

Massachusetts Public Health Council



MASSACHUSETTS
DEPARTMENT OF PUBLIC
HEALTH

November 9, 2016

Proposed Amendments to 105 CMR 141.000: *Licensure of Hospice Programs*

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Public Health Council
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- M.G.L. c. 111 § 57D authorizes DPH to license and regulate the conduct of hospice programs.
- 105 CMR 141.000, *Licensure of Hospice Programs*, regulates hospice services, which may be offered in multiple types of health care settings and in the community, including a patient's home, a nursing home, or a free-standing hospice facility operated by a hospice program.
- This regulation ensures a high quality of care, industry standardization and strong consumer protection for individuals receiving care at end of life.
- These amendments are proposed as part of the regulatory review process, mandated by Executive Order 562, which requires all state agencies to undertake a review of each and every regulation under its jurisdiction currently published in the Code of Massachusetts Regulations.

The proposed amendments will achieve the following:

- Remove outdated or conflicting provisions and unnecessary language;
- Define “primary care provider” to reflect the role of a range of health care professionals in providing care to hospice patients;
- Update the transfer of ownership procedure;
- Clarify training requirements for hospice program employees providing dementia care to residents in nursing homes;
- Align the regulations with other healthcare licensure regulations; and
- Allow for clear construction standards that can be more easily updated when necessary.

Proposed Amendment Highlights: Primary Care Provider

Current Regulation:

- Does not include a definition for “primary care provider”.

Proposed Amendment:

- Adds a definition for “primary care provider”:
 - “A health care professional qualified to provide general medical care for common health care problems, who supervises, coordinates, prescribes or otherwise provides or proposes health care services, initiates referrals for specialist care and maintains continuity of care within the scope of practice. “
- Clarifies that a primary care provider may provide care to hospice patients.

Rationale:

- Provides consistency with other healthcare licensure regulations.
- Reflects the role of a range of healthcare professionals, including nurse practitioners and physician assistants, in providing care to hospice patients.

Proposed Amendment Highlights: Transfer of Ownership

Current Regulation:

- Allows a person applying for a license as a result of a transfer of ownership to file an application for licensure within 48 hours of the transfer.

Proposed Amendment:

- Adds a definition for “transfer of ownership” to clarify the transfer of ownership process.
- Updates the transfer of ownership procedure to ensure that DPH completes its suitability review for licensure within 30 days of receiving a completed application form.

Rationale:

- Provides consistency with other healthcare licensure regulations.
- Prevents delays for regulated parties in DPH suitability review.

Proposed Amendment Highlights: Application for Licensure

Current Regulation:

- Allows DPH to accept an application for a hospice inpatient facility from an applicant that has been licensed for 2 years prior to the initial adoption of the inpatient hospice regulations on October 10, 2003.

Proposed Amendment:

- Allows an application for a free-standing inpatient hospice facility from an applicant that has been a licensed hospice program for more than 2 years.
- Increases the free-standing inpatient hospice facility cap, which is set according to M.G.L. c. 111, § 57D, from 6 facilities to 8 facilities.

Rationale:

- Clarifies eligibility for the licensure of new inpatient hospice facilities.
- Recognizes the increased number of inpatient hospice facilities allowed by statute.

Proposed Amendment Highlights: Dementia Care Training

Current Regulation:

- Does not address documenting dementia care training for long-term care facility employees.

Proposed Amendment:

- Adds requirement that hospice programs document dementia care training for their employees who provide direct care to nursing home residents.

Rationale:

- Clarifies that hospice programs are responsible for the initial and ongoing annual dementia care training of their employees providing services in nursing homes, pursuant to M.G.L. c. 111, § 71C.

Proposed Amendment Highlights: Incident Reporting

Current Regulation:

- Requires reporting of any of the following: fire, serious criminal acts or pending or actual strike action by its employees.

Proposed Amendment:

- Updates the reportable incident criteria for hospice programs to make the requirements consistent with those for other healthcare facilities.

Rationale:

- Provides consistency and clarity with other healthcare licensure regulations, including clinic and hospital licensure regulations.

Proposed Amendment Highlights: Medication Orders

Current Regulation:

- Requires medications ordered by a physician assistant or nurse practitioner to be reviewed by the supervising physician.

Proposed Amendment:

- Removes requirement that a physician review each initial medication order or significant change to an order by a nurse practitioner or physician assistant.

Rationale:

- Aligns regulation with statute and professional board scope of practice regulations.
- Recognizes the current role of nurse practitioners or physician assistants in health care delivery.

Proposed Amendment Highlights: Construction Standards

Current Regulation:

- Includes 105 CMR 141.299: Appendix A: General Standards of Construction: Hospice Inpatient Facility Directly Owned and Operated by a Hospice Program, a lengthy appendix detailing construction standards.

Proposed Amendment:

- Deletes entirety of Appendix.
- Adds section requiring hospice facilities to comply with DPH guidelines, based on nationally recognized standards of the Facility Guidelines Institute.
- Adds section requiring hospice inpatient facilities to have written policies to operate a safe, effective inpatient hospice facility.

Rationale:

- Provides consistency with other healthcare facilities licensure regulations.
- Allows for clear, uniform national standards that are easily updated.

Next Steps

- The Department intends to conduct a public hearing to solicit comments on the proposed amendment.
- Following the public comment period, the Department will return to the Public Health Council to report on testimony and any recommended changes to this amendment, and seek final promulgation.

