Please note that this is a Supplemental Massachusetts Register # S1331.

### Permanent Regulations

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<td><em>Governs the rates paid by health-care providers to temporary nursing agencies registered with the Department of Public Health.</em></td>
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<td><em>Establishes the rates to be paid for certain home and community-based waiver services provided under the MassHealth program. This regulation is being promulgated simultaneous with the rescission of 101 CMR 357.00 and 114.3 CMR 54.00.</em></td>
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<td><em>New chapter.</em></td>
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**105 CMR Department of Public Health**

100.000 Determination of Need

Interprets and implements M.G.L. c. 111, §§ 25B to 25G, §§ 51 through 53, 51A, and 71, requiring that the Department of Public Health must find "need" before a health care entity engages in construction or other substantial capital expenditures in order to ensure that health care resources are reasonably and equitably available to every person within the Commonwealth at the lowest reasonable aggregate cost, while advancing the Commonwealth’s goals for cost containment, improved public health outcomes, and delivery system transformation.

300.000 Reportable Diseases, Surveillance, and Isolation and Quarantine Requirements

Lists diseases designated dangerous to public health by DPH and establishes reporting, surveillance, isolation and quarantine requirements intended for application by local boards of health, hospitals, laboratories, physicians and other health care workers, veterinarians, education officials, recreational program health service providers, food industry officials, and the public. Brings the regulation up to date with current medical and laboratory practice.

**114 CMR Division of Health Care Finance and Policy**

114.3 Rates for Acquired Brain Injury Waiver and Related Services11

Rescinds regulation.

**239 CMR Board of Registration in Embalming and Funeral Directing**

3.00 Registration Requirements; Standards of Business and Professional Practice

Provides personal and business registration/licensing rules, rules for operating funeral establishments, rules governing the conduct of funeral directing and embalming, including sanitation, ethical requirements, and rules governing advertising.

4.00 Pre-need Funeral Contracts and Arrangements

Provides the basic rules for funeral establishments which choose to offer pre-need funeral contracts, in which consumers pre-pay for funeral arrangements. Specifically, provides basic rules for the handling of such funds, mandatory contractual requirements, and rules when funeral establishments are closing or changing ownership.
5.00 Continuing Education

*Mandates the amount of continuing education required, rules governing providers, and explains how the requirement is enforced.*

**310 CMR Department of Environmental Protection**

44.00 DEP Selection, Approval and Regulation of Water Pollution Abatement Projects Receiving Financial Assistance from the State Revolving Fund

*Governs how MassDEP selects and oversees local governments' waste water infrastructure projects which voluntarily receive state-subsidized financing under the State Revolving Fund program. Updates required by state statute and conforms to federal law. Codifies the eligibility criteria for the enhanced subsidies outlined in St. 2014, c. 259.*

45.00 DEP Selection, Approval and Regulation of Drinking Water Projects Receiving Financial Assistance from the State Revolving Fund

*Governs how MassDEP selects and oversees local governments' drinking water infrastructure projects which voluntarily receive state-subsidized financing under the State Revolving Fund program. Updates required by state statute and conform to federal law. Codifies the eligibility criteria for the enhanced subsidies outlined in St. 2017, c. 259.*

**520 CMR Department of Public Safety**

16.00 Enforcement of Civil Fines for Expired Elevator Certificates - *Correction*

**527 CMR Board of Fire Prevention Regulations**

12.00 Massachusetts Electrical Code (Amendments) - *Correction*

**958 CMR Health Policy Commission**

3.000 Health Insurance Consumer Protection

*Establishes requirements for carriers in administering their internal grievance procedures and establishes the requirements for the conduct of external reviews of carriers' medical necessity adverse determinations. Also sets out requirements for continuity of care and referral to specialty care. The regulation incorporates additional reporting requirements for carriers to the Office of Patient Protection.*
Regulation Filing  
To be completed by filing agency

CHAPTER NUMBER:  101 CMR 204.00

CHAPTER TITLE: Rates of Payment to Resident Care Facilities

AGENCY: Executive Office of Health and Human Services

SUMMARY OF REGULATION:  State the general requirements and purposes of this regulation.

101 CMR 204.00 governs the payment rates for services provided by resident care facilities to publicly aided and industrial accident residents.

REGULATORY AUTHORITY:  M.G.L. c. 118E

AGENCY CONTACT:  Debby Briggs, MassHealth Publications  PHONE:  617-847-3302

ADDRESS:  100 Hancock Street, 6th Floor, Quincy, MA 02171

Compliance with M.G.L. c. 30A

EMERGENCY ADOPTION - if this regulation is adopted as an emergency, state the nature of the emergency.

PRIOR NOTIFICATION AND/OR APPROVAL - If prior notification to and/or approval of the Governor, Legislature or others was required, list each notification, and/or approval and date, including notice to the Local Government Advisory Commission.

Executive Order 145 notifications:  10/21/16
Executive Order 562 approval:  1/10/17

PUBLIC REVIEW - M.G.L. c. 30A sections 2 and/or 3 requires notice of the hearing or comment period, including a small business impact statement, be filed with the Secretary of the Commonwealth, published in appropriate newspapers, and sent to persons to whom specific notice must be given at least 21 days prior to such hearing or comment period.

Date of public hearing or comment period:  11/30/16

The text of the regulations published in the electronic version of the Massachusetts Register is unofficial and for informational purposes only. The official version is the printed copy which is available from the State Bookstore at http://www.sec.state.ma.us/spr/sprcat/catidx.htm.
FISCAL EFFECT - Estimate the fiscal effect of the public and private sectors.

For the first and second year: none

For the first five years: ____________________________

No fiscal effect: ____________________________

SMALL BUSINESS IMPACT - M.G.L. c. 30A section 5 requires each agency to file an amended small business impact statement with the Secretary of the Commonwealth prior to the adoption of a proposed regulation. If the purpose of this regulation is to set rates for the state, this section does not apply.

Date amended small business impact statement was filed: N/A

CODE OF MASSACHUSETTS REGULATIONS INDEX - List key subjects that are relevant to this regulation:

PROMULGATION - State the action taken by this regulation and its effect on existing provisions of the Code of Massachusetts Regulations (CMR) or repeal, replace or amend. List by CMR number:

101 CMR 204.00 is being amended.

ATTESTATION - The regulation described herein and attached hereto is a true copy of the regulation adopted by this agency. ATTEST:

SIGNATURE: SIGNATURE ON FILE ____________________________ DATE: Jan 13 2017

Publication - To be completed by the Regulations Division

MASSACHUSETTS REGISTER NUMBER: S1331 DATE: 01/27/2017

EFFECTIVE DATE: 01/27/2017

CODE OF MASSACHUSETTS REGULATIONS

Remove these pages: 4.1 - 4.4 301, 302 305, 306

Insert these pages: 4.1 - 4.4 301, 302 305, 306

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**101 CMR 429.00: RATES FOR CERTAIN SEXUAL AND DOMESTIC VIOLENCE SERVICES**

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**101 CMR 512.00: NURSING FACILITY USER FEES**

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**101 CMR 614.00: HEALTH SAFETY NET PAYMENTS AND FUNDING**

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101 CMR 204.00: RATES OF PAYMENT TO RESIDENT CARE FACILITIES

Section

204.01: General Provisions
204.02: General Definitions
204.03: General Rate Provisions
204.04: Variable Cost Allowance
204.05: Capital and Other Fixed Costs
204.06: Equity and Use and Occupancy Allowance
204.07: Reporting Requirements
204.08: Other Provisions

204.01: General Provisions

(1) Scope and Effective Date. 101 CMR 204.00 governs the payment rates effective October 1, 2016, for services provided by resident care facilities to publicly aided and industrial accident residents. Residential care units of nursing facilities are governed by 101 CMR 206.00: Standard Payments to Nursing Facilities.

(2) Disclaimer of Authorization of Services. 101 CMR 204.00 is not authorization for or approval of the substantive services or the time period for which rates are determined pursuant to 101 CMR 204.00. Governmental units and insurers that purchase services from eligible providers are responsible for the definition, authorization, and approval of services provided to publicly aided or industrial accident residents.

204.02: General Definitions

Meaning of Terms. As used in 101 CMR 204.00, unless the context requires otherwise, terms have the meanings ascribed in 101 CMR 204.02.

Actual Utilization Rate. The percentage of occupancy of a resident care facility. It is calculated by dividing total resident days by maximum available bed days.

Additions. New units or enlargements of existing units that may or may not be accompanied by an increase in licensed bed capacity.

Average Equity Capital. The average of the difference between a provider's beginning and ending allowable book value and the provider's beginning and ending balances for allowable long-term liabilities, calculated pursuant to 101 CMR 204.06.

Base Year. The calendar year or portion of the calendar year that is used to compute the prospective rates as defined in 101 CMR 204.04. The base year for rates effective October 1, 2016, is 2012.

Building. The structure that houses residents. Building costs include the direct cost of construction of the shell and expenditures for service equipment and fixtures such as elevators, plumbing, and electrical fixtures that are made a permanent part of the structure. Building costs also include the cost of bringing the building to productive use, such as permits, engineering and architect's fees, and certain legal fees. Building costs include interest paid during construction but not mortgage acquisition costs. When the fixed assets of a facility are sold, the allowable book value of all improvements will become part of the allowable basis of the building for the buyer.

Center. The Center for Health Information and Analysis (CHIA) established under M.G.L. c. 12C.

Change of Ownership. A bona fide transfer, for reasonable consideration, of all the powers and indicia of ownership. A change of ownership may not occur between related parties and must be a sale of assets of the facility rather than a method of financing. A change in the legal form of the provider does not constitute a change of ownership unless the other criteria are met.
Community Support Facility. A resident care facility licensed by the Department in compliance with 105 CMR 150.000: Licensing of Long Term Care Facilities that provides or makes arrangements to provide appropriate mental health services in addition to the minimum basic care and services required by 105 CMR 150.000: Licensing of Long Term Care Facilities for residents who do not routinely require nursing or other medically related services.

Community Support Resident. An individual in need of resident care facility services, who is 50 years of age or older, and who, upon the written consent of the individual (if he or she is competent to give such consent) or guardian (if he or she is not competent), and a physical evaluation by a psychiatrist or other physician, and a psychiatric evaluation by a psychiatrist, is deemed appropriate by both for residency and services provided by a community support facility pursuant to 105 CMR 150.000: Licensing of Long Term Care Facilities or its most recent applicable regulation. Any exceptions and additional factors used to determine whether a resident is a community support facility resident shall be in accordance with 105 CMR 150.000: Licensing of Long Term Care Facilities.

Community Support Resident Days. The number of days of occupancy by community support residents in a community support facility or a resident care facility with community support residents. Community support resident days include the day of admission but not the day of discharge. Where admission and discharge occur on the same day, one community support resident day will be used. Those days a bed is held vacant for a publicly aided community support resident temporarily placed in a different care situation, pursuant to an agreement between the provider and the Department of Transitional Assistance in accordance with duly established policies of said Department, are included as community support resident days. Those days a bed is held vacant for a non-publicly aided resident, whether or not there is a charge for such reservation by the facility, are included as community support resident days.

Constructed Bed Capacity. A resident care facility's "Bed Capacity (or Clinical Bed Capacity)" as defined in 105 CMR 100.020: Definitions, which states: the capacity of a building to accommodate a bed and the necessary physical appurtenances in accordance with the applicable standards imposed as a condition of operation under state law. It shall include a room designed or able to accommodate a bed and necessary physical appurtenances, whether or not a bed and all such appurtenances are actually in place, with any necessary utilities (e.g., drinking water, sprinkler lines, oxygen, electric current, electric signals, etc.), with either outlets or capped lines within the room.

Deferred Charges. Expenditures, such as prepaid insurance, rent or licenses, not recognized as a cost of operations for the period in which they were incurred but carried forward to be written off in one or more future periods. Deferred charges are not expenditures that can be identified with and justified as relating to physical assets that will contribute services to future operations.

Department. The Massachusetts Department of Public Health.

Desk Audit. A comprehensive audit performed at the Center's offices in which the auditor evaluates the accuracy of the information in the cost reports and supporting documentation in accordance with an audit program.

Direct Restorative Therapy. Services of physical therapists, occupational therapists, and speech, hearing, and language therapists provided directly to individual residents to reduce physical or mental disability and to restore the resident to maximum functional level. Direct restorative therapy services are provided only upon written order of a physician, physician assistant, or nurse practitioner who has indicated anticipated goals and frequency of treatment to the individual resident.

EOHHS. The Executive Office of Health and Human Services established under M.G.L. c. 6A.

Equipment. Tangible fixed assets, usually moveable, that are accessory or supplemental to such larger items as buildings and structures.
Resident Days. The number of days of occupancy by residents in a facility. Included in the computation of resident days is the day of admission but not the day of discharge. Where admission and discharge occur on the same day, one resident day is used. Those days in which a bed is held vacant and reserved for a publicly aided resident temporarily placed in a different care situation, are included as resident days. Those days on which a bed is held vacant and reserved for a non-publicly aided resident, whether or not there is a charge for such reservation by the facility, are included as resident days.

Responsible Person. A person 21 years of age or older who has received a high school diploma, is of good moral character, and has the ability to communicate orally and in writing in English or the primary language used by residents of the facility, and who will make mature and accurate judgments regarding the care needs of the residents as required by 105 CMR 150.000: Licensing of Long Term Care Facilities.

Sole Proprietor. A business enterprise other than a corporation or partnership in which the net worth belongs entirely to one individual.

Support Service Coordinator. A person who has received a BA or BS degree in a human service field of study such as psychology, nursing, or social work and who is employed by a community support facility to identify, monitor, and meet the support service needs of community support residents.

Support Services. Those services provided for the benefit of community support resident(s) in order to enhance psycho-social and physical functioning as defined by the Department in 105 CMR 150.000: Licensing of Long Term Care Facilities.

Unit. Unit shall have the same definition as in 105 CMR 150.000: Licensing of Long Term Care Facilities.

Variable Costs. Costs that change depending on the volume of occupancy. Variable costs include the allowable amounts reported in the following accounts from the cost report: administrator/responsible person salaries and benefits; clerical salaries; EDP/payroll/bookkeeping services; office supplies; telephone, except directory advertising; motor vehicle expense; conventions and meetings; advertising, help wanted; licenses and dues, resident care related; total education and training; total employee benefits, except officers, profit sharing and other benefits; accounting services not related to appeals; total payroll taxes, except officer; non-profit DES claims; malpractice and general liability insurance; total Workers' Compensation, except officer; total group life/health, except officer; total plant operations; total dietary; total laundry; total housekeeping; total nursing; quality assurance professional; community support coordinator; total physician services; house supplies, not resold; pharmacy consultant; social service worker; indirect therapy salaries; indirect therapy consultants; total recreation, except transportation; realty company variable add-back; management company variable and fixed cost add-back, less non-allowable self disallowances; vending machine income; and other operating cost recoverable income.

204.03: General Rate Provisions

(1) General. EOHHS will determine a payment rate for each facility as follows.
(a) The facility's October 1, 2016 rate is equal to the greater of:
   1. the sum of
      a. allowable variable costs determined under 101 CMR 204.04;
      b. allowable capital and other fixed costs and working capital allowance as determined under 101 CMR 204.05; and
      c. allowable equity or use and occupancy allowance determined under 101 CMR 204.06; or
   2. the facility's certified rate in effect on May 31, 2015.
(b) For facilities with certified rates in effect on May 31, 2015 that are:
   1. less than $70, the minimum increase is $3.00; and
   2. greater than or equal to $70 and less than $90, the minimum increase is $1.00
(2) **Other Provisions.**

(a) **Audits.** EOHHs will establish rates after a comprehensive desk audit of the base year cost report. The Center may also, whenever possible, conduct on-site field audits to ensure the accuracy of the claims for reimbursement and consistency in reporting. EOHHs will disallow any cost for which the provider does not produce adequate documentation requested by the Center during a desk or field audit.

(b) **General Cost Principles.** In order to be reimbursed, a cost must

1. be ordinary, necessary, and directly related to the care of publicly aided residents;
2. be consistent with the prudent buyer concept;
3. be for goods and services actually provided in the resident care facility;
4. not have the transaction effect of circumventing 101 CMR 204.00 under the principle that the substance of the transaction must prevail over form;
5. actually be paid by the provider. Examples of costs that are not considered paid for purposes of reimbursement include, but are not limited to, costs that are discharged in bankruptcy, forgiven, converted to a promissory note; and accruals of self-insured costs based on actuarial estimates; and
6. not be paid to a related party that has not been identified on the reports.

(c) **Non-allowable Costs.** Rates will not include those costs that are not reimbursable, as defined below, are reimbursed through an allowance, or are for services that are billed directly.

1. Costs that are not reimbursable include
   a. bad debts, refunds, charity and courtesy allowances, and contractual adjustments to the Commonwealth and other third parties;
   b. recovery of expense items, that is, expenses that are reduced or eliminated by applicable income including but not limited to, rental of quarters to employees and others, income from meals sold to persons other than residents, telephone income, vending machine income, and medical records income. Vending machine income will be recovered against the variable cost, included in the variable cost allowance;
   c. federal and state income taxes, except the non-income related portion of the Massachusetts corporate excise tax;
   d. expenses that are not directly related to the provision of resident care including, but not limited to, expenses related to other business activities and fundraising, gift shop expenses, research expenses, rental expense for space not required by the Department and expenditure of funds received under federal grants for compensation paid for training personnel, and expenses related to grants or contracts for special projects;
   e. compensation and fringe benefits for residents on a provider's payroll;
   f. any amounts in excess of any schedule or limitation contained in 101 CMR 204.00;
   g. penalties and interest incurred because of late payment of loans or other indebtedness, late filing of federal and state tax returns, or from late payment of municipal taxes;
   h. any increase in compensation or fringe benefits granted as an unfair labor practice after a final adjudication by the court of last resort;
   i. accrued expenses that remain unpaid more than 120 days after the close of the reporting year, excluding vacation and sick time accruals, are not included in the prospective rates. When the Center receives satisfactory evidence of payment, EOHHs may reverse the adjustment and include that cost, if otherwise allowable, in the applicable prospective rates. Except as provided above, a cost must actually be paid by the provider in order to be reimbursable. Examples of costs that are not considered paid for purposes of reimbursement include, but are not limited to, costs that are discharged in bankruptcy, forgiven; costs that are converted to a promissory note; and accruals of self-insured costs that are based on actuarial estimates;
   j. expenses for purchased service nursing services purchased from temporary nursing agencies that are not registered with the Department under 105 CMR 157.000: The Registration and Operation of Temporary Nursing Service Agencies;
   k. any expense or amortization of a capitalized cost relating to costs incurred prior to the opening of the facility;
Regulation Filing  
To be completed by filing agency

CHAPTER NUMBER:  
101 CMR 345.00

CHAPTER TITLE:  
Temporary Nursing Services

AGENCY:  
Executive Office of Health and Human Services

SUMMARY OF REGULATION:  
State the general requirements and purposes of this regulation.

101 CMR 345.00 governs the rates paid by health-care providers to temporary nursing agencies registered with the Department of Public Health.

REGULATORY AUTHORITY:  
M.G.L. c. 118E

AGENCY CONTACT:  
Debby Briggs, MassHealth Publications  
PHONE: 617-847-3302

ADDRESS:  
100 Hancock Street, 6th Floor, Quincy, MA 02171

Compliance with M.G.L. c. 30A

EMERGENCY ADOPTION -  
If this regulation is adopted as an emergency, state the nature of the emergency.

PRIOR NOTIFICATION AND/OR APPROVAL -  
If prior notification to and/or approval of the Governor, Legislature or others was required, list each notification, and/or approval and date, including notice to the Local Government Advisory Commission.

Executive Order 145 notifications: 10/21/16
Executive Order 562 approval: 1/10/17

PUBLIC REVIEW -  
M.G.L. c. 30A sections 2 and/or 3 requires notice of the hearing or comment period, including a small business impact statement, be filed with the Secretary of the Commonwealth, published in appropriate newspapers, and sent to persons to whom specific notice must be given at least 21 days prior to such hearing or comment period.

Date of public hearing or comment period: 11/30/16
FISCAL EFFECT - 

Estimate the fiscal effect of the public and private sectors.

For the first and second year: total annualized decrease of $370,129

For the first five years: 

No fiscal effect: 

SMALL BUSINESS IMPACT - 

M.G.L. c. 30A section 5 requires each agency to file an amended small business impact statement with the Secretary of the Commonwealth prior to the adoption of a proposed regulation. If the purpose of this regulation is to set rates for the state, this section does not apply.

Date amended small business impact statement was filed: N/A

CODE OF MASSACHUSETTS REGULATIONS INDEX - 

List key subjects that are relevant to this regulation:

PROMULGATION - 

State the action taken by this regulation and its effect on existing provisions of the Code of Massachusetts Regulations (CMR) or repeal, replace or amend. List by CMR number:

101 CMR 345.00 is being amended.

ATTESTATION - 

The regulation described herein and attached hereto is a true copy of the regulation adopted by this agency. ATTEST:

SIGNATURE: 

SIGNATURE ON FILE 

DATE: Jan 13 2017

Publication - To be completed by the Regulations Division

MASSACHUSETTS REGISTER NUMBER: S1331 DATE: 01/27/2017

EFFECTIVE DATE: 01/27/2017

CODE OF MASSACHUSETTS REGULATIONS

Remove these pages: 

Insert these pages: 851 - 856

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101 CMR 345.00: TEMPORARY NURSING SERVICES

Section

345.01: General Purpose
345.02: Definitions
345.03: Rate Provisions
345.04: General Rate Provisions
345.05: Reporting Requirements
345.06: Transfer of Ownership
345.07: Severability

345.01: General Purpose

1) Scope and Purpose. 101 CMR 345.00 governs the rates paid by health-care providers to temporary nursing agencies registered with the Department of Public Health.

2) Effective Date. The rates contained in 101 CMR 345.00 are effective on or after December 1, 2016.

345.02: Definitions

As used in 101 CMR 345.00, terms have the meanings ascribed in 101 CMR 345.02.

Center. The Center for Health Information and Analysis established under M.G.L. c. 12C.

Department. The Department of Public Health established under M.G.L. c. 111.

EOHHS. The Executive Office of Health and Human Services established under M.G.L. c. 6A.

Fixed-term Travel Employees. Employees who
(a) work exclusively at a particular health-care facility for a specified period of at least 90 days pursuant to a contract between the provider and a temporary nursing agency;
(b) must relocate a distance of at least 200 miles and establish a temporary residence for the contract term to work at the contracting provider; and
(c) incur expenses for temporary accommodations paid by the agency. Providers are required to maintain documentation concerning fixed-term travel employees for a period of two years following the expiration of the contract.

Governmental Unit. The Commonwealth, any department, agency, board, division, or commission of the Commonwealth, and any political subdivision of the Commonwealth.

Health Service Area (HSA). Regional boundaries created for the purposes of health-care planning pursuant to P.L. 93-641. A list of the municipalities in each HSA is included in an appendix to 101 CMR 345.00.

Hospital. A hospital licensed under M.G.L. c. 111, § 51, including but not limited to, an acute hospital, chronic hospital, rehabilitation hospital, or psychiatric hospital.

Medical Personnel. Registered nurses, licensed practical nurses, and certified nursing assistants, associated with a temporary nursing agency. All such medical personnel are employees unless the agency demonstrates that they should be treated as independent contractors.

Nursing Facility. A nursing or convalescent home; an infirmary maintained in a town; a charitable home for the aged, as defined in M.G.L. c. 111, § 71; or a nursing facility operating under a hospital license issued by the Department pursuant to M.G.L. c. 111, and certified by the Department for participation in MassHealth. It includes facilities that operate a licensed residential-care unit within the nursing facility.

Overtime. Per hour of care in excess of 40 hours per week or eight hours per day, as defined in an agreement between the health-care facility and the agency.

Price. The total amount per hour charged by the agency for a specific service to the provider.
Registered Nurse, Specialist. A registered nurse with advanced nursing knowledge and clinical skills acquired through an appropriate nursing education program in accordance with 244 CMR 4.00: *Advanced Practice Registered Nursing*, including but not limited to, an operating room nurse, clinical nurse specialist, intensive-care unit nurse, coronary-care unit nurse, and infection-control nurse.

Related Party. An individual or organization associated or affiliated with, or that has control of, or is controlled by, the agency; or is related to the agency or any director, stockholder, trustee, partner, or administrator of the agency by common ownership or control or in a manner specified in §§ 267(b) and (c) of the Internal Revenue Code of 1954, provided, however, that 10% is the operative factor as set out in §§ 267(b) (2) and (3). Related individuals include spouses, parents, children, spouses of children, grandchildren, siblings, fathers-in-law, mothers-in-law, brothers-in-law, and sisters-in-law.

Temporary Nursing Agency (Agency). An agency is defined in accordance with the provisions of 105 CMR 157.010: *Scope and Applicability*. It includes any person, firm, corporation, partnership, or association registered with the Department that is engaged for hire in the business of procuring or providing temporary employment in health-care facilities for medical personnel, referred to as "nursing pools" in M.G.L. c. 111, § 72Y. Each separate location of the business of an agency registered with the Department is an agency. An agency does not include a medical personnel staff arrangement set up by a health-care facility solely for its own use in which the only costs are the salaries paid to such medical personnel; or an individual who engages only in providing his or her own services on a temporary basis to health-care facilities.

345.03: Rate Provisions

(1) General. All prices are per hour. An agency’s price for a service provided to a nursing facility or hospital may not exceed the maximum price set forth in 101 CMR 345.03(2) or (3). Rates vary by health service area (HSA). The location of the nursing facility or hospital determines the maximum price that may be charged.

(a) Holidays. Rates for holidays may not exceed 150% of the maximum prices set forth in 101 CMR 345.03(2) or (3). An agency and the purchasing nursing facility or hospital may define the specific times for each shift and the days that constitute holidays in the written agreement for services as required by 105 CMR 157.220: *Written Agreements*.

(b) Overtime. An agency and a nursing facility or hospital may agree to an overtime differential to be added to a maximum service price to compensate an employee for overtime hours worked.

(c) Exemptions. Fixed-term travel employees are not subject to the maximum prices set forth in 101 CMR 345.03.

(d) 12-hour Shift. An agency and a nursing facility or hospital may agree to a single price per hour for services provided during a 12-hour shift. The price per hour cannot exceed the weighted average of the combined maximum prices for the applicable shifts as set forth in 101 CMR 345.03(2) or (3). For example, an RN in HSA 1 providing weekday services at a nursing facility from 7:00 A.M. to 7:00 P.M. could be billed at a single rate of $52.71, using eight hours at $52.19 and four hours at $53.74 (8 x $52.19 + 4 x $53.74 = $632.48/12 = $52.71).

(2) Maximum Prices, Nursing Facilities.

(a) Registered Nurse (RN) – Nursing Facility.

<table>
<thead>
<tr>
<th>Shift</th>
<th>HSA 1 Western</th>
<th>HSA 2 Central</th>
<th>HSA 3 Merrimack Valley</th>
<th>HSA 4 Greater Boston</th>
<th>HSA 5 Southeastern</th>
<th>HSA 6 North Shore</th>
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<tbody>
<tr>
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<td>$51.95</td>
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<td>$53.44</td>
<td>$53.74</td>
<td>$56.53</td>
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<td>Weekend 3</td>
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1/27/17 101 CMR - 852

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345.03: continued

(b) Licensed Practical Nurse (LPN) – Nursing Facility.

<table>
<thead>
<tr>
<th>Shift</th>
<th>HSA 1 Western</th>
<th>HSA 2 Central</th>
<th>HSA 3 Merrimack Valley</th>
<th>HSA 4 Greater Boston</th>
<th>HSA 5 Southeastern</th>
<th>HSA 6 North Shore</th>
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(c) Certified Nurse Aide (CNA) – Nursing Facility.

<table>
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<tr>
<th>Shift</th>
<th>HSA 1 Western</th>
<th>HSA 2 Central</th>
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(3) Maximum Prices, Hospitals.

(a) Registered Nurse (RN) - Hospital.

<table>
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(b) Registered Nurse Specialist (RN-Specialist) - Hospital.

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345.03: continued

(c) Licensed Practical Nurse (LPN) - Hospital.

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(d) Certified Nurse Aide (CNA) - Hospital.

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345.04: General Rate Provisions

1) The rates determined in accordance with 101 CMR 345.00 are full compensation for temporary nursing services rendered to a nursing facility or hospital, including any related administrative or supervising duties provided by the agency in connection with patient care.

2) An agency may charge a nursing facility or hospital less than the rate determined by 101 CMR 345.00.

3) An agency may not bill, receive payments, or propose to do business with a nursing facility or hospital at a rate greater than the rate established by EOHHS. If an agency violates this requirement, EOHHS may
   (a) notify the Department to suspend or revoke the agency’s registration in accordance with the provisions of 105 CMR 157.000: The Registration and Operation of Temporary Nursing Service Agencies; or
   (b) request that the Attorney General bring an action to restrain or prevent the agency from operating.

345.05: Reporting Requirements

1) Temporary Nursing Service Cost Report. Each agency must complete and file a Temporary Nursing Service Cost Report with EOHHS or its designee each calendar year.
   (a) EOHHS will issue an administrative bulletin to inform providers of the issuance of the Cost Report and the due date for filing the Cost Report. Agencies will have a minimum of 45 days’ notice from the issuance of the Cost Report and the due date.
   (b) Agencies that employ only fixed-term travel employees are not required to file a Temporary Nursing Service Cost Report. Such agencies must file a certified or audited financial statement with EOHHS or its designee annually, due no later than the required due date of the Temporary Nursing Service Cost Report.

