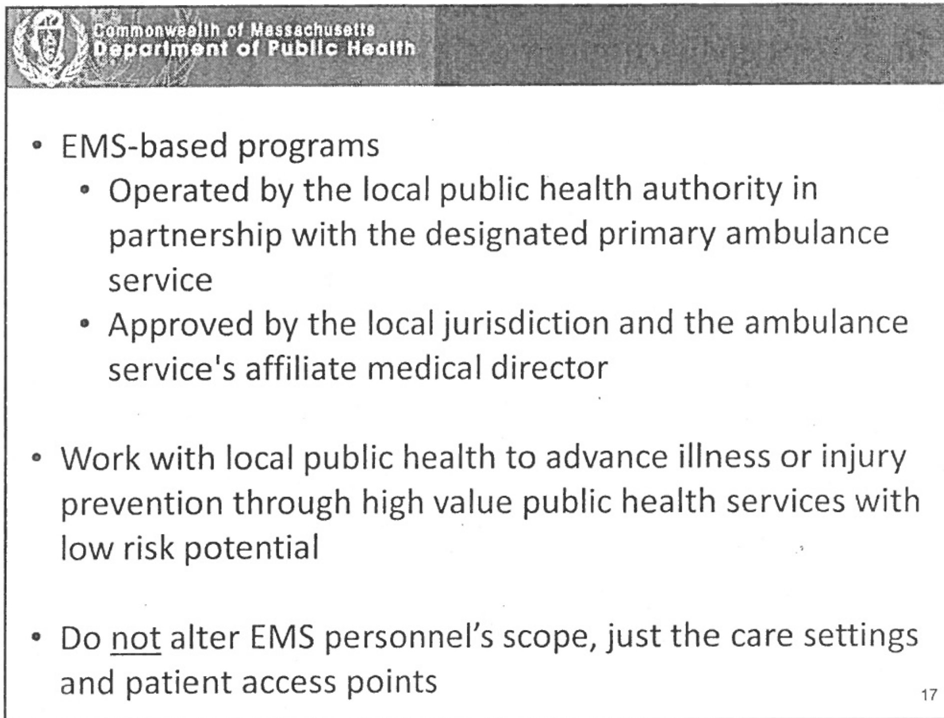
Department of Public Health
• Regulations create an MIH Program sub-category that includes an ED Avoidance component, with the following criteria for the program:
1. Be a licensed EMS provider
2. Be a Primary Ambulance Service with contractual responsibility over a designated population
3. Be an approved MIH program
16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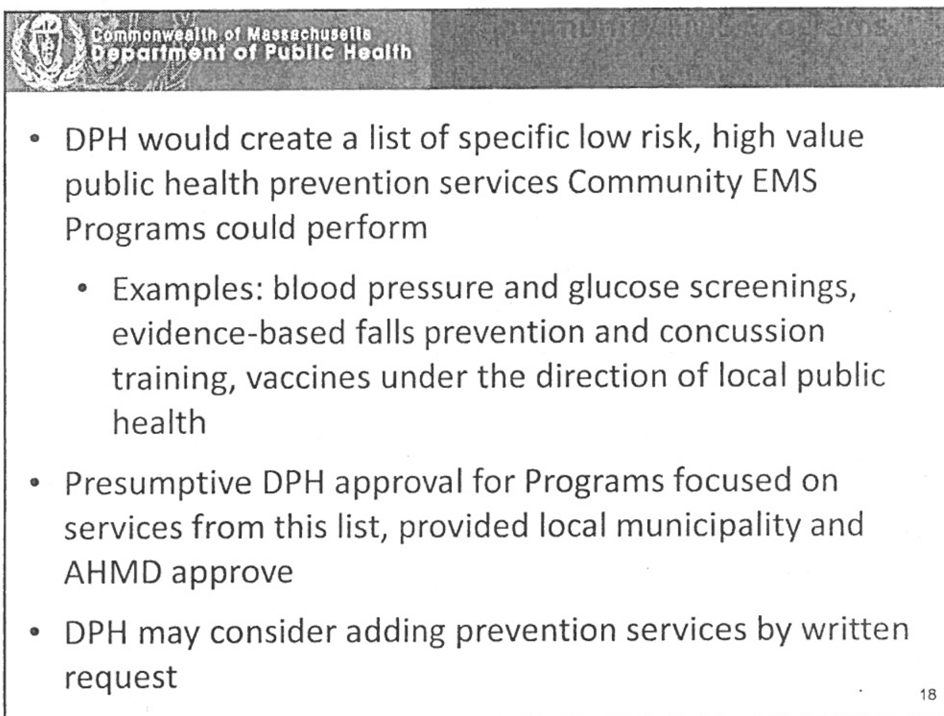
Department of Public Health
• EMS-based programs
• Operated by the local public health authority in partnership with the designated primary ambulance service
• Approved by the local jurisdiction and the ambulance service's affiliate medical director
• Work with local public health to advance illness or injury prevention through high value public health services with low risk potential
• Do not alter EMS personnel's scope, just the care settings and patient access points
17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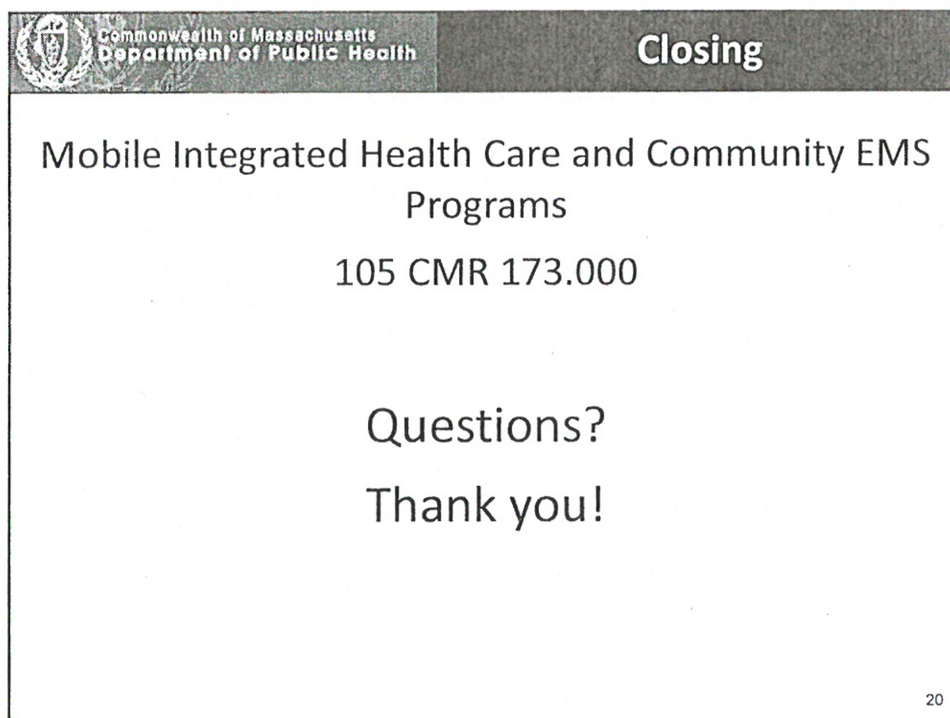
Department of Public Health
• DPH would create a list of specific low risk, high value public health prevention services Community EMS Programs could perform
• Examples: blood pressure and glucose screenings, evidence-based falls prevention and concussion training, vaccines under the direction of local public health
• Presumptive DPH approval for Programs focused on services from this list, provided local municipality and AHMD approve
• DPH may consider adding prevention services by written request
18