- Thank you for the opportunity to present this information today.
- For more information on 105 CMR 141, *Licensure of Hospice Programs*, please find the relevant statutory language (M.G.L. c. 111, § 3, 57D) and the full current regulation here:
<https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXVI/Chapter111>
<http://www.mass.gov/courts/docs/lawlib/104-105cmr/105cmr141.pdf>

Proposed Amendments to 105 CMR 153.000: *Licensure Procedure and Suitability Requirements for Long-Term Care Facilities*

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- The regulation, 105 CMR 153.000, *Licensure Procedure and Suitability Requirements for Long-Term Care Facilities*, sets forth the licensure procedures and suitability requirements for long-term care facilities, including nursing homes and rest homes.
- This regulation ensures that residents of long-term care facilities are provided with a high quality of care, through industry standardization, and strong consumer protection and health care safety.
- These amendments are proposed as part of the regulatory review process, mandated by Executive Order 562, which requires all state agencies to undertake a review of each and every regulation under its jurisdiction currently published in the Code of Massachusetts Regulations.

The proposed amendments will achieve the following:

- Remove outdated or conflicting provisions and unnecessary language;
- Eliminate unnecessary administrative burdens and improve efficiencies;
- Consolidate provisions to provide consistency and clarity on orders freezing new admissions; and
- Align resident notification processes for greater clarity.

Proposed Amendment Highlights: Administrative Efficiencies

Current Regulation:

- Requires applications be notarized; expired licenses be mailed back to DPH; and an attestation form be submitted to DPH in addition to an actual copy of a published notice.

Proposed Amendment:

- Eliminates unnecessary administrative burdens.
- Allows for the filing of a license application prior to the expiration of the 90 day suitability review period so as to allow for concurrent review by DPH.

Rationale:

- Improves efficiencies for regulated parties.

Proposed Amendment Highlights: Freeze on New Admissions

Current Regulation:

- Prohibits a long-term care facility from admitting residents if the Commissioner determines that the facility has not substantially complied with applicable licensure regulations or has initiated termination.

Proposed Amendment:

- Provides consistency by combining two sections into one section on limiting admissions.
- Identifies the specific regulations and statutory sections that may result in DPH imposing a freeze.
- Clarifies that, in the event of a jeopardy determination, a freeze may be imposed immediately.

Rationale:

- Provides consistency and clarity for regulated parties.
- Eliminates confusion and provides efficiency through consolidation.
- Aligns licensure remedy with CMS sanctions.

Current Regulation:

- Requires DPH to notify residents in a license revocation action.

Proposed Amendment:

- Requires the facility to notify its own residents in a license revocation action.

Rationale:

- Aligns with current requirements in the case of a voluntary closure or change of ownership.

Next Steps

- The Department intends to conduct a public hearing to solicit comments on the proposed amendment.
- Following the public comment period, the Department will return to the Public Health Council to report on testimony and any recommended changes to this amendment, and seek final promulgation.

- Thank you for the opportunity to present this information today.
- For more information on 105 CMR 153, *Licensure Procedure and Suitability Requirements for Long-Term Care Facilities*, please find the relevant statutory language (M.G.L. c. 111, § 3, 71 through 73B) and the full current regulation here:
<https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXVI/Chapter111>
<http://www.mass.gov/courts/docs/lawlib/104-105cmr/105cmr153.pdf>

Proposed Rescission of 105 CMR 151.000: *General Standards of Construction for Long-Term Care Facilities in Massachusetts*

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- As part of regulatory review, as mandated by Executive Order 562, the Bureau of Health Care Safety and Quality (BHCSQ) proposes rescinding 105 CMR 151.000, *General Standards of Construction for Long-Term Care Facilities in Massachusetts*, having determined that:
 - Relevant provisions should be incorporated into more appropriate sections of the Code of Massachusetts Regulation, 105 CMR 150.000, *Licensing of Long-Term Care Facilities*.

Incorporation with 105 CMR 150.000

- Long-term care facilities are currently required to comply with 3 separate regulations for their governance (105 CMR 150.000, 105 CMR 151.000 and 105 CMR 153.000).
- Incorporating relevant sections of this regulation into 105 CMR 150.000 will provide greater clarity by consolidating standards for long-term care facilities.
- Rescission of this regulation will eliminate construction standards that presently duplicate physical plant standards in 105 CMR 150.000, creating confusion.
- Incorporating relevant sections into 105 CMR 150.000 will ensure compliance with structural and architectural guidelines, without requiring reference to several different regulations.

Next Steps

- Staff intends to conduct the public comment hearing and return to the PHC to report on testimony and any recommended changes to this proposal.
- Following final action by the PHC, the Department will be able to file the final rescission with the Secretary of the Commonwealth.

- Thank you for the opportunity to present this information today.
- For more information on 105 CMR 151.000, *General Standards of Construction for Long-Term Care Facilities in Massachusetts*, please find the relevant statutory language (sections 3, 71, and 72 of chapter 111 of the General Laws) and the full current regulation here:

<https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXVI/Chapter111>

<http://www.mass.gov/courts/docs/lawlib/104-105cmr/105cmr151.pdf>

Proposed Amendments to 105 CMR 150.000: *Licensing of Long-Term Care Facilities*

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- This regulation, 105 CMR 150.000, *Licensing of Long-Term Care Facilities*, sets forth standards governing long-term care facilities, including nursing homes and rest homes.
- The regulation ensures a high quality of care, industry standardization, and strong consumer protection for residents in long-term care facilities.
- These amendments are proposed as part of the regulatory review process, mandated by Executive Order 562, which requires all state agencies to undertake a review of each and every regulation under its jurisdiction currently published in the Code of Massachusetts Regulations.

The proposed amendments will achieve the following:

- Eliminate outdated or unnecessary requirements;
- Make terminology consistent with other long-term care regulations;
- Align nursing care hourly requirements with federal CMS requirements;
- Update medication storage, administration and tracking provisions to be consistent with current practice;
- Update record requirements to reflect current practice; and
- Incorporate long-term care facility construction standards from the proposed rescinded long-term care facility construction regulation, 105 CMR 151.000.