2) Fixed-term Travel Employee Disclosure Form. Each agency that provides the services of a fixed-term travel employee must complete and file this form for all fixed-term travel employees in its employ who provided these services during the cost report year.
345.05: continued

(3) Additional Information. Each agency must make available all records, books, and reports relating to its operation including such data and statistics as EOHHS or its designee may request.

(4) Extension of Filing Date. EOHHS or its designee may grant a request for an extension of the filing due date for a maximum of 15 calendar days. In order to receive an extension, the agency must demonstrate exceptional circumstances that prevent the agency from meeting the deadline and file the request no later than the filing due date.

(5) Audit. Agencies are subject to the duties and responsibilities set forth in M.G.L. c. 12C, § 22, whether or not receiving payment from a governmental unit. All information submitted by an agency is subject to audit. An agency must maintain supporting documentation sufficient to demonstrate compliance with all provisions of 101 CMR 345.00.

(6) Failure to File Information. If an agency fails to file timely and complete information required by EOHHS or its designee, including cost reports and supporting documentation, EOHHS may notify the Department and request revocation of such agency's registration.

345.06: Transfer of Ownership

All issues related to the transfers of ownership including, but not limited to, merger, acquisition, or name change, are governed by the Department regulations set forth in 105 CMR 157.00: The Registration and Operation of Temporary Nursing Service Agencies.

345.07: Severability

The provisions of 101 CMR 345.00 are hereby declared to be severable. If any such provisions or the application of such provisions to any eligible provider or circumstances are held invalid or unconstitutional, such invalidity will not be construed to affect the validity or constitutionality of any remaining provisions of 101 CMR 345.00 or the application of such provisions to eligible providers or circumstances other than those held invalid.

REGULATORY AUTHORITY

101 CMR 345.00: M.G.L. c. 118E.
The regulation at 101 CMR 357.00 establishes the rates to be paid for services provided under the Money Follows the Person Waivers. This regulation is being rescinded with rates to be promulgated in the regulation at 101 CMR 359 in accordance with M.G.L. Chapter 118E, Sections 13C and 13D.

REGULATORY AUTHORITY:  M.G.L. c. 118E

AGENCY CONTACT:  Deborah Briggs  PHONE:  617-847-3302

ADDRESS:  100 Hancock Street, Quincy, MA 02171

Compliance with M.G.L. c. 30A

EMERGENCY ADOPTION -  if this regulation is adopted as an emergency, state the nature of the emergency.

PRIOR NOTIFICATION AND/OR APPROVAL -  If prior notification to and/or approval of the Governor, Legislature or others was required, list each notification, and/or approval and date, including notice to the Local Government Advisory Commission.

Executive Order 562 approval: January 10, 2017
Executive Order 145 notification: October 7, 2016

PUBLIC REVIEW -  M.G.L. c. 30A sections 2 and/or 3 requires notice of the hearing or comment period, including a small business impact statement, be filed with the Secretary of the Commonwealth, published in appropriate newspapers, and sent to persons to whom specific notice must be given at least 21 days prior to such hearing or comment period.

Date of public hearing or comment period:  November 14, 2016
FISCAL EFFECT - Estimate the fiscal effect of the public and private sectors.

For the first and second year: FY17: $4,245,484.50; FY18: $8,490,969

For the first five years: ____________________________________________________________

No fiscal effect: _________________________________________________________________

SMALL BUSINESS IMPACT - M.G.L. c. 30A section 5 requires each agency to file an amended small business impact statement with the Secretary of the Commonwealth prior to the adoption of a proposed regulation. If the purpose of this regulation is to set rates for the state, this section does not apply.

Date amended small business impact statement was filed: N/A

CODE OF MASSACHUSETTS REGULATIONS INDEX -

Elders, Health Care, Housing, Persons with Disabilities

PROMULGATION - State the action taken by this regulation and its effect on existing provisions of the Code of Massachusetts Regulations (CMR) or repeal, replace or amend. List by CMR number:

101 CMR 357.00 is being repealed.

ATTESTATION - The regulation described herein and attached hereto is a true copy of the regulation adopted by this agency. ATTEST:

SIGNATURE: ___________________________ SIGNATURE ON FILE ___________________________ DATE: Jan 13 2017

Publication - To be completed by the Regulations Division

MASSACHUSETTS REGISTER NUMBER: S1331 DATE: 01/27/2017

EFFECTIVE DATE: 01/27/2017

The text of the regulations published in the electronic version of the Massachusetts Register is unofficial and for informational purposes only. The official version is the printed copy which is available from the State Bookstore at http://www.sec.state.ma.us/spr/sprcat/catidx.htm.
(101 CMR 357.00: RESERVED)
Regulation Filing  

To be completed by filing agency

CHAPTER NUMBER:  101 CMR 359.00

CHAPTER TITLE: Rates for Home and Community Based Services Waivers

AGENCY: Executive Office of Health and Human Services

SUMMARY OF REGULATION: State the general requirements and purposes of this regulation.

In accordance with M.G.L. Chapter 118E, Sections 13C and 13D, the regulation at 101 CMR 359.00 establishes the rates to be paid for certain home and community-based waiver services provided under the MassHealth program. This regulation is being promulgated simultaneous with the rescission of 101 CMR 357.00 and 114.3 CMR 54.00.

REGULATORY AUTHORITY: M.G.L. c. 118E

AGENCY CONTACT: Deborah Briggs  PHONE: 617-847-3302

ADDRESS: 100 Hancock Street, Quincy, MA 02171

Compliance with M.G.L. c. 30A

EMERGENCY ADOPTION - if this regulation is adopted as an emergency, state the nature of the emergency.

PRIOR NOTIFICATION AND/OR APPROVAL - If prior notification to and/or approval of the Governor, Legislature or others was required, list each notification, and/or approval and date, including notice to the Local Government Advisory Commission.

Executive Order 562 approval: January 10, 2017
Executive Order 145 notification: October 7, 2016

PUBLIC REVIEW - M.G.L. c. 30A sections 2 and/or 3 requires notice of the hearing or comment period, including a small business impact statement, be filed with the Secretary of the Commonwealth, published in appropriate newspapers, and sent to persons to whom specific notice must be given at least 21 days prior to such hearing or comment period.

Date of public hearing or comment period: November 14, 2016
FISCAL EFFECT - Estimate the fiscal effect of the public and private sectors.
For the first and second year: FY17: $4,245,484.50; FY18: $8,490,969
For the first five years: 
No fiscal effect: 

SMALL BUSINESS IMPACT - M.G.L. c. 30A section 5 requires each agency to file an amended small business impact statement with the Secretary of the Commonwealth prior to the adoption of a proposed regulation. If the purpose of this regulation is to set rates for the state, this section does not apply.

Date amended small business impact statement was filed: N/A

CODE OF MASSACHUSETTS REGULATIONS INDEX - List key subjects that are relevant to this regulation:
Elders, Health Care, Housing, Persons with Disabilities

PROMULGATION - State the action taken by this regulation and its effect on existing provisions of the Code of Massachusetts Regulations (CMR) or repeal, replace or amend. List by CMR number:
101 CMR 359.00 is being adopted.

ATTESTATION - The regulation described herein and attached hereto is a true copy of the regulation adopted by this agency. ATTEST:

SIGNATURE: SIGNATURE ON FILE DATE: Jan 13 2017

Publication - To be completed by the Regulations Division

MASSACHUSETTS REGISTER NUMBER: S1331 DATE: 01/27/2017

EFFECTIVE DATE: 01/27/2017

CODE OF MASSACHUSETTS REGULATIONS
Remove these pages: 928.1, 928.2 Insert these pages: 928.1 - 928.18

The text of the regulations published in the electronic version of the Massachusetts Register is unofficial and for informational purposes only. The official version is the printed copy which is available from the State Bookstore at http://www.sec.state.ma.us/spr/srcatcatidx.htm.
359.01: General Provisions

(1) Scope. 101 CMR 359.00 governs the payment rates, effective January 1, 2017, for services in four Home and Community-based Services (HCBS) Waivers purchased by a governmental unit. The four HCBS Waivers are: Acquired Brain Injury Non-residential Habilitation (ABI-N) Waiver, Acquired Brain Injury Residential Habilitation (ABI-RH) Waiver, Money Follows the Person Community Living (MFP-CL) Waiver, and Money Follows the Person Residential Supports (MFP-RS) Waiver. Listed in 101 CMR 359.01(a) through (d) are the waiver services available in each waiver.

(a) ABI-N Waiver Services:
1. Adult Companion
2. Chore Services
3. Day Services
4. Home Accessibility Adaptations
5. Homemaker
6. Individual Support & Community Habilitation
7. Occupational Therapy
8. Personal Care
9. Physical Therapy
10. Respite Services
11. Specialized Medical Equipment
12. Speech Therapy
13. Supported Employment
14. Transitional Assistance
15. Transportation

(b) ABI-RH Waiver Services:
1. Assisted Living Services
2. Day Services
3. Occupational Therapy
4. Physical Therapy
5. Residential Habilitation
6. Shared Living - 24 Hour Supports
7. Specialized Medical Equipment
8. Speech Therapy
9. Supported Employment
10. Transitional Assistance
11. Transportation

(c) MFP-CL Waiver Services:
1. Adult Companion
2. Chore Services
3. Community Family Training
4. Day Services
5. Home Accessibility Adaptations
6. Home Health Aide
7. Homemaker
8. Independent Living Supports
9. Individual Support & Community Habilitation
10. Occupational Therapy
11. Orientation and Mobility Services
12. Peer Support
13. Personal Care
359.01: continued

14. Physical Therapy
15. Prevocational Services
16. Respite Services
17. Shared Home Supports
18. Skilled Nursing
19. Specialized Medical Equipment
20. Speech Therapy
21. Supported Employment
22. Supportive Home Care Aide
23. Transportation
24. Transitional Assistance
25. Vehicle Modification

(d) MFP-RS Waiver Services:
1. Assisted Living Services
2. Day Services
3. Home Accessibility Adaptations (available only in Shared Living - 24 Hour Supports)
4. Individual Support & Community Habilitation
5. Occupational Therapy
6. Orientation and Mobility Services
7. Peer Support
8. Physical Therapy
9. Prevocational Services
10. Residential Family Training
11. Residential Habilitation
12. Shared Living - 24 Hour Supports
13. Skilled Nursing
14. Specialized Medical Equipment
15. Speech Therapy
16. Supported Employment
17. Transitional Assistance
18. Transportation

(2) Disclaimer of Authorization of Services. 101 CMR 359.00 is neither authorization for nor approval of the services for which rates are determined pursuant to 101 CMR 359.00. Governmental units that purchase MFP Waiver Services and/or ABI Waiver Services are responsible for the definition, authorization, and approval of services extended to participants.

(3) Administrative Bulletins. EOHHS may issue administrative bulletins to clarify its policy on substantive provisions of 101 CMR 359.00.

(4) Coding Updates and Corrections. EOHHS may publish service code updates and corrections by Administrative Bulletin. Updates may reference coding systems including but not limited to the American Medical Association's Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS) maintained by the Centers for Medicare and Medicaid Services (CMS). The publication of such updates and corrections will list
(a) codes for which only the code numbers change, with the corresponding cross references between existing and new codes;
(b) deleted codes for which there are no corresponding new codes; and
(c) codes for entirely new services that require pricing. These codes will be paid on an individual consideration basis until rates are established.

359.02: Definitions

Meaning of Terms. As used in 101 CMR 359.00, unless the context requires otherwise, terms will have the meanings ascribed in 101 CMR 359.02.
Acquired Brain Injury Home- and Community-based Service Waiver (ABI Waiver). Two Massachusetts home- and community-based services waivers for persons with acquired brain injury are approved by the Centers for Medicare and Medicaid Services (CMS) under Section 1915(c) of the Social Security Act. The two separate Acquired Brain Injury Waivers, each with different covered services and eligibility requirements, are: the Acquired Brain Injury with Residential Habilitation (ABI-RH) Waiver and the Acquired Brain Injury Non-residential Habilitation (ABI-N) Waiver.

Activities of Daily Living (ADL). Certain basic tasks required for daily living, including the ability to bathe, dress/undress, eat, toilet, transfer in and out of bed or chair, get around inside the home, and manage incontinence.

Adult Companion Service. Nonmedical care, supervision, and socialization provided to a participant. Companions may assist or supervise the participant with such light household tasks as meal preparation, laundry, and shopping.

Agency Rate. The fee for services performed by a person whose wage is paid by a corporation or partnership that is a MassHealth provider.

Assisted Living Services. Services consist of personal care and supportive services (homemaker, chore, personal care services, meal preparation) that are furnished to participants who reside in a qualified assisted living residence (ALR) that includes 24-hour on-site response capability to meet scheduled or unpredictable resident needs and to provide supervision, safety and security. Services may also include social and recreational programs, and medication assistance (consistent with ALR certification and to the extent permitted under State law). Nursing and skilled therapy services are incidental rather than integral to the provision of Assisted Living Services. Intermittent skilled nursing services and therapy services may be provided to the extent allowed by applicable regulations.

Chore. An unusual or infrequent household maintenance task that is needed to maintain the participant's home in a clean, sanitary, and safe environment. This service includes heavy household chores such as washing floors, windows, and walls; tacking down loose rugs and tiles; and moving heavy items of furniture in order to provide safe access and egress.

Community Family Training. A service designed to provide training and instruction about the treatment regimes, behavior plans, and the use of specialized equipment that support a participant in the community. Community family training may also include training in family leadership, support of self-advocacy, and independence for the family member. The service enhances the skills of the family to assist the waiver participant to function in the community and at home.

Cost Report. The document used to report costs and other financial and statistical data. The Uniform Financial Statements and Independent Auditor's Report (UFR) are used when required.

Day Services. A structured, site-based, group program for participants that fosters community integration and offers assistance with the acquisition, retention, or improvement in self-help, socialization, and adaptive skills, and that takes place in a nonresidential setting separate from the participant's private residence or other residential living arrangement. Services often include assistance to learn activities of daily living and functional skills; language and communication training; compensatory, cognitive and other strategies; interpersonal skills; prevocational skills; and recreational and socialization skills.

Employer Expense Component (EEC). The portion of the Self-directed Service rate that is designated for the mandated employer share of FICA, federal and state unemployment taxes, Medicare, and Workers' Compensation premiums.

EOHHS. The Executive Office of Health and Human Services established under M.G.L. c. 6A.
Governmental Unit. The Commonwealth, any board, commission, department, division, or agency of the Commonwealth and any political subdivision of the Commonwealth.

Home Accessibility Adaptations. Physical modifications to the participant's home that are necessary to ensure the health, welfare, and safety of the participant or that enable the participant to function with greater independence in the home.

Home and Community-based Services (HCBS) Waiver. A federally approved program operated under Section 1915(c) of the Social Security Act that authorizes the U.S. Secretary of Health and Human Services to grant waivers of certain Medicaid statutory requirements so that a state may furnish home and community based services to certain Medicaid beneficiaries who need a level of care that is provided in a hospital, nursing facility, or Intermediate Care Facility for Individuals with Intellectual Disabilities (ICF/ID). For purposes of 101 CMR 359.00, Home and Community-based Service Waiver refers to the two ABI waivers and the two MFP waivers.

Homemaker. A person who performs light housekeeping duties (for example, cooking, cleaning, laundry, and shopping) for the purpose of maintaining a household.

Home Health Aide. A person who performs certain personal care and other health-related services as described in 130 CMR 403.000: Home Health Agency.

Independent Living Supports. A service that ensures 24-hour seven days per week access to supportive services for participants who have intermittent, scheduled and unscheduled needs for various forms of assistance, but who do not require 24-hour supervision. It provides participants with services and supports in a variety of activities such as: ADLs and instrumental activities of daily living (IADLs), support and companionship, emotional support and socialization. This service is provided by a site-based provider, and is available to participants who choose to reside in locations where a critical mass of individuals reside who require such support and where providers of such supports are available.

Individual Consideration (I.C). Payment rates for certain services are designated as Individual Consideration (I.C.). Where I.C. rates are designated, the purchasing governmental unit will determine the appropriate payment rate in accordance with the following standards and criteria:

(a) the amount of time required to complete the service or item;
(b) the degree of skill required to complete the service or item;
(c) the severity or complexity of the service or item;
(d) the lowest price charged or accepted from any payer for the same or similar service or item, including, but not limited to any shelf price, sale price, advertised price, or other price reasonably obtained by a competitive market for the service or item; and
(e) the established rates, policies, procedures, and practices of any other purchasing governmental unit in purchasing the same or similar services or items.

Individual Provider (Self-employed Provider) Rate. The fee for services performed by a person that is a Provider and is not paid a wage by another person or entity for services performed.

Individual Support and Community Habilitation. Regular or intermittent services designed to develop, maintain, and/or maximize the participant's independent functioning in self-care, physical and emotional growth, socialization, communication, and vocational skills, to achieve objectives of improved health and welfare and to support the ability of the participant to establish and maintain a residence and live in the community.

Money Follows the Person Waivers (MFP Waivers). Two Massachusetts Home and Community-based Services Waivers for persons participating in the MFP Demonstration and other qualified individuals and approved by CMS under Section 1915(c) of the Social Security Act. Massachusetts operates two separate MFP Waivers - the Money Follows the Person Residential Supports (MFP-RS) waiver, and the Money Follows the Person Community Living (MFP-CL) waiver - each with different covered services and eligibility requirements.
Non-agency Rate. The fee for services performed by Individual Providers (Self-employed Providers) or Self-directed Workers.

Occupational Therapy. Therapy services, including diagnostic evaluation and therapeutic intervention, designed to improve, develop, correct, rehabilitate, or prevent the worsening of functions that affect the activities of daily living that have been lost, impaired, or reduced as a result of acute or chronic medical conditions, congenital anomalies, or injuries. Occupational therapy programs are designed to improve quality of life by recovering competence and preventing further injury or disability, and to improve the individual's ability to perform tasks required for independent functioning, so that the individual can engage in activities of daily living.

Orientation and Mobility Services. Services that teach an individual with vision impairment or legal blindness how to move or travel safely and independently in his or her home and community, and which includes assessment, training and education provided to participants, environmental evaluations, caregiver/direct care staff training on sensitivity to blindness/low vision, and information resource on community living for persons with vision impairment or legal blindness. Orientation and Mobility Services are tailored to the individual's need and may extend beyond the home setting to other community settings as well as public transportation systems.

Participant. A MassHealth member determined by the MassHealth agency to be eligible for enrollment in one of the HCBS waivers, who chooses to receive HCBS waiver services, and for whom a service plan has been developed that includes one or more HCBS waiver services.

Peer Support. Ongoing services and supports designed to assist participants to acquire, maintain or improve the skills necessary to live in a community setting. This service provides supports necessary for the participant to develop the skills that enable them to become more independent, integrated into, and productive in their communities. The service enables the participant to retain or improve skills related to personal finance, health, shopping, use of community resources, community safety, and other adaptive skills needed to live in the community.

Personal Care. Services provided to a participant, which may include physical assistance, supervision or cueing of participants, for the purpose of assisting the participant to accomplish activities of daily living (ADLs), including, but not limited to, eating, toileting, dressing, bathing, transferring, and ambulation.

Physical Therapy. Therapy services, including diagnostic evaluation and therapeutic intervention, designed to improve, develop, correct, rehabilitate, or prevent the worsening of physical functions that have been lost, impaired, or reduced as a result of acute or chronic medical conditions, congenital anomalies, or injuries. Physical therapy emphasizes a form of rehabilitation focused on treatment of dysfunctions involving neuromuscular, musculoskeletal, cardiovascular/pulmonary, or integumentary systems through the use of therapeutic interventions to optimize functioning levels.

Prevocational Services. A service that consists of a range of learning and experimental type activities that prepares a participant for paid or unpaid employment in an integrated, community setting. Services are not job-task oriented but instead, aimed at a generalized result (e.g. attention span, motor skills). The service may include teaching such concepts as attendance, task completion, problem solving and safety as well as social skills training, improving attention span, and developing or improving motor skills. Basic skill-building activities are expected to specifically involve strategies to enhance a participant's employability in integrated, community settings.

Provider. Any individual, group, partnership, trust, corporation or other legal entity that offers services for purchase by a governmental unit and that meets the conditions of purchase or licensure that have been or may be adopted by a purchasing governmental unit.

Reporting Year. The Provider's fiscal year.
Residential Family Training. A service designed to provide training and instruction about treatment regimes, behavior plans, and the use of specialized equipment that supports the participant to participate in the community. Residential family training may also include training in family leadership, support of self-advocacy, and independence for their family member. The service enhances the skill of the family to assist the waiver participant to function in the community and at home when the waiver participant visits his or her family.

Residential Habilitation Room and Board. The amount paid by a governmental unit purchasing Residential Habilitation services for the costs of building, maintenance, upkeep, improvements, and meals, which are not covered as part of the Residential Habilitation Waiver service.

Residential Habilitation Service. Ongoing services and supports provided to a participant in a provider-operated residential setting that are designed to assist participants in acquiring, maintaining, or improving the skills necessary to live in a community setting. Residential habilitation provides participants with daily professional intervention including care, supervision, and skills training in activities of daily living, home management, and community integration in a qualified residential setting with 24-hour staffing. This service may include the provision of medical and health-care services that are integral to meeting the daily needs of participants.

Respite. Services provided to individuals unable to care for themselves; furnished on a short-term basis because of the absence or need for relief of unpaid caregivers.

Self-directed Services. A model of service delivery in which a waiver participant has decision-making authority over certain aspects of the delivery of their care.

Self-directed Worker. Participants who choose to self-direct waiver services have the authority and responsibility for recruiting and hiring workers to provide their Self-directed Services. These workers are referred to as self-directed workers and subject to the standards, requirements, policies, and procedures for such workers under the participant's Home and Community-based Services Waiver (HCBS).

Shared Home Supports. An individually tailored supportive service that assists with the acquisition, retention, or improvement in skills related to living in the community. A participant is matched with a Shared Home Supports caregiver. This arrangement is overseen by a residential support agency. Shared Home Supports does not include 24-hour care. Shared Home Supports includes such supports as: adaptive skill development, assistance with ADLs and IADLs, adult educational supports, social and leisure skill development, and supervision.

Shared Living - 24 Hour Supports. A residential option that matches a participant with a Shared Living caregiver. This arrangement is overseen by a residential support agency. Shared Living is an individually tailored 24 hour/seven day per week, supportive service available to a participant who needs daily structure and supervision. Shared Living includes supportive services that assist with the acquisition, retention, or improvement of skills related to living in the community. This includes such supports as: adaptive skill development, assistance with ADLs and IADLs, adult educational supports, social and leisure skill development, protective oversight and supervision.

Skilled Nursing Services. The assessment, planning, provision, and evaluation of goal-oriented nursing care that requires specialized knowledge and skills acquired under the established curriculum of a school of nursing approved by a board of registration in nursing. Such services include only those services that require the skills of a nurse. Skilled Nursing Services are provided by a person licensed as a registered nurse or a licensed practical nurse by a state's board of registration in nursing.

Specialized Medical Equipment and Supplies. Devices, controls, or appliances to increase abilities in activities of daily living, or to control or communicate with the environment.
Speech Therapy. Therapy services, including diagnostic evaluation and therapeutic intervention, that are designed to improve, develop, correct, rehabilitate, or prevent the worsening of speech/language communication and swallowing disorders that have been lost, impaired, or reduced as a result of acute or chronic medical conditions, congenital anomalies, or injuries. Speech and language disorders are those that affect articulation of speech, sounds, fluency, voice, swallowing (regardless of presence of a communication disability), and those that impair comprehension, spoken, written, or other symbol systems used for communication.

Supported Employment. Regularly scheduled services that enable participants, through training and support, to work in integrated work settings in which individuals are working toward compensated work, consistent with the strengths, resources, priorities, concerns, abilities, capabilities, interests, and informed choice of the individuals.

Supportive Home Care Aide. Services provided to participants with Alzheimer's/dementia or behavioral health needs to assist with ADLs and IADLs. These services include personal care, shopping, menu planning, meal preparation including special diets, laundry, light housekeeping, escort, and socialization/emotional support.

Transitional Assistance. Nonrecurring residential set-up expenses for participants who are transitioning from a nursing facility or hospital to a community living arrangement where the participant is directly responsible for his or her own set-up expenses. Allowable expenses are those that are necessary to enable a person to establish a basic household and do not constitute Room and Board.

Transportation Services. Conveyance of participants by vehicle from their residence to and from the site of HCBS waiver services and other community services, activities, and resources, including physical assistance to participants while entering and exiting the vehicle.

Vehicle Modification. Necessary adaptations or alterations to an automobile or van that is the waiver participant's primary means of transportation and that is not owned or leased by an entity providing services to the participant. Vehicle modifications are necessary when they are required to accommodate the special needs of the participant. Examples of vehicle modifications include: van lift, tie downs, ramp, specialized seating equipment and seating/safety restraint.

Waiver Services. Home- and community-based services that are covered in accordance with the requirements of 130 CMR 630.00: Home- and Community-based Services Waiver Services for participants enrolled under an ABI or MFP waiver.

359.03: Rate Provisions

(1) Services Included in the Rate. The approved rate shall include payment for all care and services that are part of the program of services of a Provider, as explicitly set forth in the terms of the purchase agreement between the Provider and the purchasing governmental unit(s).

(2) Reimbursement as Full Payment. Each Provider shall, as a condition of acceptance of payment made by any purchasing governmental units for services rendered, accept the approved program rate as full payment and discharge of all obligations for the services rendered. Payment for services included in the scope of 101 CMR 359.00 from any other source shall be used to offset the amount of the purchasing governmental unit's obligation for services rendered to the participant.

(3) Payment Limitations.
   (a) No purchasing governmental unit may pay less than or more than the approved program rate, except that a participant contribution may be applied towards the Residential Habilitation Room and Board payment in accordance with policies and procedures established by the purchasing governmental unit.
   (b) Where more than one payment rate is available for a covered service, the service is covered at the lowest available payment rate unless a higher rate is approved by the purchasing governmental unit, except as provided in 101 CMR 359.03(3)(c).
359.03: continued

(c) Notwithstanding the requirement of 101 CMR 359.03(3)(b), payment rates for certain HCBS waiver services shall be determined as follows:

1. Residential Habilitation rates shall be determined in the following manner:
   a. **Service Model Rate.** The purchasing Governmental Unit shall designate the applicable rate from among the Basic Lower Intensity, Basic, or Intermediate categories, or at Medical/Clinical Level 1 or Medical/Clinical Level 2 as outlined and defined in 101 CMR 420.00: Rates for Adult Long-term Residential Services.
   b. **Room and Board.** The purchasing Governmental Unit shall designate the applicable rate for room and board from among the Site Rates outlined in 101 CMR 420.00: Rates for Adult Long-term Residential Services.