Commonwealth of Massachusetts
Department of Public Health
Next Steps
• Public hearing and a comment period will be held on the proposed regulation
• Upon review of public testimony, any further amendments to the regulation will be considered
• DPH will return to the PHC to report on testimony and any recommended changes to the regulation
• Following final action by the PHC, the Department will file the regulation with the Secretary of the Commonwealth for final promulgation
19


Commonwealth of Massachusetts
Department of Public Health
Closing
Mobile Integrated Health Care and Community EMS Programs
105 CMR 173.000
Questions?
Thank you!
20

SECTION

173.010: Scope and Applicability
173.020: Definitions
173.030: Application Process
173.040: Eligibility and Minimum Requirements for MIH Program Approval
173.050: Additional Eligibility and Minimum Requirements for Applicant MIH Programs with ED Avoidance Program Component
173.060: Eligibility and Minimum Requirements for Community EMS Program Approval
173.070: Certificate of Approval
173.080: Grounds for Denial, Revocation, or Non-renewal of Approval
173.090: Process for Denial, Revocation or Refusal of a Certificate of Approval for an MIH or Community EMS Program
173.100: Minimum Standards of Operation
173.110: Complaints
173.120: Inspections, Statement of Deficiency, Order to Correct
173.130: Summary Suspension of Certificate of Approval
173.140: Waiver of Requirements
173.150: Severability

173.010: Scope and Applicability

(A) Unless otherwise expressly permitted by the Department, no person or entity shall establish, maintain, or hold itself out as an MIH or Community EMS Program as defined in 105 CMR 173.020 without a valid Certificate of Approval issued by the Department in accordance with 105 CMR 173.000.

(B) 105 CMR 173.000 applies to:

(1) Every person who seeks a valid Certificate of Approval from the Department to establish an MIH or Community EMS Program; and,

(2) Every person who operates an MIH or Community EMS Program.

173.020: Definitions

As used in 105 CMR 173.000, the following definitions shall apply unless the context requires otherwise:

911 EMS Patient means an individual who has activated a Primary Ambulance Response by dialing the emergency telephone access number 911, or its local equivalent.