Proposed Amendment: Title and Terminology

- Current title, *Licensing of Long-Term Care Facilities*, is changed to *Standards for Long-Term Care Facilities* to eliminate confusion with 105 CMR 153.000, *Licensure Procedure and Suitability Requirements for Long-Term Care Facilities*.
- Terminology is updated to make the regulation consistent with long-term care and other health care facility and professional regulations, including:
 - Replacing the term “patient” with “resident”; and
 - Defining “primary care provider” to include nurse practitioners and physician assistants.

Proposed Amendment: Employment Qualifications

Current Regulation:

- Prohibits the employment of substance “abusers” in long term care facilities.

Proposed Amendment:

- Prohibits the hiring or employment of an individual who cannot perform job duties or whose employment would pose a threat to the health, safety or welfare of residents;

Rationale:

- Reduces stigma associated with substance use while protecting residents from unqualified staff.
- Recognizes individual care needs.

Proposed Amendment: Dietary Services

Current Regulation:

- Allows hiring of unlicensed dietary staff.
- Establishes strict, detailed, universal dietary standards.

Proposed Amendment:

- Bases dietary requirements on individual resident care plans through expert assessment by dietitians.

Rationale:

- Provides for consideration of individualized dietary plans.
- Recognizes individual care needs.

Proposed Amendment: Automated External Defibrillators (AED)

Current Regulation:

- Requires integration of the use of automated external defibrillators (AED) as appropriate in emergency medical situations .

Proposed Amendment:

- Requires the development of policies and procedures for AED use consistent with current clinical practice; and
- Requires facilities to meet the emergency needs of residents, including the maintenance of an emergency medication kit.

Rationale:

- Ensures AED use in facilities remains consistent with current standards and best practices; and
- Ensures comprehensive policies and procedures are in place to better protect and meet the needs of residents in all emergency situations.

Proposed Amendment: Physician and Medical Services

Current Regulation:

- Requires facilities have policies and procedures regarding physician and medical services.

Proposed Amendment:

- Requires the facility medical director to implement policies and procedures for medical services and to coordinate care within the facility.

Rationale:

- Ensuring the coordination of care between facilities and medical directors;
- Aligns policies and procedures for facility medical directors with federal requirements.

Proposed Amendment: Skilled Nursing Care Facilities for Children

Current Regulation:

- Provides separate, detailed requirements relating to Skilled Nursing Care Facilities for Children (SNCFC).

Proposed Amendment:

- Removes provisions applicable to SNCFCs that are duplicative of requirements that exist for all long term care facilities; and
- Retains only those provisions that apply based on the particular needs of this population.
 - For example, 105 CMR 150.019 is retained to encourage and facilitate young residents' participation in an educational program, approved by the Department of Elementary and Secondary Education.

Rationale:

- Streamlines regulations relating to SNCFCs and provides clarity and consistency throughout the document while continuing to recognize the unique needs of this population.

Current Regulation:

- Requires Level II and Level III facilities to perform additional medical clearance prior to admitting a resident with a behavioral health diagnosis to the facility.

Proposed Amendment:

- Removes this unnecessary and duplicative requirement.

Rationale:

- Residents with no behavioral health diagnosis are not subject to such additional examination requirements prior to admission.
- All residents, including those with a behavioral health diagnosis, receive assessment, care planning and treatment.

Current Regulation:

- Sets forth the specific required nursing care hours for each level of care.
 - Level I facilities must provide a total of 2.6 hours of nursing care per resident.
 - Level II facilities must provide a total of 2.0 hours of nursing care per resident.
 - Level III facilities must provide a total of 1.4 hours of nursing care per resident.

Proposed Amendment:

- Revises nursing care requirements to be based on acuity and census rather than hourly minimums.

Rationale:

- Provides flexibility while recognizing that currently reported nursing care hours exceed these outdated requirements.
- Aligns nursing care hours with CMS requirements to meet resident needs.

Proposed Amendment Highlights: Activities Programs

Current Regulation:

- Requires facilities to provide an organized program of activities to meet the need of its residents.

Proposed Amendment:

- Specifies that activities must be available for residents with disabilities or for whom English is not their primary spoken language.

Rationale:

- Recognizes the diversity of residents in facilities;
- Aligns regulations with newly revised federal requirements for resident centered care.

Proposed Amendment Highlights: Pharmaceutical Services and Medications

Current Regulation:

- Provides detailed, outdated requirements for medication storage, administration and tracking.

Proposed Amendment:

The proposed amendment updates the provisions relative to medication storage, administration and tracking to be consistent with current practice, including:

- Removing the requirement that written orders be kept in the Doctor's Order book because DPH does not otherwise require order books;
- Eliminating the outdated requirement that medications be administered using a printed card for reference and on a medication tray; and
- Removing the outdated requirement that all facilities maintain a bound Pharmacy Record Book.

Rationale:

- Provides flexibility to facilities by expanding options for having a readily accessible method to document and track medication.

Current Regulation:

- Includes outdated provisions on facility maintenance of certain records, including:
 - Maintaining hard-bound record books; and
 - Requiring all facilities to employ a medical records librarian or a trained employee responsible for ensuring records are properly maintained.

Proposed Amendment:

- Provides facilities with the flexibility to develop, through an interdisciplinary team, and adopt, written policies to ensure complete and accurate clinical records are maintained;
- Requires processes to ensure the availability of records to residents and legally authorized representative and providers;
- Requires training to ensure competency.