2. Orientation and Mobility rates shall be determined based on one-way distance traveled to initiate the service in the following manner:
   a. **Level I:** one to 30 miles
   b. **Level II:** 31 to 60 miles
   c. **Level III:** over 60 miles

(4) **Approved Rates.** The approved rate shall be the lowest of the Provider's charge or amount accepted as payment from another payer or the rate listed:

<table>
<thead>
<tr>
<th>Service</th>
<th>HCBS Waiver</th>
<th>Units</th>
<th>Agency Rate</th>
<th>Non-agency Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Individual Provider (Self-employed Provider)</td>
<td>Self-directed Service</td>
</tr>
<tr>
<td>Adult Companion</td>
<td>ABI-N</td>
<td>Per 15 Min.</td>
<td>$5.07</td>
<td>89.75% of Agency Rate</td>
</tr>
<tr>
<td>Adult Companion</td>
<td>MFP-CL</td>
<td>Per 15 Min.</td>
<td>$5.07</td>
<td>89.75% of Agency Rate</td>
</tr>
<tr>
<td>Assisted Living</td>
<td>ABIR-H, MFP-RS</td>
<td>Per Diem</td>
<td>$104.53</td>
<td>N/A</td>
</tr>
<tr>
<td>Chore</td>
<td>ABI-N</td>
<td>Per 15 Min.</td>
<td>$7.78</td>
<td>89.75% of Agency Rate</td>
</tr>
<tr>
<td>Chore</td>
<td>MFP-CL</td>
<td>Per 15 Min.</td>
<td>$7.78</td>
<td>89.75% of Agency Rate</td>
</tr>
<tr>
<td>Community Family Training</td>
<td>MFP-CL</td>
<td>Per 15 Min.</td>
<td>See 101 CMR 414.00: Rates for Family Stabilization Services (Family Training rate divided by 4 to determine rate per 15 minute increments)</td>
<td>89.75% of Agency Rate</td>
</tr>
<tr>
<td>Day Services</td>
<td>ABI-N, ABI-RI, MFP-CL, MFP-RS</td>
<td>Per diem</td>
<td>$102.90</td>
<td>N/A</td>
</tr>
<tr>
<td>Home Accessibility Adaptations</td>
<td>ABI-N, MFP-CL, MFP-RS</td>
<td>Item</td>
<td>I.C.</td>
<td>N/A</td>
</tr>
<tr>
<td>Service</td>
<td>HCBS Waiver</td>
<td>Units</td>
<td>Agency Rate</td>
<td>Individual Provider (Self-employed Provider)</td>
</tr>
<tr>
<td>----------------------------------------------</td>
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<td>-------------------------------------------------</td>
<td>---------------------------------------------</td>
</tr>
<tr>
<td>Home Health Aide</td>
<td>MFP-CL</td>
<td>Per 15 min.</td>
<td>See 114.3 CMR 50.00: Home Health Services</td>
<td>N/A</td>
</tr>
<tr>
<td>Homemaker</td>
<td>ABI-N</td>
<td>Per 15 Min.</td>
<td>$5.82</td>
<td>N/A</td>
</tr>
<tr>
<td>Homemaker</td>
<td>MFP-CL</td>
<td>Per 15 Min.</td>
<td>$5.82</td>
<td>89.75% of Agency Rate</td>
</tr>
<tr>
<td>Independent Living Supports</td>
<td>MFP-CL</td>
<td>Per Diem</td>
<td>$82.12</td>
<td>N/A</td>
</tr>
<tr>
<td>Individual Support and Community Habilitation</td>
<td>ABI-N</td>
<td>Per 15 Min.</td>
<td>See 101 CMR 423.00: Rates for Certain In-Home Basic Living Supports; Levels G-H</td>
<td>56.60 % of Agency Rate</td>
</tr>
<tr>
<td>Individual Support and Community Habilitation</td>
<td>MFP-CL, MFP-RS</td>
<td>Per 15 Min.</td>
<td>See 101 CMR 423.00: Rates for Certain In-Home Basic Living Supports; Levels G-H</td>
<td>56.60 % of Agency Rate</td>
</tr>
<tr>
<td>Occupational Therapy</td>
<td>ABI-N, ABI-RH, MFP-CL, MFP-RS</td>
<td>Per Visit</td>
<td>See 114.3 CMR 50.00: Home Health Services</td>
<td>See 114.3 CMR 39.00: Rehabilitation Center Services, Audiological Services, Restorative Services (out-of-office visit rate)</td>
</tr>
<tr>
<td>Orientation and Mobility Services</td>
<td>MFP-CL, MFP-RS</td>
<td>Per 15 Min.</td>
<td>Level I: $31.02 Level II: $34.39 Level III:$37.77</td>
<td>Level I: $31.02 Level II: $34.39 Level III:$37.77</td>
</tr>
<tr>
<td>Peer Support</td>
<td>MFP-CL, MFP-RS</td>
<td>Per 15 Min.</td>
<td>See 101 CMR 414.00: Rates for Family Stabilization Services (rate divided by 4 to determine rate per 15 minute increments)</td>
<td>89.75% of Agency Rate</td>
</tr>
<tr>
<td>Personal Care</td>
<td>ABI-N</td>
<td>Per 15 Min.</td>
<td>$5.84</td>
<td>N/A</td>
</tr>
<tr>
<td>Personal Care</td>
<td>MFP-CL</td>
<td>Per 15 Min.</td>
<td>$5.84</td>
<td>See 101 CMR 309.00: Independent Living Services for the Personal Care Attendant Program</td>
</tr>
<tr>
<td>Service</td>
<td>HCBS Waiver</td>
<td>Units</td>
<td>Agency Rate</td>
<td>Non-agency Rate</td>
</tr>
<tr>
<td>---------------------------------</td>
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</tr>
<tr>
<td>Physical Therapy</td>
<td>ABI-N, ABI-RH, MFP-CL, MFP-RS</td>
<td>Per Visit</td>
<td>See 114.3 CMR 50.00: Home Health Services</td>
<td>See 114.3 CMR 39.00: Rehabilitation Center Services, Audiological Services, Restorative Services (out-of-office visit rate)</td>
</tr>
<tr>
<td>Prevocational Services</td>
<td>MFP-CL, MFP-RS</td>
<td>Per 15 min</td>
<td>$9.15</td>
<td>N/A</td>
</tr>
<tr>
<td>Residential Family Training</td>
<td>MFP- RS</td>
<td>Per 15 min</td>
<td>See 101 CMR 414.00: Rates for Family Stabilization Services (Family Training rate divided by 4 to determine rate per 15 minute increments)</td>
<td>89.75% of Agency Rate</td>
</tr>
<tr>
<td>Residential Habilitation Room and Board</td>
<td>ABI-RH, MFP-RS</td>
<td>Per Diem</td>
<td>See 101 CMR 420.00: Rates for Adult Long-Term Residential Services: Site Rates</td>
<td>N/A</td>
</tr>
<tr>
<td>Residential Habilitation Services</td>
<td>ABI-RH, MFP-RS</td>
<td>Per Diem</td>
<td>See 101 CMR 420.00: Rates for Adult Long-Term Residential Services: Basic Lower Intensity, Basic, or Intermediate categories, Medical/Clinical Level 1 or Medical/Clinical Level 2</td>
<td>N/A</td>
</tr>
<tr>
<td>Respite</td>
<td>ABI-N, MFP-CL</td>
<td>Per Diem</td>
<td>I.C.</td>
<td>N/A</td>
</tr>
<tr>
<td>Service</td>
<td>HCBS Waiver</td>
<td>Units</td>
<td>Agency Rate</td>
<td>Non-agency Rate</td>
</tr>
<tr>
<td>----------------------------------</td>
<td>-------------</td>
<td>-----------------</td>
<td>-------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>Shared Home Supports</td>
<td>MFP-CL</td>
<td>Per Diem</td>
<td>$76.39</td>
<td>N/A</td>
</tr>
<tr>
<td>Shared Living - 24 Hour Supports</td>
<td>ABI-RH, MFP-RS</td>
<td>Per Diem</td>
<td>See 101 CMR 411.00: <em>Rates for Certain Placement and Support Services</em></td>
<td>N/A</td>
</tr>
<tr>
<td>Skilled Nursing - LPN</td>
<td>MFP-CL, MFP-RS</td>
<td>Per Visit</td>
<td>See 114.3 CMR 50.00: <em>Home Health Services: Rates for Skilled Nursing Services</em></td>
<td>N/A</td>
</tr>
<tr>
<td>Skilled Nursing - RN</td>
<td>MFP-CL, MFP-RS</td>
<td>Per Visit</td>
<td>See 114.3 CMR 50.00: <em>Home Health Services: Rates for Skilled Nursing Services</em></td>
<td>N/A</td>
</tr>
<tr>
<td>Specialized Medical Equipment</td>
<td>ABI-N, ABI-RH, MFP-CL, MFP-RS</td>
<td>Item</td>
<td>See 114.3 CMR 22.00: <em>Durable Medical Equipment, Oxygen and Respiratory Therapy Equipment</em></td>
<td>N/A</td>
</tr>
<tr>
<td>Speech Therapy</td>
<td>ABI-N, ABI-RH, MFP-CL, MFP-RS</td>
<td>Per Visit</td>
<td>See 114.3 CMR 50.00: <em>Home Health Services</em></td>
<td>N/A</td>
</tr>
<tr>
<td>Supported Employment</td>
<td>ABI-N, ABI-RH, MFP-CL, MFP-RS</td>
<td>Per 15 Min.</td>
<td>$9.15</td>
<td>N/A</td>
</tr>
<tr>
<td>Supportive Home Care Aide</td>
<td>MFP-CL</td>
<td>Per 15 Min.</td>
<td>See 114.3 CMR 50.00: <em>Home Health Services</em> (8.03% above the rate for Home Health Aide)</td>
<td>N/A</td>
</tr>
</tbody>
</table>
(5) Self-directed Service Rates.
(a) Employer Expense Component. The rates for Self-directed Services consists of two components: the Self-directed Worker rate and the Employer Expense Component (EEC). List of the Self-directed Worker rates and EEC for Self-directed Service rates:

<table>
<thead>
<tr>
<th>Service</th>
<th>Units</th>
<th>Self-directed Worker Rate</th>
<th>Employer Expense Component</th>
<th>Self-directed Service Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult Companion</td>
<td>Per 15 min</td>
<td>$4.02</td>
<td>$0.53</td>
<td>$4.55</td>
</tr>
<tr>
<td>Chore</td>
<td>Per 15 min</td>
<td>$6.16</td>
<td>$0.82</td>
<td>$6.98</td>
</tr>
<tr>
<td>Homemaker</td>
<td>Per 15 min</td>
<td>$4.61</td>
<td>$0.61</td>
<td>$5.22</td>
</tr>
<tr>
<td>Individual Supports and Community Habilitation: Level G</td>
<td>Per 15 min</td>
<td>$5.45</td>
<td>$0.73</td>
<td>$6.18</td>
</tr>
<tr>
<td>Individual Supports and Community Habilitation: Level H</td>
<td>Per 15 min</td>
<td>$5.91</td>
<td>$0.79</td>
<td>$6.70</td>
</tr>
<tr>
<td>Peer Support</td>
<td>Per 15 min</td>
<td>$5.14</td>
<td>$0.68</td>
<td>$5.82</td>
</tr>
<tr>
<td>Personal Care</td>
<td>Per 15 min</td>
<td>See 101 CMR 309.00: Independent Living Services for the Personal Care Attendant Program (rate divided by 4 to determine rate per 15 minute increments)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(b) Overtime Calculation. Overtime payments for self-directed services shall be made in accordance with the federal Fair Labor Standards Act. Such payments shall be made to self-directed workers at rate of one and a half times that of the rate for the service or services provided. For self-directed workers that provide services paid at different rates, such overtime rate shall consist of the blended weighted rate based on the amount of hours for which each service was provided during a single work week. For the purposes of 101 CMR 359.03(5)(b), the term overtime shall mean self-directed services provided to one or more participants in excess of 40 hours per work week, where work week consists of a seven-day period beginning Sunday at 12:00 A.M. and ending the consecutive Saturday at 11:59 P.M.
(6) **Approved Modifiers.** Below are the approved modifiers for all four HCBS Waiver programs:

(a) **Modifier Classification.** Below are the classification descriptions for modifiers associated with both the ABI and MFP Waivers.

<table>
<thead>
<tr>
<th>Modifier</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>U1</td>
<td>Agency Provider</td>
</tr>
<tr>
<td>U2</td>
<td>Individual/Self-employed Provider</td>
</tr>
<tr>
<td>U4</td>
<td>ABI Non-residential Habitation (ABI-N) Waiver</td>
</tr>
<tr>
<td>U5</td>
<td>ABI Residential Habitation (ABI-RH) Waiver</td>
</tr>
<tr>
<td>U8</td>
<td>MFP Community Living (MFP-CL) Waiver</td>
</tr>
<tr>
<td>U9</td>
<td>MFP Residential Supports (MFP-RS) Waiver</td>
</tr>
<tr>
<td>UB</td>
<td>Self-directed Service</td>
</tr>
</tbody>
</table>

(b) **Service Codes and Modifiers by Service.** Below is the list of approved service codes and modifiers for all four ABI and MFP Waivers:

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult Companion</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>S5125</td>
<td>U4</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
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359.04: Filing and Reporting Requirements

1. General Provisions. Providers must satisfy the applicable reporting requirements of 957 CMR 6:00: Cost Reporting Requirements, and 808 CMR 1.00: Compliance, Reporting and Auditing for Human and Social Services.

2. Penalty for Noncompliance. The purchasing governmental unit may reduce the payment rates by 15% for any provider that fails to submit required information to the Center. The purchasing governmental unit will notify the provider in advance of its intention to impose a rate reduction.

359.05: Severability

The provisions of 101 CMR 359.00 are severable. If any provision of 101 CMR 359.00 or application of such provision to any eligible provider or fiscal intermediary is held invalid or unconstitutional, such determination will not affect the validity or constitutionality of any remaining provisions of 101 CMR 359.00 or application of such provisions to eligible providers or fiscal intermediaries in circumstances other than those held invalid.

REGULATORY AUTHORITY

101 CMR 359.00: M.G.L. c. 118E.
(101 CMR 360.00 THROUGH 409.00: RESERVED)
Regulation Filing  To be completed by filing agency

CHAPTER NUMBER:  101 CMR 414.00

CHAPTER TITLE:  Rates for Family Stabilization Services

AGENCY:  Executive Office of Health and Human Services

SUMMARY OF REGULATION:  State the general requirements and purposes of this regulation.

101 CMR 414.00 governs the payment rates for Family Stabilization Services provided to publicly aided individuals by governmental units.

REGULATORY AUTHORITY:  M.G.L. c. 118E

AGENCY CONTACT:  Debby Briggs, MassHealth Publications  PHONE:  617-847-3302

ADDRESS:  100 Hancock Street, 6th Floor, Quincy, MA 02171

Compliance with M.G.L. c. 30A

EMERGENCY ADOPTION -  if this regulation is adopted as an emergency, state the nature of the emergency.

PRIOR NOTIFICATION AND/OR APPROVAL -  If prior notification to and/or approval of the Governor, Legislature or others was required, list each notification, and/or approval and date, including notice to the Local Government Advisory Commission.

Executive Order 145 notifications:  8/24/16
Executive Order 562 approval:  12/13/16

PUBLIC REVIEW -  M.G.L. c. 30A sections 2 and/or 3 requires notice of the hearing or comment period, including a small business impact statement, be filed with the Secretary of the Commonwealth, published in appropriate newspapers, and sent to persons to whom specific notice must be given at least 21 days prior to such hearing or comment period.

Date of public hearing or comment period:  9/30/16

The text of the regulations published in the electronic version of the Massachusetts Register is unofficial and for informational purposes only. The official version is the printed copy which is available from the State Bookstore at http://www.sec.state.ma.us/spr/sprcat/catidx.htm.
FISCAL EFFECT -  Estimate the fiscal effect of the public and private sectors.

For the first and second year: estimated total annualized cost is $299,092; but only $74,773 in FY17

For the first five years: .................................................................

No fiscal effect: .................................................................

SMALL BUSINESS IMPACT -  M.G.L. c. 30A section 5 requires each agency to file an amended small business impact statement with the Secretary of the Commonwealth prior to the adoption of a proposed regulation. If the purpose of this regulation is to set rates for the state, this section does not apply.

Date amended small business impact statement was filed: N/A

CODE OF MASSACHUSETTS REGULATIONS INDEX -  List key subjects that are relevant to this regulation:

PROMULGATION -  State the action taken by this regulation and its effect on existing provisions of the Code of Massachusetts Regulations (CMR) or repeal, replace or amend. List by CMR number:

101 CMR 414.00 is being amended.

ATTESTATION -  The regulation described herein and attached hereto is a true copy of the regulation adopted by this agency.  ATTEST:

SIGNATURE: SIGNATURE ON FILE DATE: Jan 13 2017

Publication -  To be completed by the Regulations Division

MASSACHUSETTS REGISTER NUMBER: S1331 DATE: 01/27/2017

EFFECTIVE DATE: 01/27/2017

CODE OF MASSACHUSETTS REGULATIONS

Remove these pages: 951 - 960 Insert these pages: 951 - 960

The text of the regulations published in the electronic version of the Massachusetts Register is unofficial and for informational purposes only. The official version is the printed copy which is available from the State Bookstore at http://www.sec.state.ma.us/spr/sprcat/catidx.htm.
101 CMR 414.00: RATES FOR FAMILY STABILIZATION SERVICES

Section

414.01: General Provisions
414.02: Definitions
414.03: Rate Provisions
414.04: Filing and Reporting Requirements
414.05: Severability

414.01: General Provisions

(1) **Scope.** 101 CMR 414.00 establishes the payment rates for Family Stabilization Services that provide support to individuals and families to promote family stability and to prevent unnecessary out-of-home placements. These rates are established for the services listed in 101 CMR 414.01(2). The rates for other Family Stabilization Services are established by other EOHHS regulations as listed in 101 CMR 414.01(3).

(2) **Effective Date.** Rates are effective for dates of service provided on or after April 1, 2017.

(3) **Services and Rates Covered by Other Regulations.** Payment rates for the following services are not included within the scope of 101 CMR 414.00 and are governed by other regulations promulgated by EOHHS as follows.

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(4) **Disclaimer of Authorization of Services.** 101 CMR 414.00 is neither authorization for nor approval of the services for which rates are determined pursuant to 101 CMR 414.00. Governmental units that purchase Family Stabilization Services are responsible for the definition, authorization, and approval of services provided to participants.

(5) **Administrative Bulletins.** EOHHS may issue administrative bulletins to clarify its policy on substantive provisions of 101 CMR 414.00.

414.02: Definitions

As used in 101 CMR 414.00, unless the context requires otherwise, terms have the meanings ascribed in 101 CMR 414.02.

**Adolescent Support Network.** This service provides young adults with a diverse range of supportive services offered within community advocacy centers. Services are provided by staff trained specifically in the issues of this population, six days per week, and with 24-hour emergency coverage. The service utilizes flexible supports within the community to better assist youth through life transitions in order to meet each person's needs and develop his or her capacity to make empowering choices that promote safety, well-being, and productivity.

**Adult Companion Group Services.** Nonmedical care, supervision, and socialization services provided to a small group of participants. Groups consist of two or three participants for every companion. Companions may assist or supervise the participant with such light household tasks as meal preparation, laundry, and shopping.

**After-school Respite.** These services provide after school supervision and activities for children and adolescents with developmental or behavioral challenges.

**Agency Rate.** The fee for services performed by a person whose wage is paid by a corporation or partnership that is a MassHealth provider or provider of human services purchased by any governmental unit of the Commonwealth.

**Agency with Choice.** The Agency with Choice program supports individual/family self-determination in managing the receipt of certain services. This program allows individuals/families to have an increased level of self-determination when they share responsibility for the hiring and management of employees/workers who provide services to them. The Agency with Choice provider is the common law employer of record and the individual/family is the managing employer. Fees for these services are not to exceed the equivalent published rate.

**Autism Support Center Services.** The array of information and referral services, resources, and support services to children and young adults with autism spectrum disorders and their families, including information and referral, family clinics, support groups, access to the latest information on autism, family trainings, parent networking and mentoring, and social/recreational events, among other activities.

**Behavioral Support Services.** Services designed to remediate identified challenging behaviors or to help individuals acquire socially appropriate behaviors that are necessary to improve the individual's independence and integration into their community. Behavioral support services and consultation are provided by psychology, mental health, and special education professionals.

**Case Consultation Services.** Environmental intervention for medical management purposes on a psychiatric patient's behalf with agencies, employees, or institutions, which may include the preparation of reports of the patient's psychiatric status, history, treatment, or progress (other than for legal or consultative purposes) for other physicians, agencies, or insurance carriers.

**Center Size.** The number of direct-care full-time equivalent employees (FTEs) required to staff a family support center or autism support center as determined by the Department of Developmental Services (DDS).
Child Requiring Assistance (CRA). A child who is having serious problems at home and at school, including runaways, truants, and sexually exploited children, as designated by St. 2012, c. 240.

Chore. An unusual or infrequent household maintenance task that is needed to maintain the participant's home in a clean, sanitary, and safe environment. This service includes heavy household chores such as washing floors, windows, and walls; tacking down loose rugs and tiles; and moving heavy items of furniture in order to provide safe access and egress.

Client Financial Assistance/Flexible Funding. A method whereby, subject to availability, a purchasing governmental unit may provide individual resource allocations to both families of children and adults across the state. Flexible funding may be provided through a number of means, including a stipend issued directly to the family; reimbursement to the family for specific expenses and support services; or funds directed by the family to a qualified provider for specific services.

Client Financial Assistance/Flexible Funding Administration. A service where the provider performs the function necessary to successfully administer flexible funding expenditures to families for permissible support services, services, or goods.

Combined Hourly Services. These services, individual or group in nature, are based upon an hour's service time of direct-care staff. While most services are nonclinical, some may be clinical.

Community-based After-school Social and Recreation Program Services. After-school programs for blind children with the following elements: community-based recreation, social-skill development, peer support, and community integration.

Comprehensive Services. These family-oriented services reflect a range of either nonclinical or clinical, or blended models of the two, established on a per-full-day-of-service basis. Within model types, the client-to-staff ratio, or intensity of service, differentiates one from another.

Cost Report. The document used to report costs and other financial and statistical data. The Uniform Financial Statements and Independent Auditor's Report (UFR) are used when required.

Direct Youth Intervention. Provides intensive one-on-one mentoring to a youth to develop emotional self-management abilities; social, communication, and pre-vocational skills; and self-confidence; or to provide ancillary non-clinical flexible supports that promote, reinforce, and support skills acquired through youth group interventions.

Educational Coordination. This is an educational support service providing pre- and post-adoption support for foster, adoptive, or guardianship families, and is based upon an enrolled day of service.

EOHHS. The Executive Office of Health and Human Services established under M.G.L. c. 6A.

Family Navigation Services. Referral support services and expert advice designed to assist families to identify needs and to facilitate and gain access to local generic support services through coordination between family and other service providers. The family navigator acts as a guide and resource development expert to ensure that families have knowledge and access to a broad array of generic community resources, to provide assistance in navigating the system, and to recognize and promote the value of natural support services.

Family Resource Center (FRC). Community-based, culturally competent programs that provide evidence-based parent education groups, information and referral, mentoring, and other opportunities for children and families in need. FRCs also provide CRA-specific services such as intake, screening, and assessments.
414.02: continued

**Family Skills Development Program Model.** A ten-to-13-week curriculum-based program that engages multiple (ten to 12) families with children from newborn to adolescence, to participate in ten to 13 2½ hour sessions led by a trained team of four facilitators and other volunteers. The goal is to develop strategies to increase communication skills, develop family rules, use positive discipline, address conflict, share feelings, and enjoy family fun. The program includes a full meal for all participants, and may include transportation for participants and child care for infants and other children.

**Family Stabilization Services.** Services that provide support to individuals and families to promote family stability and to prevent unnecessary out-of-home placements. Family stabilization services include adult companion group services, after-school respite, autism support center services, behavioral support services, case consultation services, chore services, client financial assistance/flexible funding, client financial assistance/flexible funding administration, combined hourly services, community-based after-school social and recreation program services, comprehensive services, educational coordination, family navigation services, family support centers, family systems intervention, family training, family training groups, homemaker services, individual support and community habilitation services, individual youth support services, intensive flexible family support services (IFFS), medically complex programs, occupational therapy, peer support services, physical therapy, planned facility-based respite for children, respite in the caregiver’s home, respite in the client’s home, site-based respite, specialized medical equipment, speech therapy, unbundled intensive foster care special support services, and youth support groups.

**Family Support Centers.** Programs that establish a local presence and act as a hub for offering a wide range of general family support services and activities to families of children and adults who are eligible for DDS services. Centers provide information, referral, and service navigation to DDS eligible families, connecting these families to services they may need, and host community activities such as guest speakers and trainings. Centers also play a role in the administration of client funds. Cultural/linguistic-specific family support centers have been created to respond to the unique needs of specific cultural and linguistic family groups in specified areas or regions of the state.

**Family Systems Intervention.** Focused therapeutic interventions in a child’s home or other natural environment to improve the capacity of the family to better meet the needs of the child and of the child to function successfully within the context of his or her family and community. The service is staffed with a team consisting of a master’s level clinician trained in home-based intervention and a paraprofessional who serves as a family partner. Both are directed/supervised by a licensed mental health clinician.

**Family Training.** Training and instruction for family members concerning the treatment regimes, behavior plans, and the use of specialized equipment that supports the individual waiver participant to participate in the community. Community family training may also include training in family leadership, support of self-advocacy, and independence for the family member.

**Family Training Groups.** These groups are designed to improve parenting skills. Of the three model types, two are multi-family in nature, and the third is designed for the parents alone. These groups run usually on a once-per-week basis, and generally range from ten to 16 weeks in duration. The most robust family model may include as many as 60 attendees, while parent groups typically include up to 20.

**Governmental Unit.** The Commonwealth, any board, commission, department, division, or agency of the Commonwealth and any political subdivision of the Commonwealth.

**Homemaker.** A person who performs light housekeeping duties (for example, cooking, cleaning, laundry, and shopping) for the purpose of maintaining a household.
Individual and Family Flexible Support Services (IFFSS). An individualized and targeted set of interventions and services provided to youth with serious emotional disturbance (SED), which are intended to prevent out-of-home placement, sustain the youth with his or her family and community, and assist the youth to successfully function in the community. Through this service, a youth and his or her family develop the skills, strategies, and supports needed to live successfully in the community and to support the youth’s ongoing development of age-appropriate social, emotional, academic, and pre-vocational competencies. IFFSS is designed to be highly flexible to meet the varying needs of youth with SED and their families. The IFFSS service array includes Family Systems Intervention, Individual Youth Support, Youth Support Group, Collateral Contact/Consultation, Direct Youth Intervention, and Flexible Pool Administration. These services can be received individually or in combination, depending on the needs of the youth and family.

Individual Consideration (I.C). Payment rates for certain services are designated as individual consideration (I.C.). Where I.C. rates are designated, the purchasing governmental unit will determine the appropriate payment as the actual cost of the item or service as evidenced by invoice, published tuition amount, or other price reasonably obtained by a competitive market for the product or service.

Individual Youth Support Services. Non-school-hour one-to-one mentoring to assist a child/adolescent to develop the emotional self-management abilities, social skills, communication skills, pre-vocational skills, and self-confidence that are a requisite for participation in age-appropriate activities with peers.

Intensive Flexible Family Support Services (IFFS). Services that support families with one or more members with a disability who are experiencing significant challenges that put the child/individual at risk of out-of-home placement. This is a time-limited (six to 12 months) and goal-oriented service that provides more focused and intensive supports in response to identified areas of need and difficulty and that builds and strengthens the family's capacity to support their child at home.

Medically Complex Programs. Family-driven models of care that support families with children and young adults who have significant cognitive, physical, and complex health care needs and who are living at home. The goal is to provide comprehensive wrap-around support services, which consist of specialized case management activities that help families integrate the variety of resources and support services they are receiving in order to care for their family member at home.

Micro Family Resource Center. A reduced FRC staffing model, which may be affiliated with an FRC.

Micro Family Resource Center Add-on. Additional staff time allocated to an FRC or Micro FRC to increase its CRA staff capacity.

Occupational Therapy. Therapy services, including diagnostic evaluation and therapeutic intervention, designed to improve, develop, correct, rehabilitate, or prevent the worsening of functions that affect the activities of daily living that have been lost, impaired, or reduced as a result of acute or chronic medical conditions, congenital anomalies, or injuries. Occupational therapy programs are designed to improve quality of life by recovering competence and preventing further injury or disability, and to improve the individual's ability to perform tasks required for independent functioning, so that the individual can engage in activities of daily living.

Parent Skill Development Program Model. A 12-to-14-week program based on curricula that promote positive parenting and skill building for parents and other caregivers. Child care may be provided, but there are no children's groups. The program focuses on the specific needs of parents in their role in the family. The program includes a full meal for all participants, and may include transportation for participants and child care for infants and other children.
Peer Support Services. Services that are designed to provide training, instruction, and mentoring to individuals about self-advocacy, participant direction, civic participation, leadership, benefits, and participation in the community. These services may be provided either by an individual with an intellectual disability or an advisor or support person to a self-advocacy group.

Physical Therapy. Therapy services, including diagnostic evaluation and therapeutic intervention, designed to improve, develop, correct, rehabilitate, or prevent the worsening of physical functions that have been lost, impaired, or reduced as a result of acute or chronic medical conditions, congenital anomalies, or injuries. Physical therapy emphasizes a form of rehabilitation focused on treatment of dysfunctions involving neuromuscular, musculoskeletal, cardiovascular/pulmonary, or integumentary systems through the use of therapeutic interventions to optimize functioning levels.

Planned Facility-based Respite for Children. Services that provide out-of-home supervision and care in a licensed respite home to provide relief for the parents/primary caregivers.

Provider. Any individual, group, partnership, trust, corporation, or other legal entity that offers services for purchase by a governmental unit and that meets the conditions of purchase or licensure that have been or may be adopted by a purchasing governmental unit.

Reporting Year. The provider's fiscal year for which costs incurred are reported to the Operational Services Division on the Uniform Financial Statements and Independent Auditor's Report (UFR).

Respite in the Caregiver's Home. Supervision and care provided in the caregiver's home on a short-term basis, including on a short-term overnight basis, where there is an absence or need for relief of those persons who normally provide care for the participant. Since this service is provided in the caregiver's home, applicable license or certification is necessary.

Respite in the Recipient's Home. Supervision and care provided in the home of the client, by qualified staff that possess a high school diploma, GED, or equivalencies or relevant competencies, on a short-term basis, including on a short-term overnight basis, where there is an absence or need for relief of those persons who normally provide care for the participant.

Self-employed Provider Rate. The fee for services performed by a person that is a provider and is not paid a wage by another person or entity for services performed.

Session. A single group meeting.

Site-based Respite. Services provided by a licensed respite home designed to provide out-of-home supervision and care to provide relief for the parents/primary caregivers.

Specialized Medical Equipment and Supplies. Devices, controls, or appliances to increase abilities in activities of daily living, or to control or communicate with the environment.

Specialty Family Skills Development Program Model. A 14-to-16-week curriculum-based program that engages multiple (ten to 12) families with children from newborn to adolescence, to participate in 14 to 16, 2½ hour sessions led by a trained team of eight to 12 facilitators, professionals, specialty providers, and volunteers. These groups are designed to address families with unique and/or multiple challenges, and special support needs. The program includes a full meal for all participants, and may include transportation for participants and child care for infants and other children.

Speech/Language Therapy. Therapy services, including diagnostic evaluation and therapeutic intervention, that are designed to improve, develop, correct, rehabilitate, or prevent the worsening of speech/language communication and swallowing disorders that have resulted in lost, impaired, or reduced speech/language communication and swallowing abilities as a result of acute or chronic medical conditions, congenital anomalies, or injuries. Speech and language disorders are those that affect articulation of speech, sounds, fluency, voice, swallowing (regardless of presence of a communication disability), and those that impair comprehension, or spoken, written, or other symbol systems used for communication.
Unbundled Intensive Foster Care Special Support Services. This model of intensive foster care represents a modification of the model that is the basis for 101 CMR 411.00: Rates for Certain Placement and Support Services. This model was requested by the Department of Children and Families (DCF) and eliminates the family resource worker because a DCF employee fulfills this role.