Ambulance Service means an entity licensed by the Department pursuant to 105 CMR 170.000 to provide emergency medical services.

Applicant means a Community EMS Applicant or an MIH Applicant as further defined hereunder:

Community EMS Applicant means a local public health authority seeking an initial Certificate of Approval or renewal thereof to operate a Community EMS Program in partnership with the local jurisdiction's designated primary ambulance service.

MIH Applicant means a health care entity or entities seeking an initial Certificate of Approval or renewal thereof to operate an MIH Program.

Authorization to Practice means the approval granted to EMS personnel by the medical director of the MIH or Community EMS Program approved by the Department pursuant to 105 CMR 173.000.

Certificate of Approval means written approval to operate an MIH or Community EMS Program pursuant to 105 CMR 173.000, subject to all terms and conditions contained in the Certificate of Approval

Commissioner means the Commissioner of Public Health or his or her designee.

Community EMS Program means a program developed and operated by the local public health authority in coordination with the local jurisdiction's designated primary ambulance service(s) and which utilizes the primary ambulance service's EMS personnel to provide community outreach and assistance in order to advance illness or injury prevention within the local jurisdiction(s) in accordance with 105 CMR 173.060. The Community EMS Program shall be approved by the local jurisdiction and the ambulance service's affiliate hospital medical director.

Community Paramedic means a person who:

(1) is certified as a paramedic pursuant to M.G.L. c 111C and 105 CMR 170.000: *Emergency Medical Services System*; and,

(2) has successfully completed an education program developed or selected by the medical director of the MIH Program for which the community paramedic is employed, as well as any additional training required by Department guidelines; and,

(3) is dispatched by an MIH Program to provide services or treatment to a patient within his or her scope of practice in accordance with clinical protocols of the program.

Department means the Department of Public Health, pursuant to M.G.L. c. 17, § 1.

Duplication of Services means a proposed service which does not address a gap in service delivery, pursuant to 105 CMR 173.040(A).

ED Avoidance means a component of an MIH Program pursuant to 173.050 that includes the applicable local jurisdiction(s)'s designated primary ambulance service(s) and, following primary ambulance response, assessment and consultation with on-line medical direction, utilizes paramedics with advanced training to manage the patient as an MIH patient in accordance with the provisions of 105 CMR 173.100(A) and Department guidelines.

EMS First Responder (EFR) means a person certified pursuant to 105 CMR 170.000: *Emergency Medical Services System* who has, at a minimum, successfully completed a course in emergency medical care approved by the Department pursuant to M.G.L. c. 111, § 201 and 105 CMR 171.000 *Massachusetts First Responder Training* and who provides emergency medical care through employment by, or in association with, a licensed EFR service at the first responder level.

EMS means emergency medical services, as defined in 105 CMR 170.000.

EMS First Response Service (EFR Service) means an entity licensed by the Department pursuant to 105 CMR 170.000 to provide rapid response and EMS.

EMS Personnel means EFRs and EMTs.

Emergency Medical Technician (EMT) means an EMT-Basic, Advanced EMT or Paramedic certified by the Department pursuant to 105 CMR 170.000.

Emergency Service Program (ESP) means a designated program under the direction of the Department of Mental Health and MassHealth Office of Behavioral Health that provides behavioral health crisis assessment, intervention and stabilization services through 4 service components: Mobile Crisis Intervention (MCI) services for youth, adult mobile services, ESP community based locations and community crisis stabilization (CCS) services for ages 18 and over.

Entity or Person means an individual or his or her estate upon his or her death, or a corporation, a government agency, a partnership, a trust, an association, or an organized group of persons, whether incorporated or not, or any receiver, trustee, or other liquidating agent of any of the foregoing while acting in such capacity.

Health Care Entity means a health care facility, health care provider, local public health authority, provider organization, carrier, or any combination thereof, including, but not limited to, an ambulance service licensed under chapter 111C, a visiting nurse association, an accountable care organization, or a home health agency.

Health Care Facility means a licensed institution providing health care services or a health care setting, including, but not limited to, hospitals and other licensed inpatient centers, ambulatory, surgical or treatment centers, skilled nursing centers, residential treatment centers, diagnostic, laboratory and imaging centers, and rehabilitation and other therapeutic health settings.

Health Care Provider means a provider of medical, behavioral or health services or any other person or organization that furnishes bills or is paid for health care services delivery in the normal course of business.

Injury means harm that results in exacerbation, complication or other deterioration of a patient's condition.

Local Jurisdiction means a city or town or multiple cities or towns.

Local Public Health Authority means the appropriate and legally designated health authority of the city, town, or other legally constituted governmental unit within the Commonwealth having the usual powers and duties of the board of health or health department of a city or town.

Medical Control means the clinical oversight provided by a physician or existing primary care provider to all components of the MIH Program, including, but not limited to, medical direction, training, scope of practice and authorization to practice of a community paramedic provider, continuous quality assurance and improvement and clinical protocols.