Rationale:

- Updates and simplifies records requirements to be consistent with current practice.

Current Regulation:

- Includes outdated facility equipment requirements, including provisions relative to the use of restraints.

Proposed Amendment:

- Removes provisions specifically allowing restraints to be used on a resident upon physician orders.

Rationale:

- Requires care planning in accordance with CMS regulations and state abuse laws;
- Reflects the current federal care plan requirements to assess the resident, determine possible alternatives to restraints, and use the least restrictive means possible to meet the safety and care needs of the resident.

Proposed Amendment Highlights: Construction Standards

Current Regulation:

- Includes outdated construction standards for long-term care facilities.

Proposed Amendment:

- Incorporates the construction standards for long-term care facilities that are now included in 105 CMR 151.000, which DPH recommends for rescission.
- The incorporated provisions are updated to reflect current construction standards and compliance with Architectural Access Board regulations.

Rationale:

- Long-term care facilities are currently required to comply with 3 separate regulations for their governance (105 CMR 150.000, 105 CMR 151.000 and 105 CMR 153.000), creating duplicative and confusing regulations.
- Eliminates duplication by incorporating all construction standards into this regulation which provides standards for long-term care facilities.

Proposed Amendment Highlights: Construction Standards

Current Regulation:

- Requires facilities constructed prior to 1968 to only meet the standards in effect at time of construction.

Proposed Amendment:

- Eliminates the “grandfathering” provision and requires facilities to meet more current standards.

Rationale:

- Recognizes that changes in the acuity of residents and resident-centered care in homelike, rather than institutional environments, has rendered obsolete pre-1968 standards, which exist in few, if any, currently operating facilities.

Next Steps

- The Department intends to conduct a public hearing to solicit comments on the proposed amendment.
- Following the public comment period, the Department will return to the Public Health Council to report on testimony and any recommended changes to this amendment, and seek final promulgation.

- Thank you for the opportunity to present this information today.
- For more information on 105 CMR 150.000, *Licensing of Long-Term Care Facilities*, please find the relevant statutory language (M.G.L. c. 111, § 3, 71 and 72) and the full current regulation here:

<https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXVI/Chapter111>

<http://www.mass.gov/courts/docs/lawlib/104-105cmr/105cmr150.pdf>

Proposed Amendments to 105 CMR 156.000: *The Training of Nurses' Aides in Long-Term Care Facilities*

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Public Health Council
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- This regulation, 105 CMR 156.000, *The Training of Nurses' Aides in Long-Term Care Facilities*, sets out standards for the training of nurse aides in long-term care facilities pursuant to M.G.L. c. 111 § 72W.
- These regulations ensure a high quality of care, industry standardization and strong consumer protection for residents receiving care in a long-term care facility.
- These amendments are proposed as part of the regulatory review process, mandated by Executive Order 562, which requires all state agencies to undertake a review of each regulation under its jurisdiction currently published in the Code of Massachusetts Regulations.

Background: Regulatory Alignment

- M.G.L. c. 111 § 72W, under which these regulations were originally promulgated, was passed in 1986, prior to the federal government establishing standards for nurse aide training, and provided minimum guidance as to the requirements for nurse aide training.
- The amended regulation aligns the state and federal regulations by achieving the following:
 - Including provisions for approving, or renewing or withdrawing approval from, nurse aide training programs;
 - Reconciling training and testing deadlines; and
 - Maintaining the Nurse Aide registry and certification process.
- DPH retains involvement in the oversight of CNAs through the reporting and investigation of allegations of abuse against patients and residents.

The proposed amendments will achieve the following:

- Include consistent terminology and definitions for regulated parties, including using the term “Nurse Aide” in the title and throughout the regulation;
- Provide clarity throughout the regulation and consistency between this regulation and other long-term care regulations;
- Remove outdated or unnecessary provisions and correct several technical errors; and

Elimination of Outdated Equivalency Provisions

- The proposed amendments eliminate outdated provisions which allowed aides working at the time the regulations were adopted to substitute experience working in a nursing home for training.

Elimination of Provisions Conflicting with Federal Requirements

- The proposed amendments eliminate conflicting provisions which allowed the Commissioner or a designee to waive training requirements beyond the 2 year limit established in federal regulations.

Proposed Amendment Highlights: Training Programs

Current regulation:

- Contains no provisions for approving, renewing approval or withdrawing approval from nurse aide training programs.

Proposed amendment:

- Requires a training provider to obtain approval from DPH; and
- Includes provisions consistent with federal regulations establishing discretionary and mandatory standards for withdrawing approval of a training program.

Rationale:

- Improves DPH oversight and administration; and
- Eliminates confusion; and
- Required to maintain federal funding.

Proposed Amendment Highlights: Training and Testing

Current regulation:

- Requires completion of training within 90 days of commencing employment.

Proposed amendment:

- Maintains 90-day training requirement;
- Includes federal prohibition against a facility retaining a nurse aide who does not pass competency testing within 4 months of beginning employment.

Rationale:

- Reconciles training and testing deadlines by retaining state training deadlines and incorporating federal testing deadlines.

Next Steps:

- The Department intends to conduct a public hearing to solicit comments on the proposed amendment.
- Following the public comment period, the Department will return to the Public Health Council to report on testimony and any recommended changes to this amendment, and seek final promulgation.