Youth Support Group. A formally organized six-to-eight-week psycho-educational session serving six to 12 youths focused on social and emotional skill building and community integration activities. Family activity groups involving youth, their siblings, and caretakers are also included in this category.

414.03: Rate Provisions

(1) Services Included in the Rate. The approved rate includes payment for all care and services that are part of the program of services of an eligible provider, as explicitly set forth in the terms of the purchase agreement between the eligible provider and the purchasing governmental unit(s).

(2) Reimbursement as Full Payment. Each provider must, as a condition of acceptance of payment made by any purchasing governmental units for services rendered, accept the approved program rate as full payment and discharge of all obligations for the services rendered. Payment from any other source will be used to offset the amount of the purchasing governmental unit's obligation for services rendered to the participant.

(3) Payment Limitations. No purchasing governmental unit may pay less than or more than the approved program rate.

(4) Services Provided in Dukes or Nantucket County. In accordance with the provisions of St. 2015, c. 46, payment for services provided in programs located in Dukes or Nantucket County is the rate for the service contained in 101 CMR 414.03(5) times a factor of 1.07.

(5) Approved Rates. The approved rate is the lower of the provider's charge or amount accepted as payment from another payer or the rate listed in 101 CMR 414.03(5).

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<th>Unit of Service</th>
<th>Agency Rate</th>
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**Combined Hourly Services:**

- **Nonclinical** Hour $51.55
- **Clinical** Hour $72.76

**Comprehensive Services:**

- Model A-1 Direct Care-Nonclinical Less Intensive Enrolled day $35.44
- Model A-2 Direct Care-Nonclinical More Intensive Enrolled day $47.86
- Model B Direct Care and Clinical Less Intensive Enrolled day $65.08
- Model C Direct Care and Clinical More Intensive Enrolled day $64.42
- Model D Clinical Enrolled day $68.14
- Model E Direct Care and Clinical High Intensive Enrolled day $100.14
- Model F Direct Care and Clinical Highest Intensive Enrolled day $144.80
- Model G Direct Care and Clinical Higher Intensive Enrolled day $120.46
- Direct Youth Intervention Enrolled day $35.44
- Educational Coordination Enrolled day $17.10
- Family Navigation 15 minutes $12.26
- Family Resource Center Month $47,479
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<td>Group Session</td>
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414.04: Filing and Reporting Requirements

(1) General Provisions.
   (a) Accurate Data. All reports, schedules, additional information, books, and records that are filed or made available to EOHHS shall be certified under pains and penalties of perjury as true, correct, and accurate by the Executive Director or Chief Financial Officer of the provider.
   (b) Examination of Records. Each provider must make available to EOHHS or the purchasing governmental unit upon request all records relating to its reported costs, including costs of any entity related by common ownership or control.

(2) Required Reports. Each provider must file
   (a) an annual Uniform Financial Statement and Independent Auditor's report completed in accordance with the filing requirements of 808 CMR 1.00: Compliance, Reporting and Auditing for Human and Social Services;
   (b) any cost report supplemental schedule as issued by EOHHS; and
   (c) any additional information requested by EOHHS within 21 days of a written request.

(3) Penalty for Noncompliance. The purchasing governmental unit may reduce the payment rates by 15% for any provider that fails to submit required information to EOHHS. The purchasing governmental unit will notify the provider in advance of its intention to impose a rate reduction.

414.05: Severability

The provisions of 101 CMR 414.00 are severable. If any provision of 101 CMR 414.00 or application of such provision to any eligible provider or fiscal intermediary is held invalid or unconstitutional, such determination will not affect the validity or constitutionality of any remaining provisions of 101 CMR 414.00 or application of such provisions to eligible providers or fiscal intermediaries in circumstances other than those held invalid.

REGULATORY AUTHORITY

101 CMR 414.00: M.G.L c. 118E.
Regulation Filing  To be completed by filing agency

CHAPTER NUMBER:  101 CMR 429.00

CHAPTER TITLE: Rates for Certain Sexual and Domestic Violence Services

AGENCY: Executive Office of Health and Human Services

SUMMARY OF REGULATION: State the general requirements and purposes of this regulation.
101 CMR 429.00 governs the payment rates paid by governmental units for Certain Sexual and Domestic Violence Services provided to publicly aided individuals.

REGULATORY AUTHORITY: M.G.L. c. 118E

AGENCY CONTACT: Debby Briggs, MassHealth Publications  PHONE: 617-847-3302

ADDRESS: 100 Hancock Street, 6th Floor, Quincy, MA 02171

Compliance with M.G.L. c. 30A

EMERGENCY ADOPTION - if this regulation is adopted as an emergency, state the nature of the emergency.

PRIOR NOTIFICATION AND/OR APPROVAL - If prior notification to and/or approval of the Governor, Legislature or others was required, list each notification, and/or approval and date, including notice to the Local Government Advisory Commission.

Executive Order 145 notifications: 9/23/16
Executive Order 562 approval: 1/10/17

PUBLIC REVIEW - M.G.L. c. 30A sections 2 and/or 3 requires notice of the hearing or comment period, including a small business impact statement, be filed with the Secretary of the Commonwealth, published in appropriate newspapers, and sent to persons to whom specific notice must be given at least 21 days prior to such hearing or comment period.

Date of public hearing or comment period: 10/28/16

The text of the regulations published in the electronic version of the Massachusetts Register is unofficial and for informational purposes only. The official version is the printed copy which is available from the State Bookstore at http://www.sec.state.ma.us/spr/sprcat/catidx.htm.
FISCAL EFFECT - Estimate the fiscal effect of the public and private sectors.

For the first and second year: total annualized cost to state government is $1.65 million

For the first five years: 

No fiscal effect: 

SMALL BUSINESS IMPACT - M.G.L. c. 30A section 5 requires each agency to file an amended small business impact statement with the Secretary of the Commonwealth prior to the adoption of a proposed regulation. If the purpose of this regulation is to set rates for the state, this section does not apply.

Date amended small business impact statement was filed: N/A

CODE OF MASSACHUSETTS REGULATIONS INDEX - List key subjects that are relevant to this regulation:

PROMULGATION - State the action taken by this regulation and its effect on existing provisions of the Code of Massachusetts Regulations (CMR) or repeal, replace or amend. List by CMR number:

101 CMR 429.00 is a new chapter.

ATTESTATION - The regulation described herein and attached hereto is a true copy of the regulation adopted by this agency. ATTEST:

SIGNATURE: SIGNATURE ON FILE DATE: Jan 13 2017

Publication - To be completed by the Regulations Division

MASSACHUSETTS REGISTER NUMBER: S1331 DATE: 01/27/2017

EFFECTIVE DATE: 01/27/2017

CODE OF MASSACHUSETTS REGULATIONS

Remove these pages: Insert these pages:

1045 & 1046 1046 - 1050.2
101 CMR 429.01: General Provisions
101 CMR 429.02: Definitions
101 CMR 429.03: Rate Provisions
101 CMR 429.04: Filing and Reporting Requirements
101 CMR 429.05: Severability

101 CMR 429.01: General Provisions

1) Scope. 101 CMR 429.00 governs the payment rates for certain sexual and domestic violence services purchased by a governmental unit, including but not limited to the Department of Public Health (DPH) and the Department of Children and Families (DCF).

2) Effective Date. Rates are effective for dates of service provided on or after July 1, 2017.

3) Disclaimer of Authorization of Services. 101 CMR 429.00 is neither authorization for nor approval of the services for which rates are determined pursuant to 101 CMR 429.00. Governmental units that purchase the services described in 101 CMR 429.00 are responsible for the definition, authorization, and approval of services extended to clients.

4) Administrative Bulletins. EOHHS may issue administrative bulletins to clarify its policy on substantive provisions of 101 CMR 429.00.

101 CMR 429.02: Definitions

As used in 101 CMR 429.00, unless the context requires otherwise, terms have the meanings ascribed in 101 CMR 429.02.

Client. An individual that receives certain sexual and domestic violence services purchased by a governmental unit.

Cost Report. The document used to report costs and other financial and statistical data. The Uniform Financial Statements and Independent Auditor's Report (UFR) are used when required.

Domestic Violence Community-based Services. The Domestic Violence (DV) programs, which include Community-based, Supervised Visitation, and Child Witness to Violence, offers an array of services to survivors of domestic violence and their families. Domestic violence providers help victims of verbal abuse, financial abuse, emotional, sexual, and physical abuse by delivering specialized direct services and access to community resources.

EOHHS. The Executive Office of Health and Human Services established under M.G.L. c. 6A.

Extraordinary Circumstances/Flex Funding. A method whereby, subject to availability, a purchasing governmental unit may provide resource allocations to a client and/or provider across the state. Flexible funding may be provided through a number of means, including but not limited to, reimbursement to client for specific support services or funds directed to a qualified provider for extraordinary circumstances.

Governmental Unit. The Commonwealth, any board, commission, department, division, or agency of the Commonwealth and any political subdivision of the Commonwealth.

Housing Stabilization Flexible Funding. An additional support to survivors of domestic violence who are not eligible for other assistance and/or have exhausted other assistance available to them for the stabilization of current housing and/or securing more permanent housing.

Individual Consideration (I.C). Payment rates for certain services are designated as individual consideration (I.C.). Where I.C. rates are designated, the purchasing governmental unit will determine the appropriate payment as the actual cost of the item or service as evidenced by invoice, published tuition amount, or other price reasonably obtained by a competitive market for the product or service.
Intimate Partner Abuse Education Program. The Massachusetts Department of Public Health certified Intimate Partner Abuse Education Programs (IPAEPs) work to increase the safety of domestic violence victims and survivors by holding their intimate partners accountable for abusing them. These 80-hour educational programs help abusers to develop respectful and non-abusive attitudes and behaviors toward their partners and children. IPAEPs contact victims and survivors to help them to plan for their safety, to refer them to support services like domestic violence service agencies and child witness to violence programs, and to ask about their abuser's behavior at home.

New Sexual Assault Nurse Examiner (SANE) Site Development. One-time rate for start-up costs associated with a new MA SANE-designated hospital site or MA SANE-designated telemedicine hospital site within a rape crisis center's DPH-established service area.

Provider. Any individual, group, partnership, trust, corporation, or other legal entity that offers services for purchase by a governmental unit and that meets the conditions of purchase or licensure that have been adopted by a purchasing governmental unit.

Rape Crisis Center Services. The Rape Crisis Centers (RCC), part of the Sexual Assault Prevention and Survivor Services (SAPSS), serve as a vital community resource for survivors of sexual violence. Services are focused on the needs of the survivor and help with the short- and long-term community and health needs. Specific services include but are not limited to 24/7 hotline services, accompaniment to hospitals, police stations and court appointments, and individual and group counseling.

Rape Crisis Satellite Center. An additional physical point of access to clients with established and maintained office hours in locations external to the main RCC site.

Rape Crisis Center Spanish Hotline. A hotline service provided under the supervision of a DPH-funded rape crisis center with the existing infrastructure to support the response by Spanish-speaking rape crisis counselor(s) within 15 minutes of each call, 24 hours/day.

Reporting Year. The provider's fiscal year for which costs incurred are reported to the Operational Services Division on the Uniform Financial Statements and Independent Auditor's Report (UFR).

Sexual and Domestic Violence Equity Services. Sexual and domestic violence (SDV) affects some groups of people at disproportionate levels as seen in higher prevalence, poorer access to services and/or worse outcomes from SDV. Research on disparities has identified some of these groups as Black women, LGBTQ, immigrants, people with disabilities, D/deaf and Hard of Hearing, people in rural areas. The service offers, but is not limited to, supports services, outreach, education, and community engagement with groups and individuals who are disproportionately adversely affected.

Sexual and Domestic Violence Equity Legal Services. Services for the relief/amelioration of immigration or humanitarian crisis encountered by refugees and immigrants, such as legal representation and humanitarian relief following natural disasters, immigration raids, etc.

Rate Provisions

1) Services Included in the Rate. The approved rate includes payment for all care and services that are part of the program of services of an eligible provider, as explicitly set forth in the terms of the purchase agreement between the eligible provider and the purchasing governmental unit(s).

2) Reimbursement as Full Payment. Each eligible provider must, as a condition of acceptance of payment made by any purchasing governmental units for services rendered, accept the approved program rate as full payment and discharge of all obligations for the services rendered. Payment from any other source will be used to offset the amount of the purchasing governmental unit's obligation for services rendered to the publicly assisted client.
429.03: continued

(3) **Payment Limitations.** No purchasing governmental unit may pay less than or more than the approved program rate.

(4) **Capacity Payment for Domestic Violence Community-based Services.** The rates established under 101 CMR 429.03 for Domestic Violence Community-based Services is for the purchasing of 80% of a provider's capacity to render such services.

(5) **Approved Rates.** The approved rate is the lower of the provider's charge or amount accepted as payment from another payer or the rate listed in 101 CMR 429.03.

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<tr>
<th>Program</th>
<th>Rate</th>
<th>Unit</th>
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<tbody>
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429.03: continued

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Add-on Rates

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<td>Extraordinary Circumstances /Flex Funding</td>
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<tr>
<td>Sexual &amp; Domestic Violence Legal Advocacy</td>
<td>$2,500</td>
<td>Per Case</td>
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</tbody>
</table>

429.04: Filing and Reporting Requirements

1) General Provisions
   a) Accurate Data. All reports, schedules, additional information, books, and records that are filed or made available to EOHHS must be certified under pains and penalties of perjury as true, correct, and accurate by the Executive Director or Chief Financial Officer of the provider.
   b) Examination of Records. Each provider must make available to EOHHS or the purchasing governmental unit upon request all records relating to its reported costs, including costs of any entity related by common ownership or control.

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REGULATORY AUTHORITY

101 CMR 429.00: M.G.L. c. 118E.
Regulation Filing  To be completed by filing agency

CHAPTER NUMBER: 105 CMR 100.000

CHAPTER TITLE: Determination of Need

AGENCY: Department of Public Health

SUMMARY OF REGULATION: State the general requirements and purposes of this regulation.
105 CMR 100.000 interprets and implements M.G.L. c. 111, §§ 25B to 25G, §§ 51 through 53, 51A, and 71, requiring that the Department of Public Health must find "need" before a health care entity engages in construction or other substantial capital expenditures in order to ensure that health care resources are reasonably and equitably available to every person within the Commonwealth at the lowest reasonable aggregate cost, while advancing the Commonwealth’s goals for cost containment, improved public health outcomes, and delivery system transformation.


AGENCY CONTACT: Rebecca Rodman PHONE: 617-994-9811

ADDRESS: 250 Washington Street, Boston MA 02108

Compliance with M.G.L. c. 30A

EMERGENCY ADOPTION - if this regulation is adopted as an emergency, state the nature of the emergency.

PRIOR NOTIFICATION AND/OR APPROVAL - If prior notification to and/or approval of the Governor, Legislature or others was required, list each notification, and/or approval and date, including notice to the Local Government Advisory Commission.

Notice to Mass. Municipal Ass'n and Department of Housing and Community Development pursuant to EO145 on August 12, 2016.

PUBLIC REVIEW - M.G.L. c. 30A sections 2 and/or 3 requires notice of the hearing or comment period, including a small business impact statement, be filed with the Secretary of the Commonwealth, published in appropriate newspapers, and sent to persons to whom specific notice must be given at least 21 days prior to such hearing or comment period.

Date of public hearing or comment period: 10/07/16
FISCAL EFFECT -  Estimate the fiscal effect of the public and private sectors.

For the first and second year: ________________________________

For the first five years: ________________________________

No fiscal effect: There will be no fiscal effect

SMALL BUSINESS IMPACT -  M.G.L. c. 30A section 5 requires each agency to file an amended small business impact statement with the Secretary of the Commonwealth prior to the adoption of a proposed regulation. If the purpose of this regulation is to set rates for the state, this section does not apply.

Date amended small business impact statement was filed: 1/12/17

CODE OF MASSACHUSETTS REGULATIONS INDEX -  List key subjects that are relevant to this regulation:

Determination of Need
Substantial Capital Expenditure
Health Care Construction

PROMULGATION -  State the action taken by this regulation and its effect on existing provisions of the Code of Massachusetts Regulations (CMR) or repeal, replace or amend. List by CMR number:

Amends 105 CMR 100.000

ATTESTATION -  The regulation described herein and attached hereto is a true copy of the regulation adopted by this agency. ATTEST:

SIGNATURE: ____________________________ SIGNATURE ON FILE ____________________________ DATE: Jan 13 2017

Publication - To be completed by the Regulations Division

MASSACHUSETTS REGISTER NUMBER: S1331 DATE: 01/27/2017

EFFECTIVE DATE: 01/27/2017

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100.001: General Provisions

The purpose and objective of 105 CMR 100.000 is to encourage competition and the development of innovative health delivery methods and population health strategies within the health care delivery system to ensure that resources will be made reasonably and equitably available to every person within the Commonwealth at the lowest reasonable aggregate cost advancing the Commonwealth's goals for cost containment, improved public health outcomes, and delivery system transformation.

100.100: Definitions

As used in 105 CMR 100.000, the following terms have the following meanings unless otherwise interpreted by the Department:

Addition means:
(1) The initial provision of a DoN-required Service or procedure, or acquisition of medical equipment defined as DoN-required Equipment; or
(2) The initial provision of any services that may be provided by a Health Care Facility, including, but not limited to, a change from a single specialty to a multi-specialty Freestanding Ambulatory Surgery Center.
Affiliate. Any relationship between two organizations that reflects, directly or indirectly, a partial or complete controlling interest or partial or complete common control.

Ambulatory Surgery. Health care services restricted to those defined by the Department as surgical services, not requiring overnight stay, typically provided to ambulatory patients on an elective, urgent, or emergency basis, wherever provided.

Applicant. The Provider Organization that files the Application for Determination of Need with the Department for, or on behalf of, the Entity seeking a Notice of Determination of Need for a Proposed Project pursuant to 105 CMR 100.000. In instances where there is no Provider Organization, Applicant shall mean the Entity which files the Application for Determination of Need with the Department for itself, or on behalf of, an Affiliate seeking a Notice of Determination of Need for a Proposed Project pursuant to 105 CMR 100.000.

Application means either:
   (1) a formal written request for a Determination of Need, submitted to the Department pursuant to 105 CMR 100.405; or
   (2) a formal written request for an amendment to a previously approved Notice of Determination of Need, submitted to the Department pursuant 105 CMR 100.635.

Attorney General or AGO. The Massachusetts Attorney General or his or her designee. For the purposes of 105 CMR 100.000, the Attorney General may intervene in any hearing regarding an Application for Determination of Need, whether or not the Attorney General requested the hearing, by providing written notification of such intervention to the Department.

Bed Capacity. The capacity of a Health Care Facility to accommodate a bed and the necessary physical plant requirements, in accordance with all applicable standards, imposed as a condition of operation pursuant to all federal and state laws and regulations.

Capital Expenditure means:
   (1) Any expenditure, or obligation to make an expenditure, past, present or future, which, under generally accepted accounting principles, is not properly chargeable as a cost of operation and maintenance, and which includes any fee(s) for architectural, engineering, legal, accounting, or any other professional services, any interest charges, and any other financing cost capitalized throughout the Construction period of the project, and any Site acquisition cost(s); or
   (2) Any expenditure or obligation to make an expenditure, past, present, or future, for obtaining by lease, or comparable arrangement, capital equipment, or a building or part thereof; provided, that in both cases, such expenditure or obligation is incurred, or will be incurred, as an incident to Construction as defined in 105 CMR 100.100.

   Every calculation of a Capital Expenditure must take into account all expenditures related to a Proposed Project. All calculations shall be based on costs as of the Application Filing Date, assuming Construction commenced on that date, with no inclusion of estimates regarding inflation. Calculations shall be subject, but are not limited to, the following parameters:
      (a) In calculating a Capital Expenditure, Applicants shall account for all expected future expenditures in connection with a Proposed Project, as well as any past or present expenditures necessary for a Proposed Project's completion, including, but not limited to: the purchase price of an earlier acquired Site; expenses related to completion of feasibility or other planning studies used in developing a project or preparing an Application; expenses incurred in seeking grants, loans, or other financing; legal or consultant fees; and, any other such expenditures which can be reasonably attributed to the completion of a Proposed Project.
      (b) Where Construction is to be undertaken on leased property, or where leased equipment is to be installed, the fair market value of such property or equipment, as appropriate and in conformance with the terms of M.G.L. c. 111, § 25B, shall be used in calculating the proposed Capital Expenditure attributed to such property or equipment. See definition of Substantial Capital Expenditure.
Center for Health Information and Analysis or CHIA. The Government Agency established pursuant to M.G.L. c. 12C.

1) Certified ACO. An Entity which is certified by the HPC as an accountable care organization pursuant to M.G.L. c. 6D, § 15 and which meets the HPC's Final Accountable Care Organization (ACO) Certification Standards.

2) Clinic. An Entity licensed by the Department pursuant to 105 CMR 140.000: Licensure of Clinics.

Commissioner. The Commissioner of Public Health or his or her designee.

Conditions. All terms and Conditions, both Standard and Other, included in a Notice of Determination of Need issued by the Department.

Conservation Project. Construction that consists solely of a project(s) that would Sustain or Restore a Health Care Facility or service for its designated purpose, and to its original functionality, without Modernization, Addition, or Expansion. For the purposes of Conservation Project, the following words shall mean:

1) Sustain. The maintenance and repair activities necessary to keep a Health Care Facility or service in good working order. It includes regularly scheduled adjustments and inspections, preventive maintenance tasks, and emergency response and service calls for minor repairs. It also includes major repairs or replacement of facility components that are expected to occur periodically throughout the life cycle of said Health Care Facility or service. This work includes, but is not limited to, regular roof replacement, refinishing of wall surfaces, repairing and replacement of heating and cooling systems, replacing tile and carpeting, and similar types of work. It does not include environmental compliance costs, facility leases, or other tasks associated with facilities operations, such as custodial services, grounds services, waste disposal, and the provision of central utilities.

2) Restore. To return a Health Care Facility or service to such a condition that it may be used for its designated purpose or to, but not beyond, the Health Care Facility or service's original functionality. This may include coming into compliance with all applicable federal, state, and local licensure, safety, and building requirements including nationally recognized Health Care facility construction guidelines and accreditation standards, such as those issued by the Facility Guidelines Institute, the American Institute of Architects, or the Joint Commission.

3) Modernization. The alteration, Addition, Expansion, or replacement of all, or part, of a Health Care Facility or service to accommodate new or increased functionality, or to replace components of a Health Care Facility or service beyond that necessary to Sustain or Restore said facility or service.

Construction. The Construction of a new Health Care Facility; the alteration of, Expansion of, making of major repairs to, remodeling of, renovation of, or replacement of an existing Health Care Facility; the initial, additional, or replacement equipping of any Health Care Facility; and the acquisition of consulting, architectural, engineering, legal, accounting, or any other professional services, and of a Site, when such acquisition is directed toward an undertaking sufficiently specific to constitute part of the subject matter of an Application for Determination of Need pursuant to 105 CMR 100.000.

Conversion. The substitution of a service or equipment that is defined as a Substantial Change in Service by the Department, in place of a current service or equipment.

Department. The Department of Public Health, which shall include the Public Health Council, pursuant to M.G.L. c. 17, § 1, except as otherwise specified.

Department Staff. Employees or agents acting on behalf of the Commissioner or the Department, including, but not limited to, consultants hired to support staff review and staff report development of an Application for Determination of Need.

Determination of Need Process. The process by which the Department reviews and evaluates the need for a Proposed Project pursuant to M.G.L. c. 111, §§ 25B through 25G, §§ 51 through 53, and § 71, or any applicable Government Agency requirement.
Disaggregation. The act of dividing up projects, or component parts of a project that are reasonably related, for the purposes of keeping a Proposed Project below the Substantial Capital Expenditure Minimum or to decrease the Maximum Capital Expenditures. For the purposes of Disaggregation, any Conservation Project proposed at the same Health Care Facility within one year of a previously Proposed Project shall be considered a component part of any Proposed Project subject to 105 CMR 100.000.

DoN-required Service. A service or procedure that for reasons of quality, access, cost, or health systems sustainability is determined by the Commissioner to require a Notice of Determination of Need. At a minimum, DoN-required Services shall include services or procedures for which the Commissioner has determined that there is evidence that the service(s) or procedure(s) do not lead to one or more of the following: improved Patient Panel health outcomes; increased access, including, but not limited to a decrease in price; or, a reduction in the Commonwealth's Total Health Care Expenditure. The Commissioner shall issue a list of DoN-required Services in the form of Guidelines. Said Guidelines shall be reviewed and evaluated annually. Persons may submit to the Commissioner requests that a certain service(s) or procedure(s) be considered for inclusion or exclusion from said Guidelines.

DoN-required Equipment. Equipment or services that for reasons of quality, access, cost, or health systems sustainability is determined by the Commissioner to require a Notice of Determination of Need. At a minimum, DoN-required Equipment shall include magnetic resonance imagers and linear accelerators, as well as any equipment and services for which the Commissioner has determined that there is evidence that the equipment or service(s) do not lead to one or more of the following: improved Patient Panel health outcomes; increased access, including, but not limited to a decrease in price; or, a reduction in the Commonwealth's Total Health Care Expenditure. The Commissioner shall issue a list of DoN-required Equipment in the form of Guidelines. Said Guidelines shall be reviewed and evaluated annually. Persons may submit to the Commissioner requests that certain equipment or service(s) be considered for inclusion or exclusion from said Guidelines.

Emergency Situation. A situation involving either:
   (1) a Government Declaration of emergency or a Catastrophic Event; or
   (2) an existing Health Care Facility which the Commissioner determines has been destroyed, or otherwise substantially damaged, or where there is a clear and present danger of such damage, such that the damage could substantially impact public health. For the purposes of Emergency Situation, the following words shall mean:
      (a) Government Declaration. A federal, state, municipal, or local declaration of emergency that takes effect pursuant to applicable federal or state law.
      (b) Catastrophic Event. An unforeseen event that substantially affects or increases the need for health care services, such as a natural disaster, an act of terrorism, or an extended power outage. Examples of Catastrophic Events include, but are not limited to, events involving numerous serious injuries, such as fires or building collapse, a chemical spill or release, or widespread outbreak of disease or illness requiring emergency treatment or hospitalization.

Entity or Person. 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.

Expansion. Any increase or upgrade by a Health Care Facility to the existing functionality of a DoN-required Service or DoN-required Equipment; any increase or upgrade to the total number of beds, services, or stations; or any other change as further defined by the Department.

Expenditure Minimum.
   (1) Expenditure Minimum with Respect to Substantial Capital Expenditures. Expenditure Minimum with Respect to Substantial Capital Expenditures as defined in M.G.L. c. 111, § 25B, and that is adjusted annually by the Commissioner after consideration of any inflation index established by the U.S. Department of Health and Human Services and set forth by the Commissioner in a Guideline.
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(2) Expenditure Minimum with Regard to Substantial Change in Service or Increase in Staff. Expenditure Minimum with Regard to Substantial Change in Service or Increase in Staff as defined in M.G.L. c. 111, § 25B, and that is adjusted annually by the Commissioner after consideration of any inflation index established by the U.S. Department of Health and Human Services and set forth by the Commissioner in a Guideline.

Notwithstanding 105 CMR 100.100: Expenditure Minimum(1) and (2), a Proposed Project concerned solely with outpatient services other than Ambulatory Surgery, which are not otherwise defined as DoN-required Service or DoN-required Equipment, shall not require a Notice of Determination of Need, unless the expenditures and acquisitions are at least the amount that is adjusted annually by the Department after consideration of any inflation index established by the U.S. Department of Health and Human Services, in which case, a Notice of Determination of Need shall be required.

Notwithstanding 105 CMR 100.100: Expenditure Minimum(1) and (2), expenditures for, or the acquisition of, any replacement of medical, diagnostic, or therapeutic equipment defined as a DoN-required Service or DoN-required Equipment for which a Notice of Determination of Need was previously issued, or for which the DoN-required Service or DoN-required Equipment was exempted from Determination of Need, shall not require an additional Notice of Determination of Need, and shall not be included in the calculation of the Expenditure Minimum, so long as the project(s) falls within the definition of a Conservation Project as determined by the Department.

Factor or Determination of Need Factor. Each of the standard requirements for evaluation of an Application for Determination of Need as established within 105 CMR 100.000.

Filing Date. The date at which an Application for Determination of Need is filed with the Department by an Applicant.

Final Action. Unless otherwise specified, the issuance of a Notice of Determination of Need, approval, disapproval, dismissal, referral, or revocation of an Application by the Department or Commissioner.

Freestanding Ambulatory Surgery Center. An ambulatory surgery center licensed as a Clinic.

Good Cause Related to Project Implementation. The Applicant is unable to make Substantial and Continuing Progress within the period of the Notice of Determination of Need authorization due to:

(1) Unreasonably excessive delay on the part of the Department in processing any Application or request;
(2) Force majeure (e.g., a government declaration, catastrophic event, labor strike, or other cause beyond the control of the Applicant and/or the Department that could not be reasonably avoided by the Applicant's exercise of due care);
(3) Action of general application by any branch of federal, state, or local government;
(4) Winter conditions that preclude making Substantial and Continuing Progress toward completion, provided that the Applicant would have made such Substantial and Continuing Progress within the period of authorization but for such winter conditions;
(5) Failure to obtain a financing commitment, provided that, within the period of the Notice of Determination of Need authorization, the Applicant has filed a firm commitment application with the United States Department of Housing and Urban Development or successor agency, in which case, the period of the Notice of Determination of Need authorization shall be extended for a period of not more than four months beyond the period authorized; or
(6) Any other condition that may be specified by the Department; and

The Applicant is able to demonstrate to the Department that the project is diligently proceeding with the completion of all prerequisites to making Substantial and Continuing Progress within the period of the Notice of Determination of Need authorization.