Medical Direction means the authorization for treatment provided by a physician or existing primary care provider in accordance with clinical protocols, whether on-line through direct communication or telecommunication, or off-line through standing orders.

Medical Director means the physician or physicians appropriately trained to meet the unique social/cultural, linguistic, medical and population health needs of an MIH Program's patient population and designated by the MIH Program to carry out any supervisory medical control responsibilities for the MIH Program.

MIH Patient means an individual identified by a health care entity as warranting MIH Program services.

Mobile Integrated Health Care Program (MIH Program) means a program, including MIH Programs with an ED Avoidance Component, approved by the Department pursuant to 105 CMR 173.000, that utilizes community paramedic services to deliver healthcare services to patients in an out-of-hospital environment in coordination with health care facilities or other health care providers, which may include, but not be limited to, primary care providers, home care agencies, visiting nurse associations, or other in-home services; provided, that the medical care and services may include, but not be limited to, chronic disease management, behavioral health, preventative care, post-discharge follow-up visits, or transport or referral to facilities other than hospital emergency departments.

Nurse Practitioner means a licensed registered nurse authorized by the Massachusetts Board of Registration in Nursing to practice in the Commonwealth of Massachusetts as an Advanced Practice Registered Nurse pursuant to 244 CMR 4.00 and whose scope of practice includes the provision of primary care services.

Physician means a physician duly licensed to practice medicine in the Commonwealth of Massachusetts by the Massachusetts Board of Registration in Medicine, pursuant to M.G.L. c. 112, § 2 and 243 CMR.

Physician Assistant means a person who is registered pursuant to 263 CMR and who may provide medical services appropriate to his or her training, experience and skills under the supervision of a registered physician.

Primary Ambulance Response means first-line ambulance response, pre-hospital treatment and transportation by an ambulance service designated as a service zone provider or recognized in a service zone plan to provide first-line ambulance response, pre-hospital treatment and transportation pursuant to a provider contract.

Primary Ambulance Service means the business or regular activity, whether for profit or not, by an ambulance service licensed pursuant to 105 CMR 170.000, designated under a service zone plan for the purpose of providing rapid response and pre-hospital EMS, including, without limitation, patient assessment, patient treatment, patient preparation for transport and patient transport to appropriate health care facilities, in conformance with the service zone plan.

Primary Care Provider means a physician, physician assistant or nurse practitioner qualified to provide general medical care who (1) supervises, coordinates, prescribes, or otherwise provides or proposes health care services; (2) initiates referrals for specialist care; and (3) maintains continuity of care within the scope of practice.

Provider Organization means any corporation, partnership, business trust, association or organized group of persons, which is in the business of health care delivery or management, whether incorporated or not that represents one or more health care providers in contracting with carriers or third-party administrators for the payment of health care services; provided that the definition shall include, but not be limited to, physician organizations, physician-hospital organizations, independent practice associations, provider networks, accountable care organizations, and any other organization that contracts with carriers or third-party administrators for payment for health care services.

Serious Incident means an incident that results in injury to a patient not ordinarily expected as a result of the patient's condition.

Scope of Practice means the clinical skills or functions that (1) are defined by applicable state laws and regulations governing certification, licensure or registration of each individual providing services or treatment in the MIH or Community EMS Program approved by the Department pursuant to 105 CMR 173.000; and (2) the clinical protocols developed by such programs.

173.030: Application Process

(A) An applicant shall submit all required documents and fees to the Department in a manner and form as determined by the Department. The Department may expedite review of applications with a focus on underserved populations. The Department may request additional documentation and materials as deemed appropriate.

(B) An Applicant seeking renewal of a Certificate of Approval shall submit all required documentation and fees at least 120 calendar days prior to the expiration of the program's current Certificate of Approval.

(1) If all required documentation and fees are submitted to the Department in a complete and timely fashion, as determined by the Department, the Certificate of Approval shall not expire until the Department has made a determination on the application for renewal.

(2) If the required documentation and fees are not submitted to the Department in a timely fashion, as determined by the Department, the Certificate of Approval shall expire at the direction of the Department, and the MIH or Community EMS Program may not continue to operate without the express written permission of the Department.

173.040: Minimum Requirements for MIH Program Approval

(A) A complete application for MIH Program Approval shall, at a minimum:

(1) Identify and validate one or more gaps in service delivery using verifiable data and a corresponding community needs assessment;

(2) Describe how the proposed MIH Program would address identified gaps in service delivery and provide improvements in quality, access, or cost effectiveness through one or more of the following:
(a) A decrease in avoidable emergency department visits or hospital readmissions;
(b) A decrease in total medical expenditures;
(c) A decrease in cost to patient;
(d) A decrease in time to appropriate patient care in an appropriate health care setting;
(e) An increase in access to medical or follow-up care under the direction of the patient's Primary Care Provider;
(f) Improvement in clinical care coordination, including, but not limited to the patient's adherence to medication and other therapies previously prescribed by patient's Primary Care Provider;
(g) An increase in patient satisfaction;
(h) Improvement in patients' quality of life; or,
(i) An increase in cultural and linguistic competencies.