- Thank you for the opportunity to present this information today.
- For more information on 105 CMR 156.000, *The Training of Nurses' Aides in Long-Term Care Facilities*, please find the relevant statutory language and the full current regulation here:

<https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXVI/Chapter111/Section72W>

<http://www.mass.gov/courts/docs/lawlib/104-105cmr/105cmr156.pdf>

Proposed Amendments to 105 CMR 157.000: *The Registration and Operation of Temporary Nursing Service Agencies*

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Public Health Council
November 9, 2016

- This regulation, 105 CMR 157.000, *The Registration and Operation of Temporary Nursing Service Agencies*, sets out standards for the registration and operation of temporary nursing service agencies.
- This regulation ensures that patients and residents of health care facilities are provided quality nursing care.
- These amendments are proposed as part of the regulatory review process, mandated by Executive Order 562, which requires all state agencies to undertake a review of each regulation under its jurisdiction currently published in the Code of Massachusetts Regulations.

- The regulation of Temporary Nursing Service Agencies is authorized by section 72Y of chapter 111 of the General Laws.
- Temporary Nursing Service Agencies provide health care facilities, including nursing homes, with staffing solutions to ensure quality nursing care when the employment of permanent nursing care is impractical or unavailable.
- 105 CMR 157 ensures the quality and consistency of these provisional resources by:
 - Providing oversight of temporary employers required to monitor staff;
 - Establishing predictable standards as to qualifications and compliance;
 - Ensuring alignment with MassHealth and other reimbursement rules.

The proposed amendments will achieve the following:

- Clarify the procedures for filing applications for initial registration and changes of location;
- Update the process for reporting suspected drug diversion by medical personnel;
- Expand guidance on the reporting of suspected poor nursing care to the Board of Registration in Nursing;
- Add specific language on reporting obligations under the Patient Abuse Law;
- Remove outdated or unnecessary provisions; and
- Align the regulations with other health care facility regulations.

Proposed Amendment Highlights: Application Procedures

Current regulation:

- Requires applications for initial registration to be filed prior to commencing operation;
- Applications for change of existing location must be filed within 2 business days of the change.

Proposed amendment:

- Requires applications for initial registration and change of existing location to be filed with DPH at least 30 days before the planned effective date.

Rationale:

- Provides consistency in application procedures for regulated parties across licensed facilities; and
- Allows appropriate time for DPH planning and processing.

Proposed Amendment Highlights: Drug Diversion

Current regulation:

- Requires the administrator of the health care facility to immediately notify the Division of Food and Drugs in writing and by telephone of a known or suspected drug diversion.

Proposed amendment:

- Clarifies that, at a minimum, the administrator of the health agency must immediately notify the Drug Control Program of a drug diversion and file a report with DPH in accordance with DPH guidelines.

Rationale:

- Removes outdated references to the Division of Food and Drugs; and
- Allows for advances in technology for reporting.

Proposed Amendment Highlights: Poor Nursing Practice

Current regulation:

- Requires temporary nursing service agencies to refer nurses who demonstrate poor nursing practice to the Board of Registration in Nursing.

Proposed amendment:

- Clarifies that reports of poor nursing practice must be in writing, submitted within 7 days and include specific, detailed information.

Rationale:

- Provides clarity as to timeline, format and specific requirements to allow DPH and the Board of Registration in Nursing to investigate and respond appropriately.

Proposed Amendment Highlights: Patient Abuse Law

Current regulation:

- Does not include any reference to or requirements under the Patient Abuse Law (M.G.L. c. 111 § 72G).

Proposed amendment:

- Inserts specific language on the reporting obligations of a temporary nursing service agency under the Patient Abuse Law (M.G.L. c. 111 § 72G).

Rationale:

- Creates consistency among regulated parties and facilities with the Patient Abuse Law (M.G.L. c. 111 § 72G).

Next Steps:

- The Department intends to conduct a public hearing to solicit comments on the proposed amendment.
- Following the public comment period, the Department will return to the Public Health Council to report on testimony and any recommended changes to this amendment, and seek final promulgation.

- Thank you for the opportunity to present this information today.
- For more information on 105 CMR 157.000, *The Registration and Operation of Temporary Nursing Service Agencies* please find the relevant statutory language and the full current regulation here:

<https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXVI/Chapter111/Section72Y>

<http://www.mass.gov/courts/docs/lawlib/104-105cmr/105cmr157.pdf>

Drug Formulary Commission 2015-2016 Briefing

Eric Sheehan, J.D.