Good Cause Related to Project Implementation shall exclude Transfer of Ownership; transfer of Site; failure to obtain financing commitments under circumstances other than those described within 105 CMR 100.100: Good Cause Related to Project Implementation(5); an action taken by a Person related to zoning that has, or may have, the effect of limiting the Applicant's development rights with respect to a Site(s) in one city or town; and, any other reason deemed as applicable by the Department.
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**Government Agency.** Any agency of the Commonwealth of Massachusetts or of any political subdivision of the Commonwealth of Massachusetts therein, including a city or a town, but does not mean an agency of the United States, even if such agency maintains a medical institution within Massachusetts.

**Guideline.** An enforceable sub-regulatory criterion that has been issued by the Commissioner pursuant to 105 CMR 100.000, but not promulgated as regulation. The Commissioner shall ensure issuance of such Guidelines conforms with 105 CMR 100.440. The Commissioner shall notify the Public Health Council of any Guideline issued by the Department within 60 days of issuance.

**Health Care Facility.** A Hospital or a Clinic; a Long-term Care Facility; a clinical laboratory subject to licensure under M.G.L. c. 111D; a Public Medical Institution as defined in 105 CMR 100.100; or any other facility licensed by a Government Agency which requires a Notice of Determination of Need as a condition of licensure or other Government Agency requirement.

**Health Policy Commission or HPC.** The Government Agency established pursuant to M.G.L. c. 6D.

**Health Priorities.** Services or population health strategies that address identified regional, or statewide public health needs. Health Priorities shall be defined by the Commissioner in Guidelines and developed in consultation with relevant Government Agencies, community-based organizations, stakeholders, and the Public Health Council, may be guided by the state health plan pursuant to M.G.L. c. 6A, §16T and relevant community health needs assessments, and shall encourage the appropriate allocation of private and public health care resources consistent with M.G.L. c. 111, § 25C.

**Holder.** The Provider Organization which has been issued a Notice of Determination of Need by the Department pursuant to 105 CMR 100.000. In instances where there is no Provider Organization, Holder shall mean the Entity which has been issued a Notice of Determination of Need by the Department pursuant to 105 CMR 100.000.

**Hospital.** Any hospital licensed pursuant to M.G.L. c. 111, § 51.

**Immaterial Change means:**

1. An increase or decrease in cost allocation among or between architectural costs, Construction contract, fixed equipment, and Site services that does not result in any increase in the maximum Capital Expenditure;
2. A change in the proposed method of financing that does not result in any increase in the maximum Capital Expenditure or operating costs for interest in any year;
3. A change in the maximum Capital Expenditure to the extent of the inflation adjustment provided for within 105 CMR 100.310(I);
4. For all Health Care Facilities other than Hospitals, a single increase, or cumulative series of increases, in Bed Capacity totaling not more than 12 beds to the licensed Bed Capacity of the entire Health Care Facility;
5. A change in the architectural design that does not result in any changes in the spatial allocation among different components of the project, aggregate gross square footage, Bed Capacity, or maximum Capital Expenditure. Any such change in the architectural design shall be subject to the Department's architectural plan approval as provided for within 105 CMR 100.310(F); or
6. Any alteration from the previously issued Notice of Determination of Need that the Commissioner determines to be an Immaterial Change in nature.
Location or Premises means:
(1) The street address(es) of the Health Care Facility; and
(2) In the case of a Health Care Facility located within a physically contiguous campus of an institution, such as a school, university, or Hospital, Location or Premises shall mean the campus.

Long-term Care Facility. A long-term care facility, including a convalescent or nursing home, or a rest home as defined in M.G.L. c. 111, § 71.

Minor Change means:
(1) An increase or decrease in the spatial allocation among different components of the project that results in an increase or decrease of up to 25% of the originally approved gross square footage for that component, provided that any such change does not result in any change in the aggregate gross square footage, Bed Capacity, or maximum Capital Expenditure, unless otherwise approved pursuant to 105 CMR 100.00. Any such increase or decrease in the spatial allocation of the project's components shall also be subject to the Department's architectural plan approval as provided for in 105 CMR 100.310(F);
(2) An increase or decrease in the aggregate gross square footage up to 15% of the approved space or 2,000 gross square feet, whichever is greater, provided that such a change in aggregate gross square footage does not result in any change in the Bed Capacity or maximum Capital Expenditure, unless otherwise approved pursuant to 105 CMR 100.000;
(3) Any increase in the maximum Capital Expenditure of up to 10% of the inflation adjusted originally approved total expenditure and decreases in the maximum Capital Expenditure. An increase shall be allowed only for contingencies that could not have been reasonably foreseen, that are not reasonably within the control of the Holder, as determined by the Commissioner, and for which the inflationary adjustment contained within 105 CMR 100.310(I) is not appropriate;
(4) Any change in the type of equipment which the Commissioner determines not to be technologically different from that which received Notice of Determination of Need, provided that such a change does not result in any increase in the maximum Capital Expenditure, unless otherwise approved pursuant to 105 CMR 100.000, or any increase in the likely operating costs; or
(5) Any alteration from the previously issued Notice of Determination of Need that the Commissioner determines to be a Minor Change in nature.

Notice of Determination of Need or Notice. A Final Action that represents the formal approval of the Department issued pursuant to 105 CMR 100.000. A Notice of Determination of Need shall include all applicable terms and Conditions, Standard or Other, as directed and attached to the Notice of Determination of Need by the Department.

Original License. The license issued to a Person for the Premises named therein, and is granted either upon initial licensure of a facility, change of Location, or Transfer of Ownership of a Health Care Facility.

Patient Panel. The total of the individual patients regardless of payer, including those patients seen within an emergency department(s) if applicable, seen over the course of the most recent complete 36-month period by the Applicant or Holder.

Party of Record. During the pendency of an Application for a Determination of Need, the Applicant or Holder, the Attorney General, CHIA, HPC, all Government Agencies with relevant oversight or licensure authority over the Proposed Project or components therein, and any Ten Taxpayer Groups duly registered. A Party of Record may review the Application for Determination of Need for which it is appropriately registered, as well as provide written comment for consideration by the Department, including written comment by the Attorney General, CHIA, and HPC as it relates to any independent cost-analyses made pursuant to 105 CMR 100.405.

Primary Service Area. The geographic area in which a majority of patients who receive care at an Entity reside.
Proposed Project. Any Capital Expenditure, Substantial Change in Service, Original License, Transfer of Ownership, DoN-required Service, DoN-required Equipment, or any combination thereof that is proposed within an Application for Determination of Need and filed with the Department pursuant to 105 CMR 100.000. A Proposed Project may include an Applicant’s institutional master plan.

Provider Organization. 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 and is the sole corporate member or sole shareholder of one or more Health Care Facilities.

Public Medical Institution. Any medical institution, including an institution for the mentally ill or for individuals with intellectual disabilities, supported in whole or in part by public funds, either federal, state, or municipal, and staffed by professional medical and nursing personnel and providing medical care in accordance with standards established through licensure, approval, or certification by the Department for participation in programs administered under Titles XVIII or XIX of the Federal Social Security Act.

Significant Change means:
(1) Any change, modification, or deletion of components within a previously issued Notice of Determination of Need that is not an Immaterial or Minor Change, as determined by the Commissioner;
(2) Any modification or deletion of any Standard or Other condition set forth within a Notice of Determination of Need that is determined to be material by the Department;
(3) Unless otherwise approved by the Department, any extension of the authorization period of an approved project as specified in a Notice of Determination of Need;
(4) Any build out of shell space that was subject to a Notice of Determination of Need; or
(5) Any change to a project the Commissioner deems to be so significant that it alters the previously issued Notice of Determination of Need to a degree that it constitutes a new project that requires the issuance of a new Notice of Determination of Need.

Site. Land and any building or part thereof.

Solicitation of Funding. The act of approaching any member of the general public with a request or plea for a donation of funds to be used for a Proposed Project. For such purposes, Solicitation of Funding shall exclude any request or plea for a donation of funds to any such Health Care Facility or Affiliate, any shareholder, member, partner, member of the board of directors, officer, employee, or member of the medical or nursing staff.

Submission Date. The date at which an Application is deemed substantially complete by Department Staff.

Substantial Capital Expenditure. A Capital Expenditure that exceeds, or may reasonably be regarded as likely to exceed, theExpenditure Minimum; or, the obtaining by lease or comparable arrangement, by donation, or by transfer for less than fair market value of capital equipment or a building, or part thereof, with a fair market value in excess of the Expenditure Minimum. The fair market value of a lease of equipment or a building, or part thereof, shall be equal to its fair market value were it to be purchased.

See definitions of Capital Expenditure and Expenditure Minimum.

Substantial Change in Services means:
(1) With regard to Hospitals only, the Addition or Expansion of, or Conversion to:
   (a) A DoN-required Service, DoN-required Equipment, or Ambulatory Surgery, regardless of whether an Expenditure Minimum is exceeded; or
   (b) Any services that may be provided by facilities that are not Hospitals.
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(2) For any Health Care Facility other than a Hospital:
   (a) The Addition of a service or increase in staff that entails annual operating costs in excess of the Expenditure Minimum;
   (b) Any increase in Bed Capacity, other than a single increase, or cumulative series of increases, totaling not more than 12 beds to the licensed Bed Capacity of the entire Health Care Facility;
   (c) The Addition or Expansion of, or Conversion to, a DoN-required Service or DoN-required Equipment regardless of whether an Expenditure Minimum is exceeded;
   (d) The Addition or Expansion of, or Conversion to, Ambulatory Surgery; or
   (e) Upgrading Level IV beds to skilled nursing and intermediate care beds (Level II and III).

(3) A transfer of Site of any Health Care Facility, DoN-required Service, DoN-required Equipment, or a project which has been previously issued a Notice of Determination of Need but is not yet licensed, or not yet operational if no Government Agency license, that is determined by the Department to result in a Substantial Change in Service.

Substantial and Continuing Progress means:

(1) In the case of a project involving equipping of a Health Care Facility, such equipment shall have been installed and shall be operational;

(2) In the case of a project involving the provision of a DoN-required Service or DoN-required Equipment, either:
   (a) provision of such service or use of such equipment shall have commenced;
   (b) demonstration of a binding contract for the purchase or lease of the equipment with a party unrelated to the Holder or ultimate provider of the DoN-required Service or DoN-required Equipment; or

(3) In the case of a project involving the provision of a DoN-required Service or DoN-required Equipment subject to Department licensure, the project shall have received written, final plan approval from the Department;

(4) In the case of a project involving an increase in the Bed Capacity, or licensed Bed Capacity of a Health Care Facility, or a service or unit thereof, but involving no Construction or renovation, a request for an increase in the Health Care Facility's licensed capacity for such beds shall have been submitted to the Department; however, if not required to be so licensed, such beds shall be in operation;

(5) In the case of a project involving Construction, the following shall have occurred:
   (a) commencement of demolition and the physical assembly of the foundation of the project for Construction and ground floor Addition projects when a foundation is part of the project;
   (b) commencement of the physical assembly of the additional structure; or

(6) In the case of a project involving renovation, progress beyond the removal and demolition of an existing facility, or of the component structures of an existing facility.

Sufficient Interest means one of the following:

(1) Clear legal title to the proposed Site, or a legally enforceable agreement to give such title;

(2) In the case of a Hospital or Long-term Care Facility, a lease for at least five years with options to renew for not less than a total of 15 additional years, or a legally enforceable agreement to give such lease;

(3) In the case of an Ambulatory Surgery center, a lease for at least one year with options to renew for not less than one additional year, or a legally enforceable agreement to give such lease;

(4) In the case of a Clinic organized as a non-profit corporation under M.G.L. c. 180, permission to use the Premises for a period of at least two years;

(5) In the case of a Government Agency, recommendation of not more than four alternative Sites by an official Site selection committee and acceptance of that recommendation by the duly elected or appointed chief officer of that Government Agency and, in the case of a Government Agency within an executive office, acceptance of that recommendation by the Secretary of that executive office.
100.100: continued

**Taxpayer.** Any individual residing within the Commonwealth of Massachusetts and whom is subject to any Massachusetts state income, excise, or property tax during the calendar year in which he or she signs a written request for a public hearing, a statement of registration, or comments with respect to an Application filed pursuant to 105 CMR 100.000.

**Ten Taxpayer Group.** Any ten Taxpayers, organized as a group, which may participate in the review of an Application for Determination of Need. Said group must register with the Department at any time during the first 30 days following the Filing Date of an Application, or during the first ten days after a public hearing held pursuant to 105 CMR 100.445. Any such registration shall be signed by each Taxpayer and shall, in clearly legible print:

1. List each Taxpayer by name and resident address;
2. State whether or not each Taxpayer is acting as an agent for another party. If a Taxpayer is acting as an agent for another party, the Taxpayer must list that party's full name and address;
3. Identify the Application in which the Taxpayers are interested; and
4. Specify which Taxpayer is to be the recipient of all written communications concerning the Application on behalf of the Ten Taxpayer Group.

Upon receipt of any such registration, Department Staff shall promptly send a copy to each Party of Record. The Commissioner may revoke the Ten Taxpayer Group status of any group that has failed to comply with the requirements of 105 CMR 100.000.

**Total Value.** The sum of the total Capital Expenditure of a Proposed Project; or in the case of a Transfer of Ownership pursuant to 105 CMR 100.735, the total capital value or the last full year of reported operating revenues, whichever is greater, of the proposed facility or facilities to be acquired at the time of the Filing Date.

**Transfer of Ownership** shall include, but shall not be limited to, the following:

1. A transfer of a majority interest in the ownership of a Hospital or Clinic;
2. In the case of a privately-held for-profit corporation, transfer of a majority of any class of the stock thereof;
3. In the case of a partnership, transfer of a majority of trustees;
4. In the case of a trust, change of the trustee or a majority of trustees;
5. In the case of a non-profit corporation, such changes in the corporate membership and/or trustees to constitute a shift in control of the Hospital or Clinic as determined by the Commissioner; or
6. In the case where foreclosure proceedings have been instituted by a mortgagee in possession of a Hospital or Clinic.

For the purposes of 105 CMR 100.000, Transfer of Ownership may also mean any change in the ownership interest or structure of the Hospital or Clinic, or of the Hospital or Clinic's organization or parent organization(s), such that the change results in a shift in control of the operation of the Hospital or Clinic, as determined by the Commissioner. The Commissioner may, based upon a review of the organizational structure and proposed change, determine that a proposed transaction does not rise to the level of a Transfer of Ownership.

100.105: Computation of Time

Time as specified within 105 CMR 100.000, or as otherwise used within the Determination of Need Process, shall include every calendar day, whether the Department is open for business on that day or not, except that, when the last day of a specified period of time falls on a day when the Department is closed for business, such period shall end, instead, on the next day on which the Department is open for business.

100.210: Determination of Need Factors

(A) The Department shall determine that need exists for a Proposed Project, on the basis of material in the record, where the Applicant makes a clear and convincing demonstration that the Proposed Project meets each Determination of Need Factor set forth within 105 CMR 100.210, unless otherwise expressly specified within 105 CMR 100.000.
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(1) **Applicant Patient Panel Need, Public Health Value, and Operational Objectives.**
   (a) The Applicant has demonstrated sufficient need for the Proposed Project by the Applicant's existing Patient Panel;
   (b) The Applicant has demonstrated that the Proposed Project will add measurable public health value in terms of improved health outcomes and quality of life of the Applicant's existing Patient Panel, while providing reasonable assurances of health equity;
   (c) The Department has determined that the Applicant has provided sufficient evidence that the Proposed Project will operate efficiently and effectively by furthering and improving continuity and coordination of care for the Applicant's Patient Panel, including, sufficient evidence that the Proposed Project will create or ensure appropriate linkages to patients' primary care services;
   (d) The Applicant has provided evidence of consultation, both prior to and after the Filing Date, with all Government Agencies with relevant licensure, certification, or other regulatory oversight of the Applicant or the Proposed Project;
   (e) The Applicant has provided evidence of sound community engagement and consultation throughout the development of the Proposed Project, including documentation of the Applicant's efforts to ensure engagement of community coalitions statistically representative of the Applicant's existing Patient Panel. Representation should consider age, gender and sexual identity, race, ethnicity, disability status, as well as socioeconomic and health status; and
   (f) The Applicant has demonstrated that the Proposed Project will compete on the basis of price, total medical expenses, provider costs, and other recognized measures of health care spending.

(2) **Health Priorities.**
   (a) The Applicant has sufficiently demonstrated that the Proposed Project will meaningfully contribute to the Commonwealth's goals for cost containment, improved public health outcomes, and delivery system transformation; and
   (b) The Department has determined, either:
      1. The Applicant's Proposed Project, in its entirety and without Disaggregation, meets one or more of the Health Priorities set out in Department Guideline, and therefore, is exempted from 105 CMR 100.210(A)(6); or
      2. The Applicant has provided sufficient evidence that, or attestations to, the Applicant's proposed fulfillment of 105 CMR 100.210(A)(6) will sufficiently advance one or more of the Health Priorities set out in Department Guideline.

(3) **Compliance.** The Department has determined, in consultation with all Government Agencies with relevant licensure, certification, or other regulatory oversight of the Applicant or the Proposed Project, that the Applicant has provided sufficient evidence of compliance and good standing with federal, state, and local laws and regulations, including, but not limited to compliance with all previously issued Notices of Determination of Need and the terms and Conditions attached therein.

(4) **Financial Feasibility and Reasonableness of Expenditures and Costs.**
   (a) The Department, in consultation with CHIA, has determined that the Applicant has provided sufficient documentation of the availability of sufficient funds for capital and ongoing operating costs necessary to support the Proposed Project without negative impacts or consequences to the Applicant's existing Patient Panel. Said documentation shall be completed and certified under the pains and penalties of perjury by an independent certified public accountant (CPA). Said independent CPA's analysis shall include, but not be limited to: review of the Applicant's past and present operating and capital budgets; balance sheets; projected cash flow statements; proposed levels of financing for the Proposed Project, including a five-year financial sustainability analysis; and any other relevant information required for the independent CPA to provide reasonable assurances to the Department that the Proposed Project is financially feasible and within the financial capability of the Applicant, and where appropriate, as a matter of standard accounting practice, its Affiliates; and
   (b) If the Department has determined that an independent cost-analysis is required pursuant to M.G.L. c. 111, § 25C(h), the analysis has demonstrated that the Proposed Project is consistent with the Commonwealth's efforts to meet the health care cost-containment goals.

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100.210: continued

(5) **Relative Merit.** The Applicant has provided sufficient evidence that the Proposed Project, on balance, is superior to alternative and substitute methods for meeting the existing Patient Panel needs identified by the Applicant pursuant to 105 CMR 100.210(A)(1). Evaluation of 105 CMR 100.210(A)(5) shall take into account, at a minimum, the quality, efficiency, and capital and operating costs of the Proposed Project relative to potential alternatives or substitutes, including alternative evidence-based strategies and public health interventions.

(6) **Community-based Health Initiatives.** For all Proposed Projects, consistent with M.G.L. c. 111, § 25C, and unless otherwise specified within 105 CMR 100.000, the Department has approved the Applicant's proposed plans for fulfilling its responsibilities set out in the Department's Community-based Health Initiatives Guideline. Said plans shall fund projects which address one or more of the Health Priorities; shall be documented and enforceable as a Condition of any Notice of Determination of Need issued pursuant to 105 CMR 100.000; and for all Proposed Projects, unless otherwise specified within 105 CMR 100.000, such funding shall in total be greater than or equal to 5% of the total Capital Expenditure of the Proposed Project.

(B) Nothing in 105 CMR 100.210 shall be construed to prohibit the Department from issuing a Notice of Determination of Need for a project, or part thereof, where, in the case of an Applicant's failure to meet each applicable Factor, the Department determines that the defect can be sufficiently remedied by the setting of an appropriate Condition of approval pursuant to 105 CMR 100.360.

100.310: Standard Conditions

Unless otherwise expressly specified within 105 CMR 100.000, each Notice of Determination of Need issued by the Department shall be subject to the following Conditions. The Commissioner may specify additional Standard Conditions within Guideline which shall be attached to all Notices of Determination of Need, unless otherwise specified, and which shall be determined by the Commissioner as advancing the objectives of 105 CMR 100.000. Prior to issuance, such Guideline shall be developed through a public process consistent with 105 CMR 100.440 and in consultation with applicable Government Agencies, community-based organizations, relevant stakeholders, and the Public Health Council.

(A) The Notice of Determination of Need shall be subject to administrative review by the Health Facilities Appeals Board and may be stayed by the Health Facilities Appeals Board. If the Health Facilities Appeals Board is not constituted on the date of issuance of the Notice of Determination of Need, the Notice shall be considered a Final Action subject to review under M.G.L. c. 30A.

(B) The Notice of Determination of Need shall go into effect upon the Department's issuance of a written notification made pursuant to 105 CMR 100.625(A). The Holder shall submit an acknowledgment of receipt to the Department within 30 days of the written notification, documented in the form of an attestation, signed by the Holder's chief executive officer and board chair, and returned to the Department and all Parties of Record. Unless extended for Good Cause Related to Project Implementation, or as a result of an approved amendment to a previously issued Notice of Determination of Need, the Notice of Determination of Need shall constitute a valid authorization for a period of not more than three years following the approval of the Department, unless otherwise expressly noted as an Other Condition, and shall only be for the purposes of the approved project, including for the identified and approved treatments and/or patient populations. No Notice of Determination of Need shall remain in authorization unless the Holder complies with all prescribed terms and Conditions as set forth by the Department.

(C) Unless extended for Good Cause Related to Project Implementation, or as a result of an approved amendment to a previously issued Notice of Determination of Need, the Notice of Determination of Need shall constitute a valid authorization only for the Proposed Project for which the Notice of Determination of Need is made, and for only the total Capital Expenditure approved.
The Notice of Determination of Need shall constitute a valid authorization only for the Person to whom it is issued and may be transferred only upon the expressed written permission of the Department pursuant to 105 CMR 100.635(A)(3), except that a Notice of Determination of Need issued for an Original License pursuant to 105 CMR 100.730 and a Notice of Determination of Need for a Transfer of Ownership pursuant to 105 CMR 100.735 shall not be transferable.

The authorization for the Notice of Determination of Need shall expire if the Department determines that Substantial and Continuing Progress is not made, or if not duly extended by the Department for Good Cause Related to Project Implementation shown. Any request for an extension must be filed by the Holder within the period of authorization for the Notice of Determination of Need. In the event an appeal filed with the Health Facilities Appeals Board, the period of authorization of the Notice of Determination of Need shall be extended during such time that any stay is in effect.

Notwithstanding the period of authorization of the Notice of Determination of Need, if the Holder is subject to the requirements of filing final architectural plans and specifications pursuant to M.G.L. c. 111, § 51 or § 71, and if any Construction or renovation is involved, the Notice of Determination of Need shall not remain in force longer than 12 months, unless within said 12 months, the Holder has filed such final architectural plans and specifications; provided that the Commissioner may approve a written schedule for the phased submission of such plans beyond that period for any project involving Construction having an authorized Capital Expenditure in excess of an amount equal to the Expenditure Minimum with respect to Substantial Capital Expenditures with respect to Hospitals. In the event a written schedule for phased submission of such plans is approved, each portion of the project to which a submission relates shall be consistent with the overall project as approved by the Department and shall not exceed the proportional share of the total approved project cost.

Failure to submit final and complete architectural plans and specifications plans by the date specified by the Department, or by an approved schedule for plan submission pursuant to 105 CMR 100.310(F)(1), may result in:

- the initiation of revocation procedures pursuant to 105 CMR 100.640; or
- the disallowance of inflation calculated pursuant to 105 CMR 100.310(I) for the amount of time equal to the time period between the due date for submission of final plans as prescribed by the Department, and the date of actual submission by the Holder.

The disallowance of inflation for this time period shall be calculated as if the time period occurred immediately preceding the commencement of Construction.

No Construction may begin pursuant to a Notice of Determination of Need until the Holder has met all applicable Department and other Government Agency licensure requirements, including plan review. Part 1 Plan Review by the Department may coincide, as is reasonably feasible, with Department consideration of a Proposed Project pursuant to 105 CMR 100.000.

The Holder shall ensure Construction of any new building or the complete rehabilitation of a building implemented pursuant to a Notice of Determination of Need shall meet all Prerequisites and meet or exceed certifiable “silver level”, or equivalent, of the Leadership in Energy and Environmental Design-Health Care (LEED-HC) Green Guide for Healthcare (GGHC), or an equivalent nationally recognized best practice standard, as approved by the Department.

The written schedule for the phased submission of architectural plans and specifications submitted by the Holder pursuant to 105 CMR 100.310(F) shall be used to measure continuing progress toward completion of the project for which a Notice of Determination of Need has been issued.

The Government Agency license of the Health Care Facility or Health Care Facilities for which, and on behalf of, the Holder possesses a valid Notice of Determination of Need, shall be conditioned with all Standard and Other Conditions attached to the Notice of Determination of Need.
100.310: continued

(I) Unless extended for Good Cause Related to Project Implementation, the Department shall receive from the Holder firm, itemized figures specifying the final project costs, or current phase thereof, which shall not be greater than those approved by the Department pursuant to the issued Notice for Determination of Need plus any increase in cost due to the allowable rate of inflation. This submission shall occur within six months following the receipt of written final approval of architectural plans and specifications by the Department or other applicable Government Agency; or, in the case of projects for which a schedule of phased plan submission has been approved, each phase submitted. The Holder shall submit the final project costs in a format specified by the Commissioner. No additional increases in the maximum Capital Expenditure, inflationary or otherwise, shall be approved beyond 12 months after the initial licensure of beds and opening of the facility or service. The final approved project costs shall be submitted by the Commissioner to all Parties of Record. Should the Holder fail to submit final project costs pursuant to 105 CMR 100.310(I)(1), the Holder shall be subject to enforcement actions as set forth within the Notice of Determination of Need's Standard and Other Conditions.

(J) Unless explicitly exempted within 105 CMR 100.000, the terms and Conditions shall include descriptions of project(s), mutually agreed upon and approved by the Department, documenting the Holder's obligations pursuant to 105 CMR 100.210(A)(6). Said plan shall require the Holder to expend, over a five-year period, or any other period as specified by the Commissioner, an amount which in total shall be greater than or equal to 5% of the total Capital Expenditure of the approved project, except in cases where exemptions within 105 CMR 100.000 may apply. Said projects shall address one or more of the Health Priorities set out in Department Guidelines.

(K) If the Health Care Facility or Health Care Facilities for which the Notice of Determination of Need has been issued is eligible, the Holder shall provide written attestation on behalf of the Health Care Facility or Health Care Facilities, under the pains and penalties of perjury, of participation, or their intent to participate, in MassHealth pursuant to 130 CMR 400.000 through 499.000.

(L) The Holder shall report to the Department, at a minimum on an annual basis, and in a form, manner, and frequency as specified by the Commissioner. At a minimum, said reporting shall include, but not be limited to, the reporting of measures related to the project's achievement of the Determination of Need Factors, as directed by the Department pursuant to105 CMR 100.210.

(M) If it is determined by the Department that the Holder has failed to sufficiently demonstrate compliance with one or more Conditions, the Holder shall fund projects which address one or more of the Health Priorities set out in Department Guideline, as approved by the Department, which in total, shall equal up to 2.5% of the total Capital Expenditure of the approved project. Said projects shall address one or more of the Health Priorities set out in Department Guideline, and shall be in addition to those projects approved by the Department in fulfillment of 105 CMR 100.210(A)(6). In making such determination, the Department shall provide written notification to the Holder at least 30 days prior to requiring such funding, and shall provide the Holder the opportunity to appear before the Department. The Department shall consider circumstances external to the Holder that may impact the Holder's ability to demonstrate compliance.

(N) The Holder shall provide to Department Staff a plan for approval by the Office of Health Equity for the development and improvement of language access and assistive services provided to individuals with disabilities, non-English speaking, Limited English Proficiency (LEP), and American Sign Language (ASL) patients.

(O) The Holder shall provide for interpreter services to the Holder's Patient Panel. The Holder shall ensure that all medical and non-medical interpreters, inclusive of staff, contractors, and volunteers providing interpreter services to the Holder's Patient Panel maintain current multilingual proficiency and have sufficient relevant training. Training for non-medical interpreters should include, at a minimum:

1. the skills and ethics of interpretation; and
2. cultural health beliefs systems and concepts relevant to non-clinical encounters.
3. Training for medical interpreters should include, at a minimum:
100.310: continued

(a) the skills and ethics of interpretation; and
(b) multilingual knowledge of specialized terms, including medical terminology, competency in specialized settings, continuing education, and concepts relevant to clinical and non-clinical encounters.

(P) The Holder shall require and arrange for ongoing education and training for administrative, clinical, and support staff in culturally and linguistically appropriate services (CLAS), including, but not limited to, patient cultural and health belief systems and effective utilization of available interpreter services.

(Q) All Standard and Other Conditions attached to the Notice of Determination of Need shall remain in effect for a period of five years following completion of the project for which the Notice of Determination of Need was issued, unless otherwise expressly specified within one or more Condition.