(3) Describe any proposed partnerships with existing health care entities; identify all partnerships,

contracts, agreements, and affiliation agreements between the applicant and other health care entities; and propose a plan for coordination and use of existing personnel and resources without duplication of services;

(4) For proposed programs with a primary focus on MassHealth beneficiaries with behavioral health needs, identify partnership or coordination with an ESP;

(5) Demonstrate sufficient capacity to develop and operate the proposed MIH Program in accordance with 105 CMR 173.000;

(6) Designate a medical director who shall be responsible for meeting the requirements of all clinical aspects of the proposed MIH Program, including, but not limited to, 105 CMR 173.100(G);

(7) Provide a complete description of the proposed operational plan for medical control and medical direction including, but not limited to, lines of authority and responsibility, development and review of clinical protocols, training and assessment of skills, communication systems, and continuous quality assurance and improvement; and

(8) Provide a complete description of the proposed coordination and interaction with applicable 911 EMS systems in accordance with the provisions of 105 CMR 173.100.

(B) Upon receipt of a complete initial or renewal application for a Certificate of Approval to operate an MIH Program, the Department shall evaluate the application, and any other information requested by the Department, and determine approval based on the applicant's satisfaction of the minimum requirements set forth at 105 CMR 173.040(A).

<u>173.050: Additional Eligibility and Minimum Requirements for MIH Applicant with ED Avoidance Component</u>

(A) An MIH Applicant must include each designated primary ambulance service(s) in the applicable local jurisdiction(s) in order to be eligible to apply for a Certificate of Approval to operate an MIH Program that includes an ED Avoidance component.

(B) A complete application for MIH Program with ED Avoidance Component shall, at a minimum:

(1) Meet the minimum requirements set forth at 105 CMR 173.040(A);

(2) Include appropriate clinical and triage protocols and advanced training for paramedics who will operate under the proposed ED Avoidance programming in accordance with this section and Department guidelines; and,

(3) Describe the coordination and management of any 911 EMS patient who the responding paramedic finds, after assessment and consultation with online medical direction, may be more appropriately managed as an MIH patient, in accordance with the provisions of 105 CMR 173.100(B) and Department guidelines;

(C) Upon receipt of a complete initial or renewal application for a Certificate of Approval to operate an MIH Program with ED Avoidance Component, the Department shall evaluate the application, and any other information requested by the Department, and determine approval based on the applicant's satisfaction of the minimum requirements set forth at 105 CMR 173.050(A).

173.060: Community EMS Program Approval

(A) Any Community EMS Applicant seeking a valid Certificate of Approval for public health service(s) as defined in Department guideline issued pursuant to 105 CMR 173.060(B) shall be required to provide notification, in the form and manner as determined by the Department, at least 30 days prior to anticipated commencement of Community EMS Program operations.

(B) The Department shall not issue a Certificate of Approval to authorize a Community EMS Program to provide any services other than those evidence-based illness and injury prevention services, such as falls prevention, concussion training, certain vaccinations under local public health authority direction, blood pressure screenings and health promotion screening programs, pursuant to 105 CMR 180.000, that are deemed high-value public health services with low risk potential to patients as defined by the Department in guidelines. Persons may submit to the Commissioner for consideration by the Department a written request with appropriate supplemental evidence supporting the future inclusion in, or exclusion from, said guidelines of certain evidence-based illness and injury prevention service(s).

(C) All EMS provider training and activities related to the Community EMS Program must be approved by the local public health agency and the primary ambulance service's affiliate hospital medical director.

(D) The designated primary ambulance service's affiliate hospital medical director shall:

(1) Ensure all EMS personnel providing services in a Community EMS Program successfully complete additional training tailored to meet the specific needs of the particular Community EMS Program;

(2) Review the quality of the EMS personnel's delivery of services; and,

(3) Ensure EMS personnel provide services only within their scope of practice.

173.070 Certificate of Approval

(A) Following Department determination that the proposed MIH or Community EMS Program has met the minimum requirements of 105 CMR 173.000, the Department shall issue a Certificate of Approval to the applicant, subject to any terms and conditions specified by the Department.

(B) Unless otherwise expressly denied by the Department in writing, notification, as set forth in 105 CMR 173.060(A), shall constitute a valid Certificate of Approval for the purposes of a Community EMS Program pursuant to 105 CMR 173.060 and 105 CMR 173.070.

(B) A Certificate of Approval shall be valid for two years from the date of issue unless otherwise specified in the Certificate of Approval.

(C) The Department may deny an application for a Certificate of Approval for any of the reasons set forth in 105 CMR 173.080.

(D) A Certificate of Approval may not be transferred or assigned to another service, program, agency, entity, or location.