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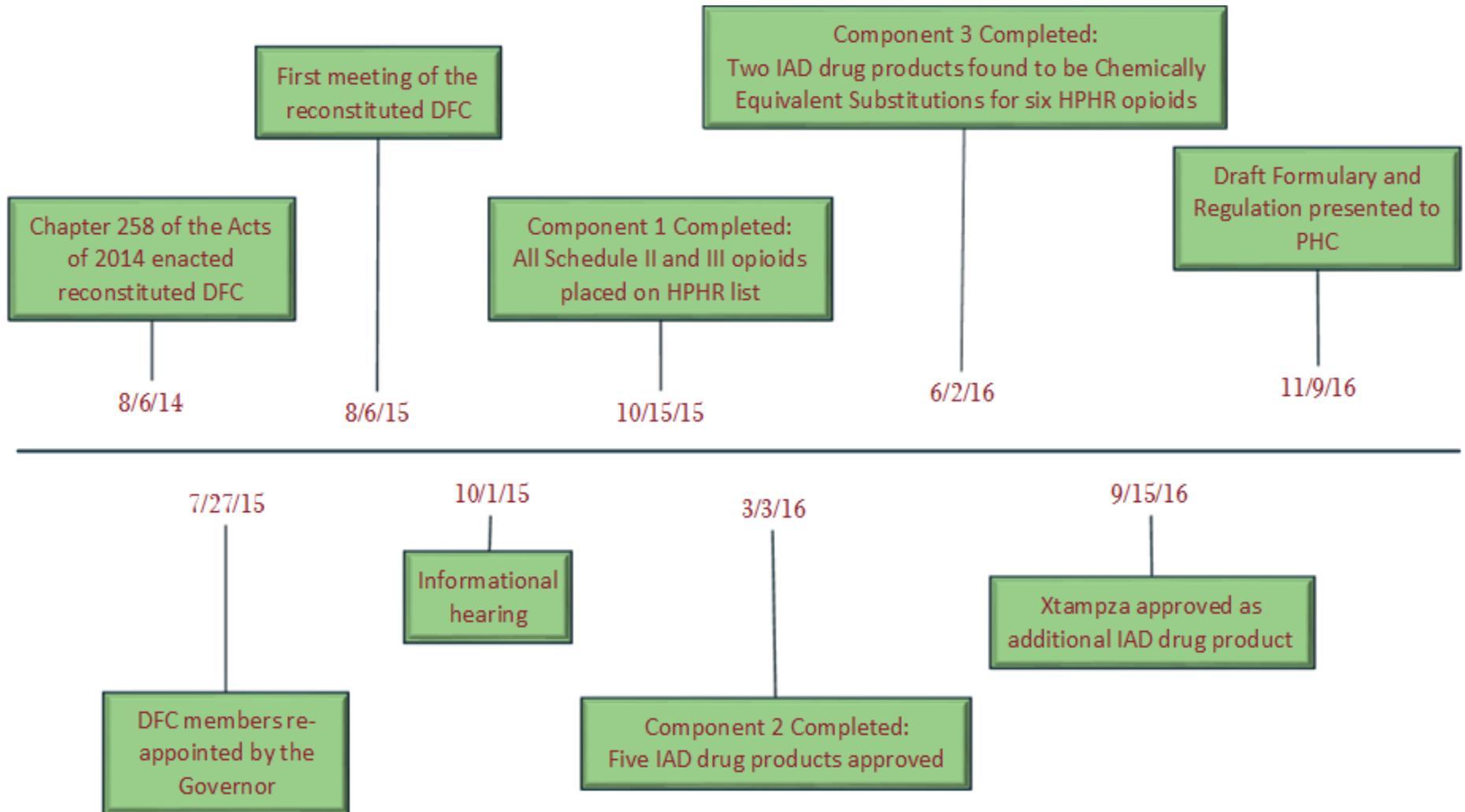
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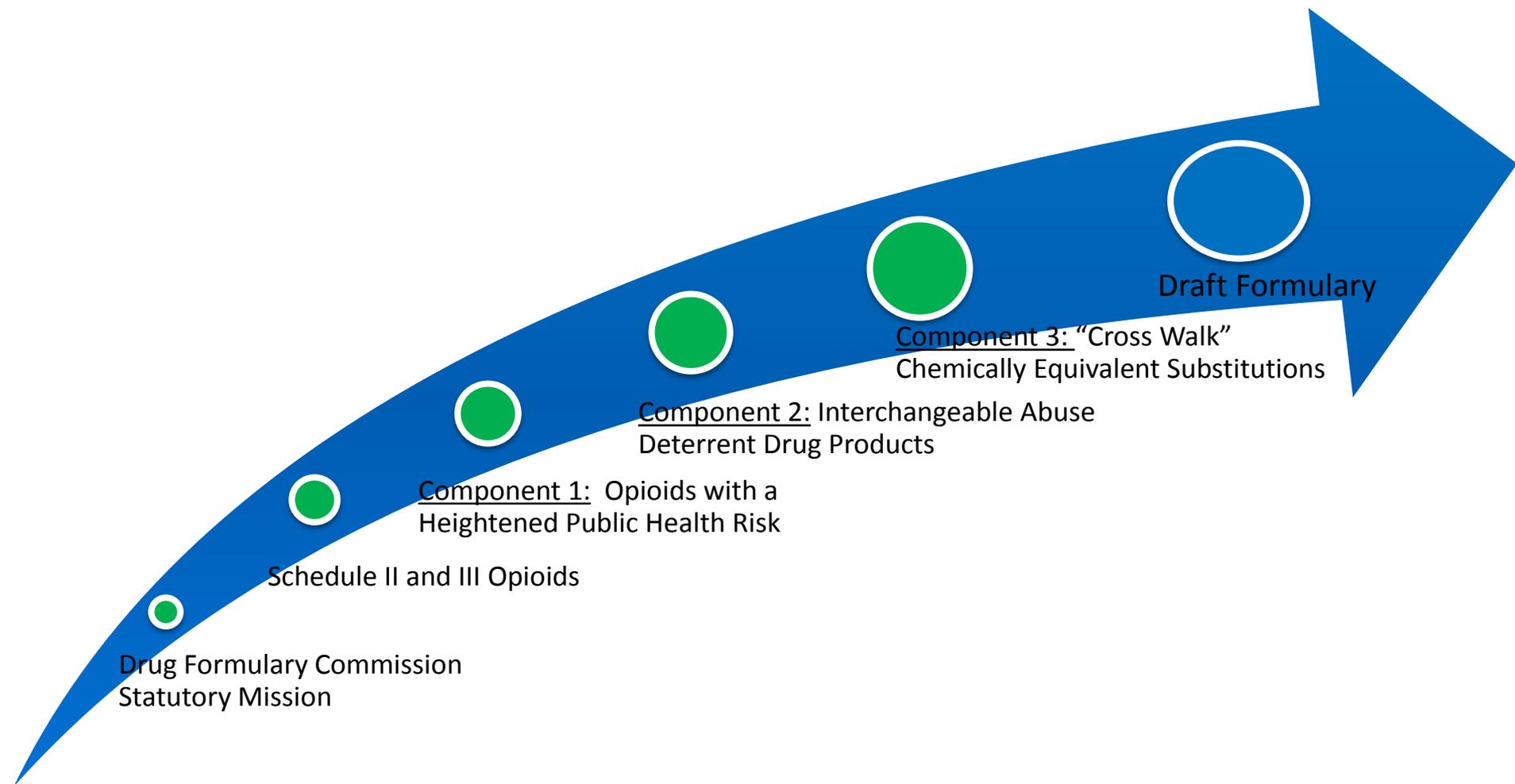
Public Health Council