100.360: Other Conditions

(A) In addition to all applicable Standard Conditions attached to a Notice of Determination of Need, the Department may prescribe any Other Conditions that are reasonably related to the scope of the project and that are consistent with the objectives of 105 CMR 100.000.

(B) If any Other Conditions are attached to a Notice of Determination of Need, the Holder shall, unless otherwise specified, be subject to all Standard Conditions specified in 105 CMR 100.310 for the purposes of implementing said Other Conditions.

100.405: Filing of Applications for Determination of Need

(A) All materials related to an Application for Determination of Need, including, but not limited to Application forms, computation sheets, notification requirements, Guidelines, and other pertinent documents shall be made publicly and readily available electronically at all times, such as on the Department's website. Applications for Determination of Need shall include, at a minimum: a statement of the Proposed Project, including the Total Value; information and supporting documentation consistent with 105 CMR 100.210; all applicable computation sheets; a filing fee; an affidavit of truthfulness, signed under the pains and penalties of perjury pursuant to 105 CMR 100.405(B); an attestation of compliance with all federal, state, and local laws, including compliance with M.G.L. c. 30, §§ 61 through 62H and the applicable regulations thereunder; a disclosure of the total proposed Construction costs specifically related to the Proposed Project, if any, which will be contracted out to local or minority-, women-, or veteran-owned businesses; and any additional requirements, attestations, or information that the Applicant wishes to place before the Department, or as the Commissioner requests or requires.

(B) All Persons seeking a Notice of Determination of Need shall file a completed Application, accompanied by an affidavit signed under the pains and penalties of perjury by the Applicant's chief executive officer and board chair and the filing fee to the Department, labeled "Attn: Determination of Need Program". Simultaneous filings of duplicate copies of the Application shall be required to the AGO, CHIA, HPC, and to all Government Agencies with relevant licensure, certification, or other regulatory oversight of the Applicant or the Proposed Project, or components therein. The filing fee shall be nonrefundable and shall be $500 or 0.2% of the Total Value of the Proposed Project, whichever is greater.

(C) All Persons seeking a Notice of Determination of Need, or an amendment to a previously issued Notice of Determination of Need, shall publish a notice of intent of its Application, and of any amendment thereto 14 days prior to the Filing Date of such Application or amendment with the Department. The notice of intent shall accurately describe the Proposed Project, and shall be published prominently on the website(s) for the Health Care Facility or Heath Care Facilities for which the Application for Notice of Determination of Need will be submitted, and in the daily newspaper(s) within the affected cities or towns of, or nearest to, the Location of the Proposed Project, or as directed by the Commissioner. Every notice of intent, at a minimum, and subject to amendment by the Commissioner, shall conform to the following standards.
(1) **Form.** The notice of intent published in the daily newspaper(s) shall be at least two inches high by three columns wide, or at least three inches high by two columns wide; shall appear within the Legal Notice, as well as the appropriate local news or interest sections of the publication, and shall be captioned: "Public Announcement Concerning a Proposed Health Care Project". The notice of intent published prominently on the website(s) for the Health Care Facility or Health Care Facilities for which the Application for Notice of Determination of Need will be submitted shall comport, at a minimum, with the most current web accessibility standards of the Commonwealth.

(2) **Content.** The notice of intent shall, at a minimum: identify the Applicant by name and address; the name and address of the Health Care Facility or Health Care Facilities involved or proposed; shall provide a brief and accurate description of the Proposed Project, including the type of Health Care Facility or Health Care Facilities involved, and the type of service(s) proposed or involved; shall state the Total Value of the Proposed Project; any anticipated price or service impacts on the Applicant's existing Patient Panel; and, shall contain the following statements: "Any ten Taxpayers of Massachusetts may register in connection with the intended Application or amendment by no later than (INSERT DATE) by contacting the Department of Public Health Determination of Need Program (INSERT CONTACT INFORMATION AS SPECIFIED BY DEPARTMENT STAFF)." Said inserted date shall be 20 days from the proposed Filing Date.

The Applicant shall simultaneously provide a copy of said notice of intent to the Department, all Parties of Record, and all carriers or third-party administrators for the payment of health care services, including Medicare and Medicaid, with which the Applicant contracts. The Commissioner may waive 105 CMR 100.405(C) in the case of an emergency Application made pursuant to 105 CMR 100.740(B). Should the Commissioner determine errors existed within the Applicant's published notice of intent pursuant to 105 CMR 100.405(C), the Applicant shall ensure a corrected notice of intent is published within a reasonable period of time, as specified by the Commissioner.

(D) Pursuant to M.G.L. c. 111, § 25C(b), at its discretion, the Department may require an independent cost-analysis, conducted at the expense of the Applicant, to demonstrate that the Proposed Project is consistent with the Commonwealth's health care cost-containment goals. If the Department requires an independent cost-analysis, the Department shall make such request no later than 30 days following the Submission Date. The four-month period for review of the Application shall be stayed until a complete and final independent cost-analysis is received and accepted by the Department. For the purposes of a Department-required independent cost-analysis, the Department shall select a mutually agreeable party to conduct such analysis, and shall develop the scope and terms of such analysis. Upon the Department's acceptance of the independent cost-analysis, the Department shall provide the analysis to all Parties of Record. Parties of Record may submit written comments in response to the accepted independent cost-analysis. All written comments must be received by the Department within 30 days of Department acceptance. The accepted independent cost-analysis shall be attached to the staff report issued pursuant to 105 CMR 100.510.

(E) Applicants are responsible for ensuring proper notification and submissions to the Secretary of Environmental Affairs pursuant to 301 CMR 11.00: MEPA Regulations.

(F) If the Applicant is subject to a performance improvement plan pursuant to M.G.L. c. 6D, § 10(d), the Applicant shall provide notification of such in its Application.

(G) If the Applicant is subject to filing with HPC pursuant to M.G.L. c. 6D, § 13, the Applicant shall provide notification of such in its Application, and the Applicant shall file such notice of material change prior to, or on the same day as the Filing Date of an Application for Determination of Need with the Department.

(H) The Department shall notify the Applicant and all Parties of Record within two business days of determining an Application meets the definition of Submission Date. The Department may provide the Applicant reasonable accommodations for any necessary technical corrections. However, the existence of any defects, as determined by the Commissioner, may constitute grounds for dismissal pursuant to 105 CMR 100.615(E).
100.405: continued

(I) The Applicant may request Part 1 Plan Review by the Department following the Filing Date of the Application for Determination of Need. Part 1 Plan Review may coincide, as is reasonably feasible, with Department consideration of the Proposed Project pursuant to 105 CMR 100.000.

100.415: Public Solicitation Requirements

(A) No Person may make Solicitation of Funding from the general public specifically for a Proposed Project subject to 105 CMR 100.000 without first obtaining a Notice of Determination of Need.

(B) An Applicant may solicit pledges for funding from the general public specifically for a Proposed Project subject to 105 CMR 100.000. However, Applicants shall properly notify all Persons of the requirement that the Proposed Project must receive Notice of Determination of Need prior to commencing Construction. In cases where an Application of Determination of Need is withdrawn pursuant to 105 CMR 100.430, or dismissed or disapproved pursuant to 105 CMR 100.615, the Applicant is responsible for ensuring all pledged funds are appropriately voided for the purposes of the withdrawn, dismissed, or disapproved project and that such persons are notified of such action(s).

100.425: Amendment of a Pending Application for Determination of Need

Unless otherwise deemed allowable by the Commissioner, no amendment shall be accepted that, in the opinion of the Commissioner, substantially alters the Proposed Project in nature, scope, costs, or financing, or in any way substantially alters or affects the Department's evaluation of the Proposed Project. 105 CMR 100.425 does not preclude the Department from requesting additional information, or making reasonable accommodations for any necessary technical corrections by the Applicant, or other changes based on updated information related to the Proposed Project. Any proposed amendments which are deemed impermissible by the Commissioner, and which result in the Applicant's inability to proceed with its filing, shall automatically result in a dismissal and the need for the Applicant to file a new Application.

100.430: Withdrawal of Application for Determination of Need

(A) An Applicant may withdraw its Application at any time by sending written notification thereof to the Department. Whenever an Application is withdrawn, all Parties of Record shall be notified by the Applicant.

(B) The Commissioner, in his or her discretion, may consider an Application to be withdrawn if an Applicant has failed to provide requested information, or otherwise has failed to prosecute the Application within a reasonable time period.

100.435: Opportunity for Comment by Parties of Record

(A) With respect to each Application, the Department shall afford reasonable opportunity to comment to all Parties of Record. Before taking preliminary or Final Action on such Application, the Department shall consider any written comments or specific recommendations submitted by a Party of Record, if filed in a timely and proper manner pursuant to 105 CMR 100.000. Comments by Parties of Record shall be submitted to the Department not more than 30 days following an Application Submission Date. This period for comment shall be extended for an additional ten days after any public hearing held pursuant to 105 CMR 100.445. The Commissioner may, in his or her discretion, extend this period for comment.

(B) In addition to the opportunity for comment set forth in 105 CMR 100.435, Parties of Record may seek to affect the Department's action on an Application in the following ways:

(1) By requesting a public hearing;
(2) By filing written reaction to the Staff report; and
(3) By making an oral presentation to the Department.
100.435: continued

(C) Whenever a Party of Record sends any written communication, or submits any written materials concerning an Application, the Department shall provide copies of such communication or materials to all other Parties of Record.

(D) The Commissioner may reasonably waive the requirements of 105 CMR 100.435 in cases of an emergency Application made pursuant to 105 CMR 100.740(B).

100.440: Opportunity for Comment by the General Public

(A) Persons, other than Parties of Record, may provide written or oral comment or testimony to the Department at a properly posted public hearing, if one is so ordered pursuant to 105 CMR 100.445, or by sending written comment to the Department within 30 days following the Application's Submission Date. This period for comment shall be extended for an additional ten days following any public hearing held pursuant to 105 CMR 100.445. The Commissioner may, in his or her discretion, extend this period for comment.

(B) The Commissioner may reasonably waive the requirements of 105 CMR 100.440(A) in cases of an emergency Application made pursuant to 105 CMR 100.740(B).

100.445: Public Hearing

(A) The Commissioner shall order a public hearing upon the written request made by any Party of Record within 30 days following the Application's Filing Date pursuant to 105 CMR 100.435; and may, in his or her discretion, order one or more public hearing(s) whenever, in his or her opinion, a public hearing would aid the Department Staff in carrying out its duties pursuant to 105 CMR 100.000.

(B) The purpose of a public hearing pursuant to 105 CMR 100.445 shall be to allow any Person to make their views known with respect to an Application before the Department. Such public hearing shall not be adjudicatory in nature, but shall be a public forum for the presentation of any comment(s) that may be relevant to the consideration of an Application.

(C) A public hearing ordered by, or requested from, the Commissioner may be held at any time. If feasible, every public hearing shall be held at a location in the Primary Service Area of the Proposed Project. Department Staff, at least ten days before any scheduled public hearing, shall provide notification of the time, place, and nature of such hearing to each Party of Record and shall publish notification of the hearing within the Primary Service Area of the Proposed Project.

(D) A designated representative of the Department shall conduct any public hearing pursuant to 105 CMR 100.445.

(E) The Commissioner may request a transcript of the public hearing to be provided at the expense of the Applicant.

100.510: Staff Report and Written Comment Period

(A) With respect to each Application not withdrawn or dismissed, following the Submission Date, Department Staff shall prepare a written Staff report to the Department. The Staff report, at a minimum, shall contain the following:

(1) A description of the Proposed Project with a summary of any significant supporting material(s) filed by the Applicant;

(2) A summary of all comments, testimony, and official statements properly received as public information from both Parties of Record and the general public;

(3) A summary of any comments, information, and rationale from Department Staff, including, but not limited to, a summary of the Application's ability to meet the requirements of each Factor pursuant to 105 CMR 100.210, and why;

(4) Any additional information or analysis Department Staff wish to bring to the Department's attention;
100.510: continued

(5) A clear statement of Department Staff's recommendation(s) or suggested options for Final or preliminary action upon the Application by the Department;

(6) For Staff reports recommending the issuance of a Notice of Determination of Need, all applicable Standard Conditions and any Other Conditions recommended for attachment as Conditions of the Notice of Determination of Need.

(B) The Staff report shall be provided to all Parties of Record and made available to the public consistent with 105 CMR 100.405(A) following receipt by the Commissioner at least 30 days prior to any Department action.

(C) In advance of the Department's meeting upon a pending Application for Determination of Need, Parties of Record may submit written comments related to the Staff's recommendation(s) and any Other Conditions recommended therein. All written comments shall be submitted to the Department at least 20 days prior to the Department meeting.

100.545: Prerequisites to Department Action

Except in the case of an emergency Application made pursuant to 105 CMR 100.740(B), the Department shall not take preliminary or Final Action upon an Application, unless first:

(A) The Application or amendment has been on file with the Department for at least 30 days following the Submission Date and the Applicant has provided the required number of copies to each Party of Record; and

(B) A public hearing has been held, if directed by the Commissioner pursuant to 105 CMR 100.445.

100.555: Postponement of Consideration of Application for Determination of Need

Any Party of Record may request postponement of consideration of an Application for Determination of Need until the next meeting of the Department. Such request may be granted only if the Commissioner determines that the request is for good cause, that failure to grant the request will significantly prejudice the Party of Record making the request from having its position considered by the Department, and that postponement would not prejudice any other Party of Record. A request for postponement under 105 CMR 100.555 must be made in writing to the Commissioner with copies simultaneously provided to all Parties of Record at least seven days before the scheduled Department meeting, and must state the rationale for the request for postponement. A Party of Record may be granted a postponement only once.

100.615: Final Action by the Department

(A) With respect to each Application for Determination of Need not withdrawn or dismissed, following the Submission Date, the Department shall act upon each Application by either disapproving an Application or by issuing a Notice of Determination of Need, subject to any and all applicable terms and Conditions set forth within 105 CMR 100.000, and based upon all written materials associated with a Proposed Project by adopting, amending, or rejecting the findings and recommendations, in whole or in part, within the Department staff report made pursuant to 105 CMR 100.510.

(B) The Department shall approve or disapprove, in whole or in part, each Application for a Determination of Need within four months after the Filing Date, or the date of which a permissible amendment to a pending Application was received by the Department; provided, however, that the Department may, on one occasion only, delay the action for up to two months after the Applicant has provided information which the Department has reasonably requested during the four-month period. This general requirement is subject to the following limited exemptions:

(1) In cases where the Department requests an independent cost analysis pursuant to 105 CMR 100.405(D) and M.G.L. c. 111, § 25C(h), the four-month period shall be stayed until a final independent cost-analysis is deemed complete and accepted by the Commissioner; or
(2) A request for postponement pursuant to 105 CMR 100.555 shall stay the running of the four-month period for Department action; or

(3) The Department takes preliminary action pursuant to 105 CMR 100.620. Such action shall constitute a Final Action taken by the Department.

(C) If the Department determines that a Proposed Project satisfies each Determination of Need Factor as set forth within 105 CMR 100.210, unless otherwise expressly specified within 105 CMR 100.000, a Notice of Determination of Need shall be issued by the Department, subject to all applicable Standard and Other Conditions. Unless a different time period is required pursuant to an attached Other Condition, the effective date of the Notice of Determination of Need shall be the date of issuance of the written notification made pursuant to 105 CMR 100.625.

(D) If the Department determines that a Proposed Project does not satisfy each Determination of Need Factor as set forth within 105 CMR 100.210, unless otherwise expressly specified within 105 CMR 100.000, the Department shall disapprove an Application, and a Notice of Determination of Need shall not be issued by the Department. The effective date of the disapproval shall be the date of issuance of the written notification made pursuant to 105 CMR 100.625.

(E) The Department may dismiss the Application without making a finding. Dismissal shall be considered Final Action by the Department. The effective date of a dismissal shall be the date of issuance of the written notification made pursuant to 105 CMR 100.625. An Application may be dismissed by the Department for reasons, including, but not limited to, one or more of the following grounds:

(1) The Applicant has made an improper communication to the Department, Department Staff, or Parties of Record, such that the Applicant has, in the opinion of the Department, exerted undue influence;

(2) The Applicant has made false or misleading statements, as determined by the Department, in writing or oral communication with the Department, Department Staff, or Parties of Record;

(3) The Applicant has repeatedly not complied with the provisions of 105 CMR 100.000, including, but not limited to filing requirements;

(4) The Application is deemed by the Department not within the jurisdiction of 105 CMR 100.000;

(5) The Government Agencies with relevant licensure, certification, or other regulatory oversight of the Applicant or the Proposed Project has deemed the Proposed Project not capable of licensure;

(6) The Applicant has failed to sufficiently provide written documentation of Sufficient Interest in a new or proposed Site.

(F) No changes, alterations, or amendments made to any Department Guideline issued pursuant to 105 CMR 100.000 following the Filing Date of an Application for Determination of Need shall be applied for the purposes of said Application.

In cases where the Department considers Final Action inappropriate, the Department may take preliminary action upon an Application. As preliminary action upon an Application, the Department may direct Department Staff to take one or more of the following actions:

(1) Notify the Applicant and all Parties of Record of its intent to resume consideration of the Application at a subsequent Department meeting;

(2) Conduct further Department Staff review of the Application in the manner directed, and to report in writing to the Department within a specified period of time;

(3) Conduct a public hearing consistent with 105 CMR 100.445 with respect to the Application on such subjects and within such period of time as specified by the Department;

(4) Request comments from Parties of Record with respect to such issues, and within such period of time, as specified by the Department;

(5) Take other action(s) necessary, in the opinion of the Department, to facilitate appropriate Final Action on the Application by the Department.
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100.625: Notification of Final or Preliminary Action

(A) Upon the Department taking Final Action upon an Application for Determination of Need pursuant to 105 CMR 100.615, the Department shall provide appropriate written notification to all Parties of Record within 14 days of said Final Action. Such written notification shall disclose the Final Action, the rationale for said action, the terms and Conditions of any Notice of Determination of Need, and the rights and duties of parties and agencies notified with respect to said action.

(B) Upon the Department taking preliminary action upon an Application for Determination of Need pursuant to 105 CMR 100.620, the Department shall provide appropriate written notification to all Parties of Record within 14 days of said preliminary action. Such written notification shall disclose the preliminary action, the rationale for said action, the terms and Conditions of any such preliminary action, and the rights and duties of parties and agencies notified with respect to said action.

100.630: Delegated Review

(A) The Department may appoint or direct the Commissioner to act on its behalf to take Final Action for certain project categories designated pursuant to 105 CMR 100.630. Such Department delegation shall be documented and made public information consistent with 105 CMR 100.405(A). At a minimum, the following shall be included for delegated review and Final Action by the Commissioner:

(1) Conservation Projects;
(2) Transfer of Site or change of a designated Location;
(3) An Application for a Proposed Project on behalf of a Long-term Care Facility with a maximum Capital Expenditure below $3,000,000;
(4) An Application deemed to be an emergency Application by the Commissioner pursuant to 105 CMR 100.740(B);
(5) An Application for a Proposed Project where the Applicant is a Government Agency;
(6) An Application submitted from an applicant that is a Certified ACO for a Proposed Project that is, in total, and without Disaggregation, a DoN-required Service or DoN-required Equipment;
(7) Any other project categories designated by the Department, including certain DoN-required Services or DoN-required Equipment.

(B) The Commissioner may choose, in his or her discretion, to direct the preparation of a Staff report and refer certain Applications eligible for delegated review to the Department for consideration and Final Action.

100.635: Amendments to a Notice of Determination of Need

(A) Following issuance of a Notice of Determination of Need by the Department, no changes may be made to the project without the issuance of a new Notice of Determination of Need. This general requirement is subject to the following limited exemptions:

(1) Immaterial Change. An Immaterial Change must be approved by the Commissioner. The Commissioner shall determine in writing whether the proposed change or modification is Immaterial, whether it falls within the scope of the Notice of Determination of Need as previously approved by the Department, and whether the proposed change is reasonable. The Holder, prior to implementing any Immaterial Change, shall submit to the Department a written attestation describing the proposed change and associated costs. The written attestation shall additionally contain a narrative comparison of the approved project and the proposed Immaterial Change. Department Staff may request additional information from the Holder in order to validate that the proposed change is Immaterial. Upon receiving sufficient information, the Commissioner shall either approve or disapprove the proposed Immaterial Change within 60 days. If the Commissioner determines that the proposed change is Minor or Significant, the Commissioner shall issue a written notification, ordering the Holder to follow the procedures set forth pursuant to 105 CMR 100.635(A)(2) or (3) as directed. All information submitted in relation to the request for Immaterial Change shall be public information consistent with 105 CMR 100.405(A).
(2) Minor Change. A Minor Change must be approved by the Commissioner. The Commissioner shall determine in writing whether the proposed change or modification is Minor, whether it falls within the scope of the Notice of Determination of Need as previously approved by the Department, and whether the proposed change is reasonable. The Holder, prior to implementing the Minor Change, shall submit to the Department a written attestation describing the proposed change and associated costs. The written attestation shall additionally contain a narrative comparison of the approved project and the proposed Minor Change. Department Staff may request additional information from the Holder in order to validate that the proposed change is Minor. No action shall be taken by the Commissioner until such amendment request has been published as public information consistent with 105 CMR 100.405(A) for at least 21 days. Following such period, the Commissioner shall either approve or disapprove the proposed Minor Change within 60 days. If the Commissioner determines that the proposed change is Significant, he or she shall issue a written notification, ordering the Holder to follow the procedures set forth pursuant to 105 CMR 100.635(A)(3). All information submitted in relation to the request for Minor Change shall be public information consistent with 105 CMR 100.405(A).

(3) Significant Change. A Significant Change must be approved by the Commissioner. Such approval may require, at the Commissioner’s discretion, additional consideration or action by the Department. The Department shall determine whether the proposed change or modification falls within the scope of the Notice of Determination of Need as previously approved by the Department, and whether the proposed change is reasonable. The Holder, prior to implementing any Significant Change, shall submit to the Department a written attestation, under the pains and penalties of perjury, describing the proposed change and associated cost implications, both to the Holder, as well as to the Holder’s existing Patient Panel. The written attestation shall additionally contain a detailed narrative, comparing the approved project to the proposed Significant Change, and the rationale for such change. Department Staff may request additional information from the Holder. The Holder shall ensure that copies of all submitted attestations and additional information are simultaneously provided to all Parties of Record to the previously approved Notice of Determination of Need. No action shall be taken by the Commissioner until such amendment request has been published as public information consistent with 105 CMR 100.405(A) for at least 21 days. A public hearing may be requested by the Department or Parties of Record within 14 days of said public information being properly posted. Following such period:

(a) For an amendment to a Notice of Determination of Need previously issued by the Commissioner pursuant to 105 CMR 100.630, the Commissioner shall make a determination, consistent with 105 CMR 100.615 or 105 CMR 100.620, within 60 days, or may refer said proposed Significant Change to the Department for further consideration and Final Action; or

(b) For an amendment to a Notice of Determination of Need previously issued by the Department, the Department shall make a determination, pursuant to 105 CMR 100.615, 100.620, or 100.640, within 60 days.

Final Action by the Department shall conform with the provisions of 105 CMR 100.625. Such Final Actions may include additional terms and Conditions to be attached to the Notice of Determination of Need. All information submitted in relation to the request for Significant Change shall be public information consistent with 105 CMR 100.405(A).

(B) Decisions made by the Commissioner pursuant to 105 CMR 100.635(A)(1), (2), and (3) may be reviewed by the Department pursuant to a written request sent to the Department by the Holder, a Party of Record, or a Government Agency within 14 days of the Commissioner’s decision, together with a written statement of objection. The Department shall notify the requester of, and at least seven days prior to, the date of the Department’s meeting at which the Commissioner’s decision will be reviewed.

(C) Unless specified by the Department in an Other Condition, the approval of an amendment to a previously issued Notice of Determination of Need shall not result in the extension of the period of authorization.
100.640: Revocation of a Previously Approved Notice of Determination of Need

(A) The Department may revoke a previously issued Notice of Determination of Need for failure by the Holder to comply with all terms and Conditions of the Notice of Determination of Need. Should the Commissioner have reasonable cause to recommend revocation of a previously issued Notice of Determination of Need by the Department, the Commissioner shall comply with the following procedures:

1. The Commissioner shall make a preliminary inquiry of the Holder in order to clarify compliance with all Notice of Determination of Need terms and Conditions.
2. The Commissioner may, following preliminary inquiry, place consideration of the proposed revocation on the agenda of a Department meeting.
3. At least 21 days prior to consideration of a proposed revocation by the Department, Department Staff shall provide written notification to the Holder and all Parties of Record to the previously approved Notice of Determination of Need. Such notification shall disclose the proposed revocation, the rationale for said proposed revocation, and the rights and duties of parties and agencies notified with respect to said proposed revocation.
4. The Department shall afford an opportunity to speak to the Holder and to all parties of Record to the previously approved Notice of Determination of Need. The Department shall take action as it deems fair and appropriate.
5. Revocation by the Department pursuant to 105 CMR 100.640 shall conform with the provisions of 105 CMR 100.625.

(B) In order to advance the Commonwealth's goals for cost containment, the AGO or HPC may refer to the Commissioner for review and consideration of proposed revocation by the Department, a Holder of a previously approved Notice of Determination of Need issued pursuant to 105 CMR 100.725(A), who, in the opinion of AGO or HPC, has violated 105 CMR 100.310(B) by utilizing such DoN-required Services or DoN-required Equipment for purposes other than the expressed approved project, including treatments and/or patient populations not approved for within the Notice of Determination of Need.

100.705: Standing to File an Application for Determination of Need

(A) No Person shall be permitted to make an Application for Notice of Determination of Need pursuant to 105 CMR 100.000 unless such Person has Sufficient Interest in the Site or facility, and unless such Site or facility may be used for the Proposed Project, meaning one of the following:

1. The Proposed Project is authorized under applicable zoning by-laws or ordinances, whether or not a special permit is required; or
2. If the Proposed Project is not authorized under applicable zoning by-laws or ordinances, a variance has been received to permit such Proposed Project; or
3. The Proposed Project is exempt from zoning by-laws or ordinances.

(B) Pursuant to St. 1988, c. 23, § 76, no Determination of Need shall be required pursuant to M.G.L. c. 111, § 25C for any Hospital facility of the Shriner's Hospitals for Children.

100.715: Substantial Capital Expenditure and Substantial Change in Service

(A) Applicability.

1. Pursuant to M.G.L. c. 111, § 25C, no Person may make a Substantial Capital Expenditure or a Substantial Change in Service, unless the Department has first issued a Notice of Determination of Need. This general requirement is subject to the following limited exemptions:

a. No Notice of Determination of Need shall be required for any Substantial Capital Expenditure or any Substantial Change in Service that is solely related to the conduct of basic biomedical research or applied medical research. However, Provider Organizations making a Substantial Capital Expenditure or Substantial Changes in Service pursuant to 105 CMR 100.715(A)(1)(a) shall notify the Department, in the form and manner as specified by the Commissioner, at least 60 days prior to undertaking such an expenditure or change in service. Such Provider Organizations shall be required to report information concerning said research project(s) to the Department, in the form, manner, and frequency as reasonably requested by the Commissioner.
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100.715: continued

(b) 105 CMR 100.715(A)(1)(a) does not apply to any Person should a Substantial Capital Expenditure or Substantial Change in Service result, at any point, in one or more of the following:

1. Any increase in the number of clinical beds or outpatient capacity of a Health Care Facility;
2. Any increase in the gross patient service revenue of a Provider Organization;
3. Determination by the Commissioner that the Provider Organization's notification pursuant to 105 CMR 100.715(A)(1)(a) does not constitute an expenditure or change in service that is solely related to the conduct of basic biomedical research or applied medical research; or
4. Failure by a Provider Organization to comply with the notification requirement outlined within 105 CMR 100.715(A)(1)(a).

(c) No Notice of Determination of Need shall be required for any Substantial Capital Expenditure or any Substantial Change in Service at a Federally Qualified Community Health Center.

(2) Pursuant to M.G.L. c. 111, § 25C, no Person may acquire by purchase, lease, or other arrangement a unit of medical, diagnostic, or therapeutic equipment for a Location other than a Health Care Facility, which has a fair market value in excess of $250,000, adjusted annually by the Commissioner after consideration of any inflation index established by the U.S. Department of Health and Human Services and set forth by the Commissioner in an informational bulletin, unless the Person first notifies the Department in writing at least 60 days prior to the acquisition of, or implementation of contractual arrangements for the acquisition of the equipment. If the Person fails to notify the Department, or if such acquisition meets the definition of a Substantial Change in Service, the Commissioner shall order the filing of an Application for Determination of Need.

(3) No Person shall make additional expenditures, including for the build out of shell space, for a project below the Substantial Capital Expenditure Minimum and for which no Notice of Determination of Need was issued, which in total, would meet or exceed the threshold for Substantial Capital Expenditure without first being issued a Notice of Determination of Need by the Department.

(4) No Person shall use Disaggregation in order to keep a proposed project below a Substantial Capital Expenditure. All Proposed Projects that in total, and without Disaggregation, constitute a Substantial Capital Expenditure, or which reasonably could become a Substantial Capital Expenditure over the course of the project, shall first require a Notice of Determination of Need.