173.080: Grounds for Denial, Revocation, or Non-renewal of Approval

Each of the following, in and of itself, shall constitute full and adequate ground on which the Department may deny an application for a Certificate of Approval, or to revoke or refuse to renew a Certificate of Approval to operate an MIH or Community EMS Program:

(A) Failure to meet applicable requirements for approval as specified in 105 CMR 173.000;

(B) Failure to meet the requirements of applicable federal or state law or regulations;

(C) Failure to provide information as required within 105 CMR 173.000;

(D) Any action or condition that endangers public health and safety, as determined by the Department;

(E) Obtaining or attempting to obtain a Certificate of Approval or renewal thereof by fraud, misrepresentation, or knowing omission(s) of material information, or by submission of incorrect, false or misleading information;

(F) Fraud, deceit or knowing omission(s) of material information or providing false or misleading statements, orally or in writing, to the Department;

(G) Conviction of an applicant, licensee or person with significant financial or management interest in the MIH or Community EMS Program, whether proposed or in operation, of Medicare or Medicaid fraud, or other criminal offense related to the operation of the program or indicating that operation of the program may endanger public health or safety;

(H) Reasonable basis for the Department to conclude that a discrepancy exists between the representations by the applicant as to the MIH or Community EMS Program services to be afforded patients and the services actually rendered or to be rendered;

(I) Failure to meet the duties and responsibilities for MIH or Community EMS Programs as required by 105 CMR 173.000;

(J) Failure to comply with any term or condition prescribed by the Department within a Certificate of Approval;

(K) Failure to submit an acceptable plan of correction as required under 105 CMR 173.120;

(L) Failure to comply with a Department-approved plan of correction or correction order in accordance with 105 CMR 173.120;

(M) Denial of entry to Department agents to conduct site visits or inspections, or an attempt to impede the work of Department agents; or,

(N) Any other violation of M.G.L. c. 111O, 105 CMR 173.000, or related Department guidelines.

Nothing herein shall limit the Department from adopting additional grounds through adjudication.

173.090: Process for Denial, Revocation or Refusal of a Certificate of Approval for an MIH or Community EMS Program

(A) If the Department initiates an action to deny, revoke, or refuse to renew a Certificate of Approval, the Department shall provide the MIH or Community EMS Program with written notice of the reasons and grounds

for the Department's action, the provisions of law relied upon, and an opportunity to request an adjudicatory hearing within 14 calendar days of receipt of the notice of agency action.

(B) Upon receipt of a request for hearing within the time period prescribed by 105 CMR 173.090(A), the Department shall afford the aggrieved party an opportunity for an adjudicatory hearing to be conducted by a designated hearing officer of the Division of Administrative Law Appeals.

(C) If a hearing is not requested within the time period prescribed by 105 CMR 173.090(A), the right to a hearing shall be waived and a final agency decision shall be issued.

(D) All adjudicatory proceedings shall be conducted in accordance with M.G.L. c. 30A and the Standard Adjudicatory Rules of Practice and Procedure, 801 CMR 1.01 et seq.

173.100: Minimum Standards of Operation

(A) MIH Programs. An MIH Program shall meet the following minimum standards of operation:

(1) If an MIH Program's on-scene health care provider, after assessment and in accordance with medical direction, determines that the patient is experiencing a medical emergency, the MIH Health Care Provider shall activate the 911 EMS system and continue to assess and treat the patient in accordance with clinical protocols until transfer of care to the responding ambulance service in accordance with 105 CMR 170.355(B)(2) and (4) and the applicable service zone plan.

(2) When a primary ambulance service of a municipality, which is also part of a Department-approved MIH Program with ED Avoidance component, receives a 911 call to respond to a patient within its MIH program, the service shall respond in accordance 105 CMR 170.000: *Emergency Medical Services System*. If after assessment and consultation with on-line medical direction, the responding paramedic finds the patient may be more appropriately managed as an MIH patient or transported to a destination other than an emergency department, the EMS personnel may initiate transfer of patient care to the MIH Program with the ED avoidance component in accordance with protocols established within Department guideline.

(3) If an MIH Program deploys or intends to deploy a vehicle when responding to an MIH call or for a scheduled home visit, such vehicle must, at a minimum, be a non-transporting vehicle appropriate for the clinical encounter as approved by the Department.

(4) Each MIH Program shall file a written report with the Department within five calendar days of any serious incident involving its program, personnel or property. Such reportable serious incidents shall include, but are not limited to, any of the following covered by its Certificate of Approval:

(a) Death that is unanticipated, not related to the natural course of the patient's illness or underlying condition, or that is the result of an error or other incident, as specified in guidelines of the Department;

(b) Full or partial evacuation of the facility for any reason;

(c) Fire;

(d) Suicide;

(e) Serious criminal acts;

(f) Pending or actual strike action by its employees, and contingency plans for operation of the MIH Program;

(g) Any anesthesia-related complications that result in serious morbidity or death of a patient;

(h) A motor vehicle crash involving an MIH vehicle reportable under MGL c. 90 §26;

(i) Medication errors resulting in injury;

(j) Failure to provide treatment in accordance with clinical protocols resulting in injury;

(k) Major medical or communication device failure or other equipment failure or user error resulting in serious injury; or,

(l) Transfer of care of a 911 patient to management as an MIH patient resulting in injury.