November 9, 2016

Timeline



Stages: Evaluation and Review Process Overview



Component 1: Generic Opioids with a Heightened Public Health Risk

HPHR Opioids - Generic

Schedule II Opioid Drug Products	Schedule III Opioid Drug Products
Generic Cross Reference Name	Generic Cross Reference Name
Oxycodone Hydrochloride	Buprenorphine/Naloxone
Acetaminophen/Oxycodone Hydrochloride	Acetaminophen/Codeine Phosphate
Acetaminophen/Hydrocodone Bitartrate	Buprenorphine Hydrochloride
Morphine Sulfate	Buprenorphine
Hydromorphone hydrochloride	APAP/Butalbital/Caff/Codeine Phos
Fentanyl	Aspirin/Butalbital/Caffeine/Codeine Phosphate
Methadone Hydrochloride	Acetaminophen/Caffeine/Dihydrocodeine Bitartrate
Hydrocodone Bitartrate/Ibuprofen	Aspirin/Carisoprodol/Codeine Phosphate
Oxymorphone Hydrochloride	Aspirin/Caffeine/Dihydrocodeine Bitartrate
Tapentadol Hydrochloride	
Codeine Sulfate	
Meperidine Hydrochloride	
Levorphanol Tartrate	
Fentanyl Citrate	
Hydrocodone Bitartrate	
Aspirin/Oxycodone Hydrochloride	
Morphine Sulfate/Naltrexone Hydrochloride	
Belladonna Alkaloids/Opium Alkaloids	
Ibuprofen/Oxycodone Hydrochloride	

Component 2: Interchangeable Abuse Deterrent Drug Products

Product Name	Manufacturer	Ingredient(s)	Dose Form	Method of Abuse Deterrence	Date DFC Approved as Potential Substitute
OxyContin [®]	Purdue	Oxycodone ER	Tablet	Crush-resistant Formulation	January 7, 2016
Hysingla ER [®]	Purdue	Hydrocodone ER	Tablet	Crush-resistant Formulation	December 17, 2015
Embeda [®]	Pfizer	Morphine ER and Naltrexone	Capsule	Antagonist	January 7, 2016
Oxaydo [®]	Egalet	Oxycodone IR	Tablet	Aversion technology with assumed ADF properties	February 4, 2016
Nucynta ER [®]	Jansen	Tapentadol	Tablet	Crush-resistant formulation	February 4, 2016
Xtampza ER [®]	Collegium	Oxycodone ER	Capsule	DETERx [®] Physical/chemical barrier	September 15, 2016

ER or Extended Release is a mechanism to prolong absorption of a drug to allow longer dosing intervals and minimize fluctuations in serum drug levels.

IR or Immediate Release indicates the release of the active ingredient within a small period of time, typically less than 30 minutes.

****All decisions of the Drug Formulary Commission may be reconsidered upon receipt of new, relevant evidence.****

Component 3: Chemically Equivalent Substitution

In considering whether an IAD drug product is a chemically equivalent substitution, the Commission considered four statutorily mandated factors:

- accessibility
- cost prohibition
- effectiveness for pain
- effectiveness of abuse deterrent property

“Chemically Equivalent Substitution”, for the purpose of creating a formulary of drugs with abuse deterrent properties that the commission has determined may be appropriately substituted for opioids that have been determined to have a heightened public health risk due to the drugs’ potential for abuse and misuse, shall mean drug products which contain the same active ingredients, and are equivalent in strength or concentration, dosage form, and route of administration, and produce a comparable biologic effect. Prodrugs or ingredients without analgesic effect that are used solely for abuse deterrent formulations need not be equivalent.

Component 3: Cross Walk

- The Commission reviewed the IAD drug products to determine if any of them were chemically equivalent substitutes for HPHR opioids.
- The following potential substitutions were proposed for evaluation †:

HPHR Opioid	IAD Drug Product
Kadian® (morphine ER capsules)	Embeda® (morphine sulfate ER/naltrexone capsule)
Morphine ER 12 or 24 hour capsules (generic Kadian®)	
Morphine ER 24 hour capsules (generic Avinza®)	
Morphine ER tablet (generic MS Contin®)	
MS Contin® (morphine ER tablet)	
Zohydro ER® (hydrocodone ER capsule)	Hysingla ER® (hydrocodone ER tablet)
Oxycodone IR capsules	Oxaydo® (oxycodone IR tablet) (rejected as a chemically equivalent substitution)
Roxicodone® tablets	
Oxycodone IR, tablets (generic Roxicodone)	

† There are no U.S. marketed HPHR opioids available for substitution by these IAD drug products. Note that one chemical (e.g. morphine) or dosing mechanism (ER/IR) may not be substituted for another (e.g. hydrocodone):

- Nucynta ER® (tapentadol ER tablet)
- OxyContin® (oxycodone ER tablet)
- Oxycodone ER tablet
- Xtampza ER capsule (Oxycodone ER)

Formulary – Substitutions

HPHR Opioid	Interchangeable Abuse Deterrent Drug Product	Commercially Available Strengths	Dosing Frequency	ADP Efficacy Category
Kadian® (morphine ER capsules)	Embeda® (morphine sulfate extended-release/naltrexone capsule)	20 mg/0.8 mg	Q24H or Q12H	Category II
Morphine ER 12 or 24 hour capsules (generic Kadian®)		30 mg/1.2 mg		
Morphine ER 24 hour capsules (generic Avinza®)		50 mg/2 mg		
Morphine ER tablet (generic MS Contin®)†		60 mg/2.4 mg		
MS Contin® (morphine ER tablet)†		80 mg/3.2 mg		
Zohydro ER® (hydrocodone ER capsule)†	Hysingla ER® (hydrocodone extended-release tablet)	20 mg	Q24H	Category II
		30 mg		
		40 mg		
		60 mg		
		80 mg		
		100 mg		
		120 mg		

Formulary – No Substitutions

HPHR Opioid	Interchangeable Abuse Deterrent Drug Product	Commercially Available Strengths	Dosing Frequency	ADP Efficacy Category
No equivalent HPHR opioid identified	Nucynta ER® (tapentadol extended-release tablet)	50 mg	Q12H	Category II
		100 mg		
		150 mg		
		200 mg		
		250 mg		
No equivalent HPHR opioid identified	Oxaydo® (oxycodone immediate-release tablet)	5 mg	Q4-6H	Category III
		7.5 mg		
No equivalent HPHR opioid identified	Oxycodone extended-release tablet‡	10 mg	Q12H or Q8H	Category II
		15 mg		
		20 mg		
		30 mg		
		40 mg		
		60 mg		
		80 mg		
No equivalent HPHR opioid identified	OxyContin® (oxycodone extended-release tablet)	10 mg	Q12H or Q8H	Category II
		15 mg		
		20 mg		
		30 mg		
		40 mg		
		60 mg		
		80 mg		
No equivalent HPHR opioid identified	Xtampza ER® (oxycodone ER capsule)	9 mg	Every 12 hours with food	Category II
		13.5 mg		
		18 mg		
		27 mg		
		36 mg		

Thank You

The Department would like to acknowledge all the members of the Drug Formulary Commission for their dedication and hard work in developing the nation's first Formulary of Chemically Equivalent Substitutions and their substantial contribution to the fight against opioid abuse and misuse in the commonwealth.

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Proposed Amendments to 105 CMR 720.000: *List of Interchangeable Drug Products*

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**Public Health Council
November 9, 2016**

- The amendments to this regulation, 105 CMR 720.000, *List of Interchangeable Drug Products*, are proposed as part of the regulatory review process, mandated by Executive Order 562, which requires all state agencies to undertake a review of each regulation under its jurisdiction currently published in the Code of Massachusetts Regulations.
- Significant changes also reflect the changes to the mission of the Drug Formulary Commission, as set forth in M.G.L. c. 17 § 13.

The proposed amendments will achieve the following:

- Changing the title of the regulation from “List of Interchangeable Drug Products” to “Drug Formulary Commission”.
- Update the references to interchangeable drug products;
- Remove the outdated list of generic drugs; and
- Include the drug formulary of chemically equivalent substitutions for opioids with a heightened public health risk.

Current Regulation:

- Contains outdated means of determining which generic drugs can be substituted for brand name drugs.

Proposed Amendment:

- Deletes unnecessary sections related to the process of placing a drug on the Formulary of Interchangeable Drug Products to reflect the current practice whereby Massachusetts defers to the FDA's list of approved generic drugs, as identified in the publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (known as "the Orange Book").
- Deletes Appendix A of the regulation which contains the list of interchangeable drugs and references to the FDA's process for approving interchangeable drugs.

Rationale:

- Makes the regulation consistent with federal law.
- Reflects the current practice whereby pharmacists consult with the First DataBank, which is updated based on regular FDA notices.

- Chapter 258 of the Acts of 2014 changed the mandate of the Drug Formulary Commission to expand its responsibilities and tasked it with preparing a drug formulary of substitutions for Schedule II or III opioids that have a heightened level of public health risk due to the drugs' potential for abuse and misuse.
- Once the formulary is adopted by regulation:
 - Prescribers may choose to prescribe the abuse-deterrent opioids in place of other opioids;
 - Pursuant to statute, where an opioid with a heightened level of public health risk has been prescribed without a notation of “dispense as written”, pharmacists must dispense an interchangeable abuse-deterrent product if one exists;
 - DPH will issue guidance and engage in outreach and education to convey these changes.

Proposed Amendment Highlights: Statutory Changes to Drug Formulary Commission

To reflect the statutory changes to the Drug Formulary Commission, the proposed regulations make the following changes:

- Adds definitions for terms necessary to implement a formulary of abuse-deterrent drug products that can be substituted for opioids with a heightened public health risk;
- Describes the information the Drug Formulary Commission considers in determining which drugs to place on the new formulary, including analysis by leading experts and interagency collaboration;
- Includes the new formulary of chemically equivalent substitutions for opioids with a heightened public risk; and
- Specifies the procedures for amending the new formulary as new abuse-deterrent opioids are approved by the FDA.

Next Steps

- The Department will conduct a public hearing to solicit comments on the proposed amendment.
- Following the public comment period, the Department will return to the Public Health Council to report on testimony and any recommended changes to this amendment, and seek final promulgation.

- Thank you for the opportunity to present this information today.
- For more information on 105 CMR 720.000, *List of Interchangeable Drug Products*, please find the relevant statutory language (M.G.L. c. 17 § 13 and M.G.L. c. 112 § 12D) and the full current regulation here:

<https://malegislature.gov/Laws/GeneralLaws/PartI/TitleII/Chapter17/Section13>

<https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXVI/Chapter112/Section12D>

<http://www.mass.gov/courts/docs/lawlib/104-105cmr/105cmr725.pdf>