(B) Determination of Need Factors. Unless otherwise specified by the Department, an Application for Determination of Need required pursuant to 105 CMR 100.715(A) shall be subject to all Determination of Need Factors specified in 105 CMR 100.210. This general requirement is subject to the following:

1. A Proposed Project on behalf of a Long-term Care Facility which is not deemed a Conservation Project by the Department shall be subject to 105 CMR 100.210(A)(6); however, funding shall in total be greater than or equal to 3% of the total Capital Expenditure of the Proposed Project.
2. A Proposed Project deemed a Conservation Project by the Department shall be exempted from Factors 105 CMR 100.210(A)(1), (2), and (5).
3. A Proposed Project on behalf of a Health Care Facility, deemed a Conservation Project by the Department shall be subject to 105 CMR 100.210(A)(6); however, funding shall in total be equal to 2.5% of the total Capital Expenditure of the proposed Conservation Project.
4. A Proposed Project on behalf of a Long-term Care Facility which is deemed a Conservation Project by the Department shall be subject to 105 CMR 100.210(A)(6); however, funding shall in total be equal to 1% of the total Capital Expenditure of the proposed Conservation Project.

(C) Standard Conditions. Unless otherwise specified by the Department, a Notice of Determination of Need issued to a Holder resulting from an Application required pursuant to 105 CMR 100.715(A) shall be subject to all Standard Conditions specified in 105 CMR 100.310; provided that, Standard Condition 105 CMR 100.310(J) shall not apply to a Notice of Determination of Need issued for a Conservation Project or for a Long-term Care Facility project made pursuant to 105 CMR 100.715.
100.715: **continued**

**D) Other Conditions.**

1. A Notice of Determination of Need issued to a Holder resulting from an Application proposed on behalf of a Long-term Care Facility made pursuant to 105 CMR 100.715(A) that is not deemed a Conservation Project by the Department shall be subject to the following Other Conditions:
   
   (a) The terms and Conditions shall include descriptions of project(s), mutually agreed upon and approved by the Department, documenting the Holder's obligations pursuant to 105 CMR 100.715(B). Said plan shall require the Holder to expend over a five-year period, or any other period as specified by the Commissioner, an amount which in total shall be greater than or equal to 3% of the total Capital Expenditure of the approved project. Said projects shall address one or more of the Health Priorities set out in Department Guidelines.

2. A Notice of Determination of Need issued to a Holder resulting from an Application for a Conservation Project proposed on behalf of a Health Care Facility other than a Long-term Care Facility made pursuant to 105 CMR 100.715(A) shall be subject to the following Other Condition(s):
   
   (a) The terms and Conditions shall include descriptions of project(s), mutually agreed upon and approved by the Department, documenting the Holder's obligations pursuant to 105 CMR 100.715(B). Said plan shall require the Holder expend over a five-year period, or any other period as specified by the Commissioner, an amount which in total shall be equal to 2.5% of the total Capital Expenditure of the approved project. Said projects shall address one or more of the Health Priorities set out in Department Guidelines.

3. A Notice of Determination of Need issued to a Holder resulting from an Application for a Conservation Project proposed on behalf of a Long-term Care Facility made pursuant to 105 CMR 100.715(A) shall be subject to the following Other Condition(s):
   
   (a) The terms and Conditions shall include descriptions of project(s), mutually agreed upon and approved by the Department, documenting the Holder's obligations pursuant to 105 CMR 100.715(B). Said plan shall require the Holder expend over a five-year period, or any other period as specified by the Commissioner, an amount which in total shall be equal to 1% of the total Capital Expenditure of the approved project. Said projects shall address one or more of the Health Priorities set out in Department Guidelines.

100.725: **DoN-required Services and DoN-required Equipment**

**A) Applicability.** No Person shall provide a DoN-required Service or use DoN-required Equipment in any Location, or may implement an Addition, Expansion, or Conversion of such DoN-required Service or DoN-required Equipment, unless the Person is first issued a Notice of Determination of Need by the Department; provided, however, maintenance or replacement of existing equipment defined as a DoN-required Equipment shall not first require a Notice of Determination of Need. For purposes of consideration of a proposed Addition, Expansion, or Conversion, the Department shall first deem that such services or equipment was established or acquired pursuant to a properly issued Notice of Determination of Need.

**B) Other Conditions.** A Notice of Determination of Need issued to a Holder resulting from an Application required pursuant to 105 CMR 100.725(A) shall be subject to the following Other Conditions:

1. In no event shall the Holder refer or influence any referral of patients to DoN-required Services or DoN-required Equipment, unless the Holder is a Registered Individual Practitioner as defined in 105 CMR 700.001: Definitions providing said services or utilizing said equipment. Public advertisement shall not be deemed a referral or influence of referrals.

2. Any Person with an ownership interest in DoN-required Services or DoN-required Equipment, whether direct or indirect, shall disclose said interest to any patients utilizing said services or equipment in a conspicuous manner.

3. The Holder shall submit annually to the Department information and data in connection with utilization and volume rates of DoN-required Services or DoN-required Equipment in a form and manner as specified by the Commissioner.
100.730: Determination of Need for Original Licensure

(A) Applicability.
(1) Pursuant to M.G.L. c. 111, §§ 51 through 53, no Person shall be issued an Original License to establish or maintain a Hospital, a Freestanding Ambulatory Surgery Center, an inpatient unit of a Health Care Facility off the Premises of the Health Care Facility, or the placement of inpatient services at a previously-licensed outpatient satellite of a Health Care Facility, unless the Department has first issued a Notice of Determination of Need for the Proposed Project at the designated location.
(2) No Person shall be issued an Original License to establish or maintain a facility licensed by a Government Agency which requires a Determination of Need as a condition of Original Licensure unless the Department has first issued a Notice of Determination of Need for the Proposed Project at the designated Location.

For Proposed Projects inclusive of Ambulatory Surgery, see 105 CMR 100.740(A)

100.735: Transfer of Ownership

(A) Applicability.
(1) Pursuant to M.G.L. c. 111, §§ 51 through 53, no Person shall be issued an Original License for a Hospital, a Freestanding Ambulatory Surgery Center, an inpatient unit of a Health Care Facility off the Premises of the Health Care Facility, or the placement of inpatient services at a previously-licensed outpatient satellite of a Health Care Facility, unless the Department has first issued a Notice of Determination of Need for such Proposed Project at the designated Location.
(2) No Person shall be issued an Original License for any facility licensed by a Government Agency which requires a Determination of Need as a condition of Original Licensure unless the Department has issued a Notice of Determination of Need for such Proposed Project at the designated Location.
(3) No Notice of Determination of Need for a Transfer of Ownership shall be issued by the Department unless the Proposed Project includes the transfer of the Health Care Facility's license in its entirety to a single transferee.

(B) Determination of Need Factors. Determination of Need Application subject to 105 CMR 100.735(A) shall be exempt from the following Determination of Need Factors, unless otherwise specified: 105 CMR 100.210(A)(2), (5), and (6).

(C) Standard Conditions. Unless otherwise specified by the Department, a Notice of Determination of Need issued to a Holder resulting from an Application required pursuant to 105 CMR 100.735(A) shall be exempt from the following Standard Conditions: 105 CMR 100.310(E), (F), (G), (I), (J), (M). Any Notice of Determination of Need issued to a Holder that is subject to a Cost and Market Impact Review pursuant to M.G.L. c. 6D § 13 and 958 CMR 7.00: Notices of Material Change and Cost and Market Impact Reviews shall be exempt from 105 CMR 100.310(B).

(D) Other Conditions. A Notice of Determination of Need issued to a Holder resulting from an Application required pursuant to 105 CMR 100.735(A) shall include the following Other Condition(s):

(1) (a) Unless rescinded pursuant to 105 CMR 100.735(D)(1)(c), any Notice of Determination of Need issued to a Holder that is subject to a Cost and Market Impact Review pursuant to M.G.L. c. 6D § 13 and 958 CMR 7.00 shall not go into effect until: 30 days following HPC's completed Cost and Market Impact Review. Unless extended for Good Cause Related to Project Implementation, or as a result of an approved amendment to a previously issued Notice of Determination of Need, the Notice of Determination of Need shall constitute a valid authorization for a period of not more than three years following the approval of the Department, unless otherwise expressly noted as an Other Condition, and shall only be for the purposes of the approved project. No Notice of Determination of Need shall remain in authorization unless the Holder complies with all prescribed terms and Conditions as set forth by the Department.
(b) The Department shall receive within 30 days of issuance of the written notification made pursuant to 105 CMR 100.625(A) a written acknowledgement of receipt of such written notification by the Holder, documented in the form of an attestation, signed by the Holder's chief executive officer and board chair, and returned to the Department and all Parties of Record.
(c) Notwithstanding 105 CMR 100.735(D)(1)(a), as part of a completed Cost and Market Impact Review, the HPC may provide a written recommendation to the Commissioner that the Notice of Determination of Need should not go into effect on the basis of findings contained within the completed and publicly released Cost and Market Impact Review. Upon receipt, the Commissioner shall determine if the Cost and Market Impact Review contains information sufficient for the Commissioner to conclude that the Holder would fail to meet one or more of the specified Factors. Should the Commissioner determine that the Holder would fail to meet one or more of the specified Factors, the Department may rescind or amend an approved Notice of Determination of Need. The Department shall consider the HPC's written recommendation pursuant to the Commissioner's determination prior to the Notice of Determination of Need going into effect, and within the context of all specified Determination of Need Factors. If a Notice of Determination of Need is rescinded by the Department, the Person for which the rescinded Notice of Determination of Need was issued must file a new Application for Determination of Need, if so desired. Such Application must satisfy 105 CMR 100.210 and shall account for the concerns expressed by the Department within their findings.

(3) If it is determined by the Department that the Holder has failed to sufficiently demonstrate compliance with the terms and Conditions of the issued Notice of Determination of Need, the Holder shall fund projects which address one or more of the Health Priorities set out in Department Guideline, as approved by the Department, which in total, shall equal up to 5% of the Total Value of the approved project. In making such determination, the Department shall provide written notification to the Holder at least 30 days prior to requiring such funding, and shall provide the Holder the opportunity to appear before the Department. The Department shall consider factors external to the Holder that may impact the Holder's ability to demonstrate compliance.

(4) Upon Notice of Determination of Need issued pursuant to 105 CMR 100.735(A), where the acquired Health Care Facility is a Holder of an approved, but not yet implemented Notice of Determination of Need, the acquired Health Care Facility's unimplemented Notice of Determination of Need shall be rendered null and void, unless the acquiring Holder receives the express written approval from the Department, pursuant to a Significant Change amendment, see 105 CMR 100.635(A)(3).

100.740: Other DoN-required Categories

(A) Ambulatory Surgery.

(1) Applicability.

(a) No Person shall be issued a Notice of Determination of Need inclusive of Ambulatory Surgery, unless the Proposed Project, as it relates to Ambulatory Surgery, constitutes:

1. Ambulatory Surgery capacity located on the main campus of an existing Hospital for which the applicant is a Certified ACO;
2. An Expansion, Conversion, Transfer of Ownership, transfer of Site, or change of designated Location for Ambulatory Surgery capacity located on a satellite campus of an existing Hospital for which the applicant is a Certified ACO;
3. A Freestanding Ambulatory Surgery Center, that is an Affiliate of, or joint venture with, a Certified ACO;
4. An Expansion, Conversion, Transfer of Ownership, transfer of Site, or change of designated Location for a Freestanding Ambulatory Surgery Center that received an Original License as a Clinic on or before January 1, 2017.

(b) For any Application for Notice of Determination of Need made pursuant to 105 CMR 100.740(A)(1)(a)1. or 3. which includes a Proposed Project within the Primary Service Area of an existing Hospital that is:

1. designated as an independent community disproportionate share or non-disproportionate share Hospital as defined by HPC's Massachusetts Hospital Cohort Designation and Affiliation Status; and
2. is not an existing joint venture or Affiliate of the applicant:
   (i) The Proposed Project must constitute a joint venture with the independent community disproportionate share or non-disproportionate share Hospital; and
   (ii) The applicant must obtain a letter of support signed by the independent community disproportionate share or non-disproportionate share Hospital's chief executive officer and board chair.
(2) **Other Conditions.** A Notice of Determination of Need issued to a Holder resulting from an Application required pursuant to 105 CMR 100.740(A)(1) shall be subject to the following Other Conditions: The Holder of the Notice of Determination of Need issued pursuant to 105 CMR 100.740(A)(1) shall provide an attestation that the Freestanding Ambulatory Surgery Center will be certified pursuant to 42 CFR Part 416 and will remain in substantial compliance therein.

(B) **Emergency Applications.**

(1) **Applicability.** Any Person believing an Emergency Situation exists may file an Application for a Determination of Need by filing with the Department a written notification, signed under the pains and penalties of perjury by both the Applicant's chief executive officer and board chair, which sets forth the identity of the Applicant, the nature of the Emergency Situation, as well as the nature, scope, Location, and projected costs of the Proposed Project. An Application filed pursuant to 105 CMR 100.740(B)(1) shall convincingly demonstrate that the Proposed Project will address the Emergency Situation, and without issuance of a Notice of Determination of Need, that the public health will be measurably harmed.

(2) **Determination of Need Factors.** Unless otherwise specified by the Department, an Application for Determination of Need required pursuant to 105 CMR 100.740(B)(1) shall be exempted from all Determination of Need Factors specified in 105 CMR 100.210.

(3) **Standard Conditions.** Unless otherwise specified by the Department, a Notice of Determination of Need issued to a Holder resulting from an Application required pursuant to 105 CMR 100.740(B)(1) shall be subject to all Standard Conditions specified in 105 CMR 100.310, except 105 CMR 100.310(J).

(4) **Other Application Processes.** Unless otherwise specified by the Commissioner, an Applicant filing an Application for Determination of Need made pursuant to 105 CMR 100.740(B)(1) shall be subject to the following:

(a) Within 30 days of receipt of the written notification required pursuant to 105 CMR 100.740(B)(1), the Commissioner shall determine whether there is, in fact, an Emergency Situation. If deemed an Emergency Situation, the Commissioner may issue a Notice of Determination of Need, notifying any Parties of Record consistent with 105 CMR 100.625. The Commissioner may subsequently require a full Application for Determination of Need consistent with 105 CMR 100.405.

(b) In the case of an Application for Determination of Need made pursuant to 105 CMR 100.740(B)(1), notice of intent of the Application may be given after the Application has been filed with the Department. Publication of notice of intent shall otherwise be as prescribed within 105 CMR 100.405(C).

### 100.745: Transfer of Site or Change of Designated Location

(A) No Person shall make a transfer of Site of a Health Care Facility, DoN-required Service, or DoN-required Equipment, unless the Person first provides written notification to the Department, in the form and manner as required by the Commissioner, and the Department determines whether or not the proposed transfer of Site will result in a Substantial Capital Expenditure or Substantial Change in Service.

(B) No Person shall change the designated Location of an Original License as outlined within 105 CMR 100.730(A), unless the Person first provides written notification to the Department, in the form and manner as required by the Commissioner, and the Department determines whether or not the proposed change of the designated Location first requires a Notice of Determination of Need.

(C) No Holder that has received a previously issued Notice of Determination of Need for a project that is not yet licensed, or not yet operational if there is no requirement for a license, shall make a transfer of Site, unless the Holder first provides written notification to the Department, in the form and manner as required by the Commissioner, and the Department determines whether or not the proposed transfer of Site will result in a Substantial Capital Expenditure or Substantial Change in Service.
100.745: continued

(D) The Department shall determine based on the information supplied within the written notification whether the proposed transfer of Site or change of designated Location will either:

1. result in a Substantial Capital Expenditure or Substantial Change in Service, and therefore will first require a Notice of Determination of Need issued pursuant to 105 CMR 100.715; or

2. shall first require a Notice of Determination of Need issued pursuant to 105 CMR 100.730.

3. Said notification to the Department shall include, at a minimum:

   a. A written description of the reasons for the requested transfer of Site;

   b. A written description of the current and proposed Site, including a comparison of the area in gross square feet associated with the services at each Site, and the current and proposed Primary Service Area;

   c. A written description of, and comparison between, the existing and proposed patient populations served;

   d. A written description of, and comparison between, existing and proposed patient access, including, but not limited to a the proposed transfer of Site or change in designated Location's impact on price, total medical expenditure, provider costs, and other recognized measures of health care spending;

   e. A detailed attestation of all anticipated expenditures to be incurred as a result of the proposed transfer of Site;

   f. Documentation of Sufficient Interest in the proposed Site and evidence that the Site may be used for the proposed purpose, in accordance with 105 CMR 100.705;

   g. An affidavit of truthfulness, signed under the pains and penalties of perjury by the Applicant's chief executive officer and board chair;

   h. Any additional information deemed necessary by the Commissioner.

100.800: Expected and Appropriate Conduct by Applicants

(A) An Applicant shall fully cooperate with the Department and all applicable Government Agencies.

(B) With respect to its own Application for Determination of Need, an Applicant may only seek to convince the Department of the appropriateness of taking favorable action on the Application by utilizing one or more of the following methods:

1. By submitting material(s) supporting the Application;

2. By requesting a public hearing(s) pursuant to 105 CMR 100.445;

3. By filing written reaction to the staff report pursuant to 105 CMR 100.510; or

4. By making an oral presentation to the Department or Parties of Record.

(C) While an Application for Determination of Need is pending, no Applicant, Party of Record, or employee or agent thereunder, shall initiate any oral, electronic, or written communication with the Commissioner or any other member of the Public Health Council concerning a pending Application, or otherwise engage in behavior that a reasonable Person could perceive to constitute an exertion of undue influence upon the Commissioner or members of the Public Health Council. Violations of this provision by a Ten Taxpayer Group may serve as grounds for the Department to revoke its status. This general requirement is subject to the following limited exemption:

Applicants and Parties of Record may be permitted to freely communicate orally or in writing with Department Staff and the Commissioner's delegate pursuant to the requirements under 105 CMR 100.000, or to inquire on the status or progress of a pending Application. All said written inquiries shall be considered written materials consistent with 105 CMR 100.405(A).

(D) Any violation of 105 CMR 100.800 may be determined by the Commissioner as exerting undue influence, and therefore may be grounds for dismissal of an Application for Determination of Need pursuant to 105 CMR 100.615(E).
100.805: Advisory Rulings

(A) Pursuant to M.G.L. c. 30A, § 8, the Department may, upon the request of any Person, make an advisory ruling with respect to the applicability to any Person, property, or state of facts of any provision of 105 CMR 100.000.

(B) Any Person desiring an advisory ruling shall direct its request, in writing, to the Department, “Attention: Office of the General Counsel, Determination of Need Program”.

(C) Each such request shall be titled "Request for Advisory Ruling" and shall set forth, clearly and succinctly, the following:
   (1) Name;
   (2) Organization, if applicable;
   (3) Address of the Person making the request;
   (4) Interest in, or relationship to, any regulated party;
   (5) A statement of the facts with respect to which the advisory ruling is requested; and
   (6) The statutory provision or the section of 105 CMR 100.000 involved.

   The Person making such a request may also include their views and opinions.

(D) It shall be within the discretion of the Department's General Counsel whether to make an advisory ruling on behalf of the Department.

(E) Copies of all Department advisory rulings rendered pursuant to 105 CMR 100.000 shall be public records and shall be made available to the public consistent with 105 CMR 100.405(A).

100.810: Sub-regulatory Guidelines and Interpretational Documentation

(A) The Commissioner may issue any Guidelines or interpretational documentation deemed necessary to achieve the purpose and objectives of 105 CMR 100.000.

100.815: Waivers and Special Exemptions

(A) The Commissioner, within his or her authority, may waive any requirement of 105 CMR 100.000. The Commissioner shall notify the Public Health Council of any waiver issued by the Department within 60 days of issuance.

(B) The Commissioner may, in his or her discretion, exempt any Proposed Project that does not involve a Substantial Capital Expenditure from any provision of 105 CMR 100.000, subject to such Conditions as he or she deems appropriate. Upon exempting any such Proposed Project pursuant to 105 CMR 100.815(B), the Department shall provide appropriate written notification in the form of properly posted public information consistent with 105 CMR 100.405(A). Such notification shall disclose the exemption, the rationale for said exemption, and any applicable terms and Conditions attached therein.

100.820: Enforcement and Penalties

Pursuant to M.G.L. c. 111, § 25G, the superior and supreme judicial courts shall have jurisdiction, upon request of the Department, or of any Ten Taxpayer Group in Massachusetts to enforce any provision of 105 CMR 100.000. A violation of any such provision shall subject the violator to liability for a civil penalty of not more than $500 for each day of such violation, assessable by the superior court. A violation of any such provision shall constitute grounds for refusing to grant, renew, modify, or revoking the license of a Health Care Facility or of any part thereof.
105 CMR: DEPARTMENT OF PUBLIC HEALTH

100.825: Severability

The provisions of 105 CMR 100.000 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

105 CMR 100.000: M.G.L. c. 111, §§ 25B through 25G, §§ 51 through 53, and § 71
Regulation Filing  

To be completed by filing agency

CHAPTER NUMBER: 105 CMR 300.000

CHAPTER TITLE: Reportable Diseases, Surveillance, and Isolation and Quarantine Requirements

AGENCY: Department of Public Health

SUMMARY OF REGULATION: State the general requirements and purposes of this regulation.

105 CMR 300.000 lists diseases designated dangerous to public health by DPH and establishes reporting, surveillance, isolation and quarantine requirements intended for application by local boards of health, hospitals, laboratories, physicians and other health care workers, veterinarians, education officials, recreational program health service providers, food industry officials, and the public. The amendments bring the regulation up to date with current medical and laboratory practice.

REGULATORY AUTHORITY: M.G.L. c. 111, s. 6 and c. 111D, s. 6

AGENCY CONTACT: Alison Mehlman PHONE: 617-624-5220

ADDRESS: 250 Washington St., 2nd floor, Boston, MA 02108

Compliance with M.G.L. c. 30A

EMERGENCY ADOPTION - if this regulation is adopted as an emergency, state the nature of the emergency.

PRIOR NOTIFICATION AND/OR APPROVAL - If prior notification to and/or approval of the Governor, Legislature or others was required, list each notification, and/or approval and date, including notice to the Local Government Advisory Commission.

Notice to Mass. Municipal Ass'n and Dept. of Housing and Community Development pursuant to EO145 on 9/15/16

PUBLIC REVIEW - M.G.L. c. 30A sections 2 and/or 3 requires notice of the hearing or comment period, including a small business impact statement, be filed with the Secretary of the Commonwealth, published in appropriate newspapers, and sent to persons to whom specific notice must be given at least 21 days prior to such hearing or comment period.

Date of public hearing or comment period: 10/31/16

The text of the regulations published in the electronic version of the Massachusetts Register is unofficial and for informational purposes only. The official version is the printed copy which is available from the State Bookstore at http://www.sec.state.ma.us/spr/sprcat/catidx.htm.
FISCAL EFFECT - Estimate the fiscal effect of the public and private sectors.

For the first and second year:  

For the first five years:  

No fiscal effect:  

These amendments have no fiscal effect.

SMALL BUSINESS IMPACT - M.G.L. c. 30A section 5 requires each agency to file an amended small business impact statement with the Secretary of the Commonwealth prior to the adoption of a proposed regulation. If the purpose of this regulation is to set rates for the state, this section does not apply.

Date amended small business impact statement was filed: 1/11/17

CODE OF MASSACHUSETTS REGULATIONS INDEX - List key subjects that are relevant to this regulation:

Infectious disease
Isolation
Quarantine

PROMULGATION - State the action taken by this regulation and its effect on existing provisions of the Code of Massachusetts Regulations (CMR) or repeal, replace or amend. List by CMR number:

Amends 105 CMR 300.000

ATTESTATION - The regulation described herein and attached hereto is a true copy of the regulation adopted by this agency. ATTEST:

SIGNATURE: SIGNATURE ON FILE DATE: Jan 13 2017

Publication - To be completed by the Regulations Division

MASSACHUSETTS REGISTER NUMBER: S1331 DATE: 01/27/2017

EFFECTIVE DATE: 01/27/2017

The text of the regulations published in the electronic version of the Massachusetts Register is unofficial and for informational purposes only. The official version is the printed copy which is available from the State Bookstore at http://www.sec.state.ma.us/spr/sprcat/catIdx.htm.
105 CMR 300.000: REPORTABLE DISEASES, SURVEILLANCE, AND ISOLATION AND QUARANTINE REQUIREMENTS

Section

300.001: Purpose
300.020: Definitions
300.100: Diseases Reportable to Local Boards of Health
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300.173: Reporting of Certain Negative and Indeterminant Diagnostic Tests Associated with Ascertainment of Infection Status
300.174: Laboratory Findings Indicative of Infectious Disease Reportable Directly to the Department by Point of Care Testing
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300.191: Access to Medical Records and Other Information
300.192: Surveillance of Diseases Possibly Linked to Environmental Exposures
300.193: Surveillance of Injuries Dangerous to Public Health
300.200: Isolation and Quarantine Requirements
300.210: Procedures for Isolation and Quarantine

300.001: Purpose

The purpose of 105 CMR 300.000 is to list diseases dangerous to the public health as designated by the Department of Public Health and to establish reporting, surveillance, isolation and quarantine requirements. 105 CMR 300.000 is intended for application by local boards of health, hospitals, laboratories, physicians and other health care workers, veterinarians, education officials, recreational program health service providers, food industry officials, and the public.

300.020: Definitions

Airborne Precautions. Measures designed to reduce the risk of transmission of infectious agents that may be suspended in the air in either small particle aerosols or dust particles (i.e. droplet nuclei < 5 microns). Patients in health care facilities must be given a private room with special air handling and ventilation (negative pressure with respect to the rest of the facility), and an appropriate level of respiratory protection is necessary when entering the patient’s room.
Board of Health or Local Board of Health. 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.

Carrier. An individual who can tolerate an infection so as not to become ill, yet is able to transmit the disease-causing organism to cause infection and illness in others.

Case or Patient. One who is ill, infected, injured or diagnosed with a reportable disease or injury.

Cluster. See 105 CMR 300.020: Outbreak or Cluster.

Communicable. Ability of an infection to be transmitted from one person or animal to another.

Contact. A person who has been in such association with an infected person or animal or with a contaminated environment as to have had exposure capable of transmitting the infection to that person.

Contact Precautions. Measures designed to reduce the risk of transmission of infectious agents that can be spread through direct contact with the patient or indirect contact with potentially infectious items or surfaces. Gloves and gowns are required for all patient contact and contact with the patient’s environment; strict hand hygiene practices must also be applied.

Counseling. Process by which individuals and groups are advised as to how to promote, maintain and/or restore health. Methods and procedures used in counseling must take account of the ways in which people develop various forms of behavior, of the factors that lead them to maintain or to alter their behavior, and of the ways in which people acquire and use knowledge.

Date of Last Exposure. That point in time when exposure that would be expected to provide an opportunity for transmission of infection between a case or carrier and a susceptible person ends, or point in time when a case or carrier is no longer capable of transmitting illness or infection to others, whichever was more recent.

Department. The Massachusetts Department of Public Health.

Disease. An abnormal condition or functional impairment resulting from infection, metabolic abnormalities, physical or physiological injury or other cause, marked by subjective complaints, associated with a specific history, and clinical signs and symptoms, and/or laboratory or radiographic findings (compare 105 CMR 300.020: Illness).

Disease Event. An occurrence of a reportable disease or laboratory evidence of infection reported to a board of health or the Department and entered into the disease surveillance and case management system, MAVEN.

Disease Surveillance and Case Management System. MAVEN, a secure electronic system utilized by the Department and local boards of health to monitor or respond to diseases dangerous to the public health. MAVEN is maintained by the Department.

Droplet Precautions. Measures designed to reduce the risk of transmission of infectious agents via large particle droplets that do not remain suspended in air, usually generated by coughing, sneezing or talking. Masks must be used, but gowns, gloves and special air handling are not generally needed.

Enteric Precautions. Measures designed to prevent direct or indirect fecal-oral transmission of disease. Gowns must be worn if soiling is likely, and gloves must be worn for touching contaminated materials; strict hand hygiene practices must also be applied. Masks are not indicated.

Exposure. Proximity to, and or contact with, a source of an infectious agent with potential for acquisition of the infection.
Food. Any raw, cooked or processed edible substance, ice, beverage, medications, or ingredient used or intended for use or for sale in whole or in part for human consumption via the alimentary tract.

Food Handler. Any person directly preparing or handling food. This could include the food handling facility owner, individual having supervisory or management duties, person on the payroll, family member, volunteer, person performing work under contractual agreement, or any other person working in a food handling facility. Food Handler also includes any person handling clean dishes or utensils. Any person who dispenses medications by hand, assists in feeding, or provides mouth care shall be considered food handlers for the purpose of 105 CMR 300.000. In health care facilities, this includes those who set up trays for patients to eat, feed or assist patients in eating, give oral medications or give mouth/denture care. In day care facilities, schools and community residential programs, this includes those who prepare food for clients to eat, feed or assist clients in eating, or give oral medications. Food Handler does not include individuals in private homes preparing or serving food for individual family consumption.

Food Handling Facility. Any fixed or mobile place, structure or vehicle, whether permanent, seasonal or temporary, in which food is prepared, processed, stored or held for sale, whether at retail or wholesale, or for service on the premises or elsewhere; or where food is served or provided to the public or segment of the public with or without charge. Food Handling Facility does not include private homes where food is prepared or served for individual family consumption.

Food Poisoning. Poisoning that results from eating foods contaminated with toxins. These toxins may occur naturally, as in certain mushrooms or seafoods; they may be chemical or biologic contaminants; or they may be metabolic products of infectious agents that are present in the food.

Health Care Provider. As defined in M.G.L. c. 111, § 1: “any doctor of medicine, osteopathy, or dental science, or a registered nurse, social worker, doctor of chiropractic, or psychologist licensed under the provisions of M.G.L. c. 112, or an intern, or a resident, fellow, or medical officer licensed under M.G.L. c. 112, § 9, or a hospital, clinic or nursing home licensed under the provisions of M.G.L. c. 111 and its agents and employees, or a public hospital and its agents and employees”.

Health Care Worker. One who provides direct care to patients or who works in a setting where such care is provided.

Hepatitis Syndrome, Acute. Illness associated with symptoms, including but not limited to, jaundice, nausea, vomiting, abdominal pain, and laboratory evidence of liver damage or dysfunction occurring without identified cause or due to an unexpected or unusual cause.

Illness. An abnormal condition or functional impairment resulting from infection, metabolic abnormalities, physical or physiological injury or other cause, marked by subjective complaints and clinical signs (compare 105 CMR 300.020: Disease).

Immunity. Possession of protective antibodies or cellular components sufficient to protect from infection and/or illness following exposure to an infectious agent (see also 105 CMR 300.020: Resistance).

Incidence. A general term used to characterize the frequency of new occurrences of a disease, infection, or other event over a period of time and in relation to the population in which it occurs. Incidence is expressed as a rate, commonly the number of new cases during a prescribed time in a unit of population. For example, one may refer to the number of new cases of tuberculosis per 100,000 population per year.

Invasive Infection. Infection involving the bloodstream or internal organs, not including infection of the skin or mucous membranes. Invasive infection is usually established by the recovery of an etiologic agent from a usually sterile body fluid or tissue.
300.020: continued

**Isolation.** Separation, for the period of communicability, of infected persons from others in such places and under such conditions as will prevent the direct or indirect transmission of an infectious agent to susceptible people or to those who may spread the agent to others. **Isolation** applies also to animals (compare 105 CMR 300.020: Quarantine).

**Laboratory.** A facility or place, however named, the purpose of which is to make biological, serological, chemical, immuno-hematological, cytological, pathological, or other examinations of materials derived from a human body. **Laboratory** includes laboratories in hospitals and other facilities.

**MAVEN.** The Massachusetts Virtual Epidemiologic Network, the Department's infectious disease surveillance and case management system.

**Novel Influenza A Viruses.** A strain of influenza A that substantially differs antigenically from circulating or recently circulating influenza A viruses.

**Outbreak or Cluster.** The occurrence in a community, facility, workplace or region of cases of an illness clearly in excess of the number of cases usually expected. The number of cases indicating an outbreak or cluster will vary according to the infectious agent or the site conditions/hazards, size and type of population exposed, previous experience or lack of exposure to the disease, and time and place of occurrence. Outbreaks or clusters are therefore identified by significant increases in the usual frequency of the disease in the same area, among the specified population, at the same season of the year.

**Personal Surveillance.** The practice of close medical or other supervision of contacts without restricting their movements in order to promote prompt recognition of infection or illness.

**Point of Care Testing.** Testing done at or near the site of patient care by use of a test cleared by the federal Food and Drug Administration for such use.

**Prophylaxis.** The administration of a drug or biologic agent to prevent the development of an infection or disease, or limit the progression of an infection.

**Quarantine.** Restricting the freedom of movement of well persons or domestic animals who have been exposed to a communicable disease for a period of time relating to the usual incubation period of the disease, in order to prevent effective contact with those not so exposed (compare 105 CMR 300.020: Isolation).

**Report of a Disease.** An official notice that shall include contact information for the clinician responsible for reporting the disease and full personal demographic, clinical, epidemiologic and laboratory information on the case, to the appropriate authority of the occurrence of a specified disease in people or animals, directly by telephone, in writing, by facsimile, or by electronic means. Content of reports to the Department shall be defined on a disease by disease basis. Also see 105 CMR 300.170 for laboratory reports.

**Resistance.** The sum total of body mechanisms which interpose barriers to the progress of invasion or multiplication of infectious agents or to damage by their toxic products.

1. Immunity is that resistance usually associated with possessing antibodies or cells having a specific activity against the etiologic agent of an infectious disease. Passive immunity is attained either naturally by maternal transfer or artificially by introducing specific protective antibodies. Passive immunity is of brief duration. Active immunity is attained by infection, with or without symptoms, or by introducing certain fractions or products of the infectious agent or the agent itself in a killed, modified or variant form.

2. Natural resistance is the ability to resist disease independently of antibodies or a specific cellular response. It commonly rests in anatomic, cellular or physiologic characteristics of the host. It may be genetic or acquired, permanent or temporary.
300.020: continued

**Respiratory Hygiene/Cough Etiquette.** Measures to prevent the transmission of all respiratory infections, that includes covering of the nose/mouth when coughing or sneezing, use and safe disposal of tissues and hand hygiene.

**Risk.** The probability of an individual developing a given disease or experiencing a change in health status over a specific period of time.

**Spinal Cord Injury.** The occurrence of an acute traumatic lesion of neural elements in the spinal canal (spinal cord or cauda equina) resulting in temporary or permanent sensory deficit, motor deficit, or bowel or bladder dysfunction.

**Standard Precautions.** Refers to consistent and prudent preventive measures to be used at all times regardless of patient’s infection status. The Department adopts, by reference, as standard precautions for infection control, the 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings, published by the U.S. Centers for Disease Control and Prevention and its Healthcare Infection Control Practices Advisory Committee.

**Surveillance of Disease.** Monitoring the occurrence and spread of disease and indications of such occurrence and spread.

**Susceptible.** A person or animal not possessing resistance to a pathogenic agent. Such a person or animal is liable to contract a disease if or when significantly exposed to such agent.

**Suspect Case.** A person or animal with clinical and/or laboratory evidence suggestive of the existence of a disease or condition dangerous to the public health but prior to the confirmation of such a diagnosis.

**Traumatic Amputation.** An unintentional severing of some or all of a body part.

**Traumatic Brain Injury.** An occurrence of injury to the head, arising from blunt or penetrating trauma or from acceleration-deceleration forces, with one or more of the following conditions attributed to the injury: decreased level of consciousness, amnesia, skull fracture, or objective evidence of a neurological or neuropsychological abnormality or diagnosed intracranial lesion.

**Tuberculosis.**
- **Active Tuberculosis.** A disease that is caused by *Mycobacterium tuberculosis* or other members of the *Mycobacterium tuberculosis* complex family in any part of the body and that is in active state as determined by either:
  - (a) a positive diagnostic test for tuberculosis on any human specimen and the person has not completed the appropriate prescribed course of medication for active tuberculosis disease;
  - (b) radiographic, current clinical, or laboratory evidence sufficient to support a clinical diagnosis of tuberculosis for which treatment is indicated.
- **Tuberculosis Infection (also known as Latent Tuberculosis Infection).** Condition in which living *tubercle bacilli* are present in an individual, without producing clinically active disease. Infected individuals usually have a positive tuberculin skin test or laboratory test for tuberculosis infection (such as an interferon release assay or IGRA), but are not infectious.

**Unusual Illness.** An illness, by any indication, occurring for the first time or under rare circumstances, or an illness associated with signs and symptoms not otherwise expected to occur based on the known or presumed etiology of the illness.

**Work-related Disease.** A disease or condition which is believed to be caused or aggravated by conditions in the individual’s workplace.

**Work-related Serious Traumatic Injury to a Person Younger Than 18 Years Old.** An injury to a person younger than 18 years old which:
300.020: continued

(1) results in death, hospitalization, or, in the judgment of the treating physician, results in significant scarring or disfigurement, permanent disability, significant loss of consciousness, or loss of a body part or bodily function; or which

(2) the physician determines is less significant but is of the same or similar nature to injuries previously sustained at the same place of employment.

Zoonotic. Infectious disease of animals that can be transmitted to humans.

300.100: Diseases Reportable to Local Boards of Health

Cases or suspect cases of the diseases listed as follows shall be reported by household members, physicians and other health care providers as defined by M.G.L. c. 111, § 1, and other officials designated by the Department, by telephone, in writing, by facsimile or other electronic means, as deemed acceptable by the Department, including transmission from electronic health records, immediately, but in no case more than 24 hours after diagnosis or identification, to the board of health in the community where the case is diagnosed or suspect case is identified. When available, full demographic, clinical and epidemiologic information, as defined by the Department, must be included for each report. The local board of health's responsibility, upon receipt of a report, is set forth in 105 CMR 300.110 and 300.160. Physicians and other health care providers shall also report the diseases listed as follows when identified to be present through point of care testing.

Anthrax
Arbovirus infection, including but not limited to, infection caused by: chikungunya virus, dengue, eastern equine encephalitis virus, Jamestown Canyon virus, West Nile virus, yellow fever virus, and Zika virus
Botulism
Brucellosis
Cholera
Creutzfeldt-Jakob disease or variant Creutzfeld-Jakob disease
Diphtheria
Foodborne illness due to toxins (including mushroom toxins, ciguatera toxins, scombrototoxin, tetrodotoxin, paralytic shellfish toxin and amnesic shellfish toxin, staphylococcus enterotoxin, and others) Encephalitis, any cause
Hansen's disease (leprosy)
Hemolytic uremic syndrome (HUS)
Hepatitis A
Hepatitis B
Hepatitis C
Hepatitis D
Hepatitis E
Hepatitis syndrome, acute
Lymphocytic choriomeningitis
Malaria
Measles
Meningitis, bacterial, community-acquired
Meningitis, viral (aseptic) or other infectious (non-bacterial)
Meningococcal disease, invasive infection (with N. meningitidis)
Mumps
Pertussis
Plague
Polioencephalitis
Powassan
Pox virus infections in humans, including variola (smallpox), monkeypox, vaccinia, and other orthopox or parapox viruses
Rabies in humans
Respiratory infection thought to be due to any novel coronavirus, including but not limited to severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS)
300.100: continued

Reye syndrome
Rickettsialpox
Rocky Mountain spotted fever
Rubella
Tetanus
Toxic shock syndrome
Trichinosis
Tularemia
Typhoid Fever
Typhus
Varicella (chickenpox)
Viral hemorrhagic fevers, including but not limited to infection caused by Ebola virus, Marburg virus and other filoviruses, arenaviruses, bunyaviruses and flaviviruses

The following diseases shall also be reported to the local board of health. These diseases are often primarily ascertained through laboratory testing and reported to the Department pursuant to 105 CMR 300.170 through 300.174. If reported to the Department pursuant to 105 CMR 300.170 through 300.175, this may serve in lieu of direct reporting to local boards of health:

- Anaplasmosis
- Amebiasis
- Babesiosis
- Campylobacteriosis
- Cryptosporidiosis
- Cyclosporiasis
- Ehrlichiosis
- Giardiasis
- Glanders
- Group A streptococcus, invasive infection
- Group B streptococcus, invasive infection in children younger than one year old
- Haemophilus influenzae, invasive infection
- Hantavirus infection
- Influenza
- Legionellosis
- Listeriosis
- Lymphocytic choriomeningitis virus infection
- Lyme disease
- Melioidosis
- Noroviruses infection
- Psittacosis
- Q Fever
- Salmonellosis
- Shigellosis
- Shiga toxin-producing organisms isolated from humans, including enterohemorrhagic *E. coli* (EHEC)
- *Streptococcus pneumoniae*, invasive infection in individuals younger than 18 years old
- Vibriosis (non-Cholera)
- Yersiniosis

300.110: Case Reports by Local Boards of Health

Each local board of health shall report to the Department the occurrence or suspected occurrence of any disease reported to the board of health, pursuant to 105 CMR 300.100. When available, the case’s full demographic, clinical and epidemiologic information, as defined by the Department, must be included for each report. Each local board of health shall utilize the secure electronic disease surveillance and case management system (MAVEN) designated and maintained by the Department. Each case shall be reported immediately, but no later than 24 hours after receipt by the local board of health.
300.120: Confidentiality

(A) All confidential personally identifying information, whether kept in an electronic system or paper format, including but not limited to, reports of disease, records of interviews, written or electronic reports, statements, notes, and memoranda, about any individual that is reported to or collected by the Department or local boards of health pursuant to 105 CMR 300.000, shall be protected by persons with knowledge of this information. Except when necessary for the Commonwealth’s or local jurisdiction's disease investigation, control, treatment and prevention purposes, or for studies and research authorized by the commissioner pursuant to M.G.L. c. 111, § 24A, the Department and local boards of health shall not disclose any personally identifying information without the individual’s written consent. Only those Department and local board of health employees who have a specific need to review personal data records for lawful purposes of the Department or local board of health shall be entitled access to such records. The Department and local boards of health shall ensure that all paper records and electronic data systems relating to information that is reported to or collected by the Department or local boards of health pursuant to 105 CMR 300.000 are kept secure and, to the greatest extent practical, kept in controlled access areas.

(B) Notwithstanding 105 CMR 300.120(A), the Department shall not disclose to the federal government, the Commonwealth or any of its political subdivisions or any agency, agent, or contractor of said Commonwealth or federal government, the identity of any individual with HIV or AIDS reported to the Department under 105 CMR 300.000.

300.131: Illness Believed to Be Due to Food Consumption

Every person who is a health care provider or who is in a supervisory position at a school, day care, hospital, institution, clinic, medical practice, laboratory, labor or other camp who has knowledge of the occurrence or suspected occurrence of case or cases of illness believed to have been due to the consumption of food, shall report the same immediately by telephone, by facsimile or other electronic means to the local board of health in the community in which the facility is located or the Department directly. If the Department is notified directly, it shall notify the local board of health within 24 hours.

300.132: Illness Believed to Be Transmissible Through Food

The manager or supervisor of any food handling facility, when he or she knows or has reason to believe that an employee has contracted any disease transmissible through food or has become a carrier of such disease, shall report the same immediately by telephone, by facsimile or other electronic means to the local board of health in the community in which the facility is located or the Department directly. If the Department is notified directly, it shall notify the local board of health within 24 hours.

300.133: Illness Believed to Be Unusual

In addition to the diseases listed in 105 CMR 300.100, every person who is a health care provider or who is in a supervisory position at a school, day care, hospital, institution, clinic, medical practice, laboratory, labor or other camp who has knowledge of the occurrence of a case or a suspect case of an unusual illness, shall report the same immediately by telephone, by facsimile or other electronic means to the local board of health in the community in which the facility is located or the Department directly. If the Department is notified directly, it shall notify the local board of health within 24 hours.

300.134: Illness Believed to Be Part of a Suspected or Confirmed Cluster or Outbreak

In addition to the diseases listed in 105 CMR 300.100, every person who is a health care provider or who is in a supervisory position at a school, day care, hospital, institution, clinic, medical practice, laboratory, labor or other camp who has knowledge of the occurrence of any suspected or confirmed cluster or outbreak of any illness, shall report the same immediately by telephone, by facsimile or other electronic means to the local board of health in the community in which the facility is located or the Department directly. If the Department is notified directly, it shall notify the local board of health within 24 hours.
300.135: Reporting of Pediatric Influenza Deaths, Severe and Unusual Illness Due to Influenza, Cases of Antiviral Treatment or Prophylaxis Failure, and Illnesses Believed to Be Due to Novel Influenza Viruses

(A) Health care providers shall report to the Department within 24 hours, in a form or manner deemed acceptable by the Department:

1. All suspected and confirmed deaths due to influenza in pediatric patients and in pregnant women. Pediatric patients are defined as individuals younger than 18 years old;
2. All suspect or confirmed human cases of influenza that are unusual or unusually severe, including but not limited to cases with encephalopathy, myocarditis or pericarditis;
3. All cases of influenza suspected or proven to be a result of resistance to an influenza antiviral agent; and
4. Suspect or confirmed cases of human infection due to influenza A viruses that are different from currently circulating human influenza H1 and H3 viruses. These viruses include those that are subtyped as non-human in origin and those that are unsubtypable with standard methods and reagents.

(B) The Department will notify the local board of health via MAVEN of all such reports.

300.136: Reporting of Infection or Suspected Infection Believed to Be Transmitted by a Transfused Blood Product or Transplanted Organ, Tissue or Tissue Product

In addition to the diseases listed in 105 CMR 300.100, every person who is a health care provider or who is in a supervisory position at a hospital, institution, clinic, medical practice, or laboratory, who has knowledge of the occurrence of a case or a suspect case of an infection or suspected infection that may be transmitted by a transfused blood product or transplanted organ, tissue, or tissue product, shall report the same immediately by telephone, by facsimile or other electronic means to the local board of health in the community in which the facility is located or contact the Department directly.

300.140: Reporting of Animal Diseases with Zoonotic Potential by Veterinarians

As required under M.G.L. c. 129, § 28 any veterinarian or local board of health with knowledge of the existence of a domestic animal affected with, or suspected to be affected with a contagious disease must report the disease to the Department of Agricultural Resources (DAR), Bureau of Animal Health. DAR will immediately notify the Department of any suspicion or occurrence of any such disease if it is potentially infectious to humans. Notwithstanding requirements to report such cases to DAR, veterinarians shall also report to the Department within 24 hours any case of anthrax, plague, West Nile virus infection, or Eastern equine encephalitis virus infection diagnosed in an animal. The Department will notify the local board of health of all such reports within 24 hours.

300.150: Declaring a Disease or Condition Immediately Reportable, under Surveillance and/or Subject to Isolation and Quarantine: Temporary Reporting, Surveillance and/or Isolation and Quarantine

In addition to the diseases and conditions listed in 105 CMR 300.000, the Commissioner, as necessary to reduce morbidity and mortality in the Commonwealth, shall require the reporting, authorize the surveillance and/or establish isolation and quarantine requirements, on a time-limited basis, of confirmed and suspect cases of diseases or conditions which are newly recognized or recently identified or suspected to be a public health concern. Such declarations shall be authorized for a period of time not to exceed 12 months. Such requirements for a particular disease or condition beyond this time period shall be continued pursuant to 105 CMR 300.000.

300.160: Diseases Reportable by Local Boards of Health to the Department

Whenever there shall occur in any municipality, report of a case or condition listed in 105 CMR 300.000, a case of unusual illness or cluster or outbreak of disease, including but not limited to suspected food poisoning, or an increased incidence of diarrheal and/or unexplained febrile illness, it shall be the duty of the local board of health to report immediately by secure electronic disease surveillance and case management system (MAVEN) designated and maintained by the Department and, if indicated by the Department, by telephone the existence of such an unusual disease, outbreak, cluster, or increased incidence of illness to the Department. Information contained in the report shall be defined by the Department and shall include when available full demographic, clinical, epidemiologic and laboratory information.
In addition to the requirements of 105 CMR 300.100, 300.171, 300.180(A) and (C) all laboratories, including those outside of Massachusetts, performing examinations on any specimens derived from Massachusetts residents that yield evidence of infection due to the organisms listed below shall report such evidence of infection directly to the Department through secure electronic laboratory reporting mechanisms, or other method, as defined by the Department, within 24 hours. A laboratory contact must be included with each report in addition to the test results, source of specimen, date of specimen collection, case’s full name, date of birth, sex, race and ethnicity, address, telephone number, and name of the ordering health care provider, when available. Upon receipt of a laboratory report, the Department shall notify the local board of health in the town in which the case resides within 24 hours via the MAVEN surveillance and case management system.

Anaplasma sp.
Arborviruses, including but not limited to, chikungunya virus, eastern equine encephalitis virus, dengue fever virus, Jamestown Canyon virus, West Nile virus, yellow fever virus, and Zika virus

Babesia sp.
Bacillus anthracis
Bordetella bronchiseptica
Bordetella holmsei
Bordetella parapertussis
Bordetella pertussis
Borrelia burgdorferi
Borreliia miyamotoi
Brucella sp.
Burkholderia mallei
Burkholderia pseudomallei
Campylobacter sp.
Chlamydia psittaci
Clostridium botulinum
Clostridium difficile
Clostridium perfringens
Clostridium tetani
Corynebacterium diphtheriae
Coxiella burnetii
Cryptosporidium sp.
Cyclospora cayetanensis
Ehrlichia sp.
Entamoeba histolytica
Enteroviruses
Escherichia coli O157:H7
Francisella tularensis
Giardia sp.
Group A streptococcus, from a usually sterile site
Group B streptococcus, from a usually sterile site in children younger than one year old
Haemophilus influenzae, from a usually sterile site
Hantavirus
Hemorrhagic fever viruses, including but not limited to Ebola virus, Marburg virus, and other filoviruses, arenaviruses, bunyaviruses and flaviviruses

Hepatitis A virus
Hepatitis B virus
Hepatitis C virus
Hepatitis D virus
Hepatitis E virus
Evidence of human prion disease
Influenza A and B viruses
Legionella sp.
Listeria sp.
Lymphocytic choriomeningitis virus
Measles virus
Mumps virus
*Mycobacterium leprae*
*Mycobacterium tuberculosis*, *M. africanum*, *M. bovis*
*Neisseria meningitidis*, from a usually sterile site
Noroviruses
Novel coronaviruses causing severe disease
Novel influenza A viruses
*Plasmodium sp. including P. falciparum, P. malariae, P. ovale, P. vivax*
Poliovirus
Powassan virus
Pox viruses, including but not limited to variola, vaccinia, and other orthopox and parapox viruses, but excluding molluscum contagiosum viruses
Rabies virus
*Rickettsia akari*
*Rickettsia prowazekii*
*Rickettsia rickettsii*
Rubella virus
*Salmonella* sp.
Shiga toxin
Shigella sp.
Simian herpes virus
*Streptococcus pneumoniae*, from a usually sterile site in individuals younger than 18 years old
*Trichinella spiralis*
Laboratory evidence of tuberculosis infection
*Varicella zoster virus*
*Vibrio* sp.
*Yersinia pestis*
*Yersinia* sp.

Evidence of infection due to the organisms listed as follows shall also be reported directly to the Department through secure electronic laboratory reporting mechanisms, or other method, as defined by the Department, within 24 hours. A laboratory contact must be included with each report in addition to the test results, source of specimen, date of specimen collection, case's full name, date of birth, sex, race and ethnicity, address, telephone number, and name of the ordering health care provider, when available.

*Chlamydia trachomatis*
*Haemophilus ducreyi*
Herpes simplex virus, neonatal infection (in child younger than 60 days old)
Human immunodeficiency virus (HIV)
*Klebsiella granulomatis*
*Neisseria gonorrhoeae*
*Treponema pallidum*

300.171: Reporting of Antimicrobial Resistant Organisms and Cumulative Antibiotic Susceptibility Test Results (Antibiograms)

(A) All Laboratories shall report results indicating antimicrobial resistance in the following organisms directly to the Department through secure electronic laboratory reporting mechanisms, or other method, as defined by the Department. Information shall include the name of a laboratory contact, the specified test results, date of specimen collection, source of specimen, and the case's full name, date of birth, sex, race and ethnicity, full address, telephone number, and name of the ordering health care provider, when available.

Carbapenemase-producing and/or carbapenem-resistant *Enterobacteriaceae*
*Neisseria gonorrhoeae* resistant to ceftriaxone
Vancomycin-resistant *Staphylococcus aureus* (VRSA)
Vancomycin-intermediate *Staphylococcus aureus* (VISA)
300.171: continued

Invasive methicillin-resistant *Staphylococcus aureus* (MRSA)
Invasive penicillin-resistant *Streptococcus pneumoniae*

If antimicrobial resistance of an unexplained or novel nature is identified in any infectious organism, the laboratory must contact the Department within five business days.

(B) All hospitals shall report annual cumulative antibiotic susceptibility test results (antibiograms). This report shall include information specified by the Department and be sent in the manner deemed acceptable by the Department.

300.172: Submission of Selected Isolates and Diagnostic Specimens to the State Public Health Laboratory

All laboratories performing examinations on any specimens derived from Massachusetts residents shall submit the following directly to the State Public Health Laboratory for further examination.

- *Bacillus anthracis* isolates and suspect isolates
- *Brucella* sp. isolates and suspect isolates
- *Burkholderia mallei* isolates and suspect isolates
- *Burkholderia pseudomallei* isolates and suspect isolates
- Carbapenem-resistant and carbapenemase-producing *Enterobacteriacea* isolates
- *Campylobacter* sp. isolates
- *Clostridium botulinum* isolates and suspect isolates
- Specimens obtained from human sources with indication or suspicion of eastern equine encephalitis (EEE) virus infection
- *Franciscella tularensis* isolates and suspect isolates
- Influenza viruses diagnostic specimens or isolates known or suspected to contain antiviral resistant virus
- *Legionella* sp., isolates and suspect isolates
- *Listeria monocytogenes* isolates
- Specimens with indication or suspicion of measles virus infection
- Specimens with indication or suspicion of mumps virus infection
- *Mycobacterium tuberculosis* isolates
- *Neisseria gonorrhoeae* isolates
- *Neisseria meningitidis* isolates from a usually sterile site
- *Salmonella* sp. isolates
- Shiga toxin producing organism isolates including *E. coli* O157, and any broths which test positive for shiga toxin producing organisms where the organism has not been isolated
- *Shigella* sp. isolates
- *Staphylococcus aureus*, vancomycin-intermediate and vancomycin-resistant isolates only
- *Streptococcus pneumoniae* isolates from a usually sterile site and only from individuals younger than 18 years old
- *Vibrio* sp. isolates
- Specimens obtained from human sources with indication or suspicion of West Nile virus infection
- *Yersinia pestis* isolates and suspect isolates
- *Yersinia* sp. (non pestis) isolates
- Organisms with antimicrobial resistance of a novel nature

300.173: Reporting of Certain Negative and Indeterminant Diagnostic Tests Associated with Ascertainment of Infection Status

For the purposes of accurately classifying cases of syphilis, viral hepatitis and tickborne diseases, all laboratories performing examinations on any specimens derived from Massachusetts residents shall report directly to the Department through secure electronic laboratory mechanisms, or other method, as defined by the Department, within 24 hours, negative results of the following specific laboratory tests:

1. Any test for syphilis associated with a concurrent positive serologic test;
2. Hepatitis C serologic and nucleic acid amplification tests;
3. Any negative or indeterminate diagnostic test result for HIV infection associated with a concurrent positive test;
300.173: continued

(4) Any tests that are part of a panel of diagnostic tests for vector-borne infections that are associated with a concurrent positive result of one or more tests in the panel;

(5) Any tests that are part of a panel of diagnostic tests for viral hepatitis infections that are associated with a concurrent positive result of one or more tests in the panel.

300.174: Laboratory Findings Indicative of Infectious Disease Reportable Directly to the Department by Point of Care Testing

Physicians and other healthcare providers using point of care tests for diagnosis of infectious diseases must report test results to the Department when they are indicative of an infectious disease reportable directly to the Department by laboratories (per 105 CMR 300.170) unless such point of care testing is subject to routine reflex testing by a supplementary or confirmatory testing the results of which would be reportable.

300.175: Potential Exposures to Certain Infectious Agents in Clinical Laboratories and Research Settings Reportable Directly to the Department

Any person who is in a supervisory position at a human or veterinary diagnostic or research laboratory located in Massachusetts who has knowledge that a human has had exposure to certain infectious agents in the laboratory, shall report the same immediately by telephone to the Department. These infectious agents include, but are not necessarily limited to, *Bacillus anthracis* (excluding Sterne strains), *Brucella suis*, *Brucella melitensis*, *Brucella abortus*, *Brucella canis*, *Brucella* sp. vaccine strains, *Burkholderia mallei*, *Burkholderia pseudomallei*, *Francisella tularensis*, *Neisseria meningitidis*, and *Yersinia pestis*

In addition, bites, scratches or contact with body fluids from macaque monkeys shall be reported in the same manner.

300.180: Diseases Reportable Directly to the Department

(A) Reporting of Suspect or Confirmed Active Tuberculosis Disease. Any health care provider, laboratory, board of health or administrator of a city, state or private institution or hospital who has knowledge of a case of confirmed tuberculosis or clinically suspected tuberculosis, as defined in 105 CMR 300.020, shall notify the Department within 24 hours by telephone, in writing, by facsimile or other electronic means, as defined by the Department. When available, full demographic, epidemiologic, clinical and laboratory information on the case, as defined by the Department shall be included in each report. Upon receipt of such notice, the Department shall notify the local board of health in the community where the case resides via MAVEN.

(B) Reporting of Tuberculosis Infection (also known as Latent Tuberculosis Infection). Any health care provider, board of health or administrator of a city, state or private institution or hospital who has knowledge of a case of tuberculosis infection as determined by skin test or other test for determining the presence of tuberculosis infection shall notify the Department in a written or electronic format as designated by the Department. A skin test for tuberculosis which meets criteria for indicating tuberculosis infection according to the published guidelines of the U.S. Centers for Disease Control and Prevention or the Department is itself reportable. When available, full demographic, epidemiologic, clinical and laboratory information on the case, as defined by the Department shall be included in each report.

(C) Any health care provider, laboratory, board of health or administrator of a city, state or private institution or hospital who has knowledge of the diseases listed as follows shall notify the Department within 24 hours, by telephone, in writing, by facsimile or other electronic means, as defined by the Department. When available, full demographic, epidemiologic, and clinical and laboratory information on the case, as defined by the Department must be included in each report.

- Acquired immunodeficiency syndrome (AIDS);
- Chancroid;
- Chlamydial infection;
- Gonorrhea;
- *Granuloma inguinale*;
300.180: continued

Herpes simplex infection, neonatal (onset within 60 days after birth);
Human immunodeficiency virus (HIV) infection;
Lymphogranuloma venereum;
*Ophthalmia neonatorum* caused by any agent;
Pelvic inflammatory disease of any etiology;
Syphilis.

(D) The following work-related diseases and injuries are reportable directly to the Department by physicians and other health care providers in a manner approved by the Department no later than ten days after diagnosis or identification. Said report must include, at a minimum, the reporter’