(5) Each MIH Program shall immediately report to the Department, for any patient treated by the MIH Program, any suspected instance(s) of abuse, neglect, mistreatment of that patient or misappropriation of that patient's property at or by a nursing home, rest home, home health, home maker or hospice.

(6) Each MIH Program shall report to the Department any other serious incident or accident occurring on premises covered by the MIH Program's Certificate of Approval that seriously affects the health and safety of a patient or that causes serious physical injury to a patient within seven calendar days of the date of occurrence of the event.

(7) Each MIH Program shall comply with all guidelines established by the Department for submission of data required by 105 CMR 173.100(A)(8)(u).

(8) Each MIH Program shall have written policies and procedures consistent with the requirements established in 105 CMR 173.100, Department guidelines, accepted standards of care for the delivery of health care services and treatment, and applicable laws. All policies and procedures required under 105 CMR 173.100(A) shall be provided to personnel providing services or treatment on behalf of an MIH Program. In addition, such policies and procedures shall be made available to the Department upon request. At a minimum, the policies and procedures shall address:

(a) Documentation of organizational structure including medical control, affiliation agreements, lines of authority, responsibility, communication, personnel practices, and staff assignment;

(b) Statement of goals, objectives and types of services offered by the program;

(c) Suitability of personnel providing services or treatment in the MIH Program, including confirmation that such personnel are currently certified, licensed or registered in accordance with applicable laws and regulations;

(d) Medical control and medical direction, including authorization to practice of EMS personnel;

(e) Process for development and periodic review of clinical protocols;

(f) Documentation of training and assessment standards for all personnel providing treatment and services;

(g) Process for obtaining medications from a pharmacy in accordance with 105 CMR 700.000;

(h) Compliance with applicable federal and state laws and regulations, including, but not limited to such laws and regulations governing possession and administration of controlled substances;

(i) Process for ensuring that each health care provider providing services and treatment in the MIH Program maintains an appropriate and current registration to possess controlled substances and instruments for administration of controlled substances in accordance with 105 CMR 700.000;

(j) Compliance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and regulatory requirements in 42 CFR Part 493;

(k) Process for ensuring that each health care provider providing services or treatment in the MIH Program obtains CLIA certificates appropriate for the type of testing to be performed;

(l) Maintenance of equipment and medical devices in accordance with manufacturers' recommendations;

(m) Obtaining a patient's informed consent at each clinical encounter;

(n) Compliance with federal and state confidentiality laws and regulations;

(o) Security of and access to patient medical records and information;

(p) Management of patients who experience a medical emergency and require activation of the 911 EMS system in accordance with the provision of 105 CMR 173.100(A);

(q) Management of 911 EMS Patients by a designated primary ambulance service that is part of an approved MIH Program with an ED avoidance component pursuant to 105 CMR 173.050 when the primary ambulance service's responding paramedic appropriately determines whether a patient may be more appropriately managed as an MIH patient or transported to a destination other than an emergency department in accordance with the provision of 105 CMR 173.100(B) and Department guidelines;

(r) Dispatch and communications;

(s) Infection control procedures;

(t) Continuous quality assurance and improvement program;

(u) Collection and maintenance of data relative to access, availability, quality, and cost associated with delivery of program services, to be submitted on a quarterly basis in accordance with Department guidelines;

(v) Non-discrimination;

(w) Serious incident response and reports in accordance with 105 CMR 173.100(A)(4).

(9) An MIH Program's medical director's responsibilities shall include but not be limited to the following:

(a) Develop and update clinical protocols appropriate to:
(i) the unique medical needs of the MIH Program's patient population; and,
(ii) the particular personnel providing MIH services such as EMS personnel, nurses, Nurse Practitioners, Physician Assistants and others;

(b) Grant authorization to practice to Community Paramedics and other EMS personnel providing health care services on behalf of MIH Programs;

(c) Ensure that all MIH Program personnel are properly trained and provide health care services or treatment:
(i) within the scope of their practice;
(ii) in accordance with the clinical protocols developed for the MIH Program; and,
(iii) in accordance with any additional training required by Department guidelines;

(d) Ensure that the MIH Program maintains a secure and effective telecommunication system and that all on-line medical direction is recorded;

(e) Make on-line medical direction available to MIH Program personnel during all hours of operation;

(f) Ensure that all physicians and other primary care providers who provide on-line medical direction to MIH personnel receive appropriate training in:
(i) the scope of practice of each type of MIH Program personnel;
(ii) the specific clinical protocols developed for the MIH Program; and,
(iii) any additional training required by Department guidelines; and,

(g) Coordinate the MIH Program's continuous quality assurance and improvement program.

(B) Community EMS Programs. A Community EMS Program shall meet the following minimum standards of operation:

(1) If a Community EMS Program's on-scene health care provider, after assessment and in accordance with medical direction, determines that the patient is experiencing a medical emergency, the health care provider shall activate the 911 EMS system and continue to assess and treat the patient in accordance with clinical protocols until transfer of care to the responding ambulance service in accordance with 105 CMR 170.355(B)(2) and (4) and the applicable service zone plan.

(2) If a Community EMS Program deploys or intends to deploy a vehicle when responding to a Community EMS call or a scheduled home visit, such vehicle must, at a minimum, be a non-transporting vehicle appropriate for the clinical encounter as approved by the Department.

(3) Each Community EMS Program shall have written policies and procedures consistent with the requirements established in Department guidelines, accepted standards of care for the delivery of health care services and treatment, and applicable laws.

173.110: Complaints

(A) Upon receipt of any complaint or serious incident report , the Department shall take appropriate steps to investigate, as appropriate, whether the reported or alleged act or practice violates M.G.L. c. 111O, any provision of 105 CMR 173.000, any guidelines, or any condition imposed by the Department in its Certificate of Approval. The Department may also refer the complaint or serious incident report to the appropriate governmental authority responsible for licensure, certification, registration, approval, or oversight as deemed necessary.

(B) If, after investigation, the Department finds that the act or practice violates M.G.L. c. 111O, any provision of 105 CMR 173.000, Department guideline, or any condition imposed by the Department in its Certificate of Approval, the Department may issue a correction order in accordance with 105 CMR 173.120 or an agency action in accordance with 105 CMR 173.090.

173.120: Inspections, Statement of Deficiency, Order to Correct

(A) The Department, either announced or unannounced, may inspect any MIH or Community EMS Program for compliance with 105 CMR 173.000, Department guidelines, or conditions imposed by the Department in its Certificate of Approval.

(B) Whenever the Department finds upon inspection or through information in its possession that an MIH or Community EMS Program is not in compliance, it may issue an order to correct the deficiency. The correction order shall include a statement of the deficiencies found, the provision of law relied upon, and a reasonable prescribed period for correction.

(C) Within 10 days, an MIH or Community EMS Program shall submit to the Department a written plan of correction for each violation cited in the deficiency statement.

(D) Every plan of correction shall set forth, with respect to each deficiency, the specific corrective step(s) to be taken, a timetable for such steps, and the date by which compliance will be achieved. The timetable and the compliance dates shall be consistent with achievement of compliance in the most expeditious manner possible.

(E) The Department shall review the plan of correction for compliance and will notify the MIH or Community EMS Program whether the plan is accepted or rejected.

(F) Upon expiration of the time specified for correction, the Department may re-inspect the MIH or Community EMS Program in order to determine whether it is in compliance with the correction order.

173.130: Summary Suspension of Certificate of Approval

(A) In accordance with 173.090, the Commissioner may summarily suspend an MIH or Community EMS Program Certificate of Approval, pending further proceedings for revocation of or refusal to renew a Certificate of Approval, whenever the Commissioner finds that the continued operation of such program poses an imminent threat to public health and safety.

(B) The Department shall issue written notice of the suspension action which shall contain the reasons and grounds for immediate suspension, the provisions of law relied on, and an opportunity to request an adjudicatory hearing within 14 days of receipt of the notice of the suspension action.

(C) Upon receipt of a request for hearing within the time period prescribed by 105 CMR 173.090, the Department shall promptly afford the aggrieved party an opportunity for an adjudicatory hearing to be

conducted by a designated hearing officer of the Division of Administrative Law Appeals. If a hearing is not requested within the required time period, the right to a hearing shall be waived and a final agency decision shall issue.

(D) Until the suspension is lifted or final agency determination is made, the MIH or Community EMS Program may not operate.

173.140: Waiver of Requirements

(A) The Commissioner may waive the applicability of one or more of the requirements imposed on a particular MIH or Community EMS program by 105 CMR 173.000 if the Commissioner finds that:

(1) Compliance would cause undue hardship; and,

(2) The MIH or Community EMS Program's non-compliance would not adversely affect the quality of patient care or patient safety; and,

(3) The MIH or Community EMS Program has instituted compensating features that are acceptable to the Department.

(B) The MIH or Community EMS Program shall provide to the Commissioner written documentation supporting its request for a waiver.

173.150: Severability

The provisions of 105 CMR 173.000 are severable. If a court of competent jurisdiction declares any section, subsection, paragraph, or provision unconstitutional or invalid, the validity of the remaining provisions shall not be affected.

REGULATORY AUTHORITY

M.G.L. c. 111O and M.G.L. c. 111, § 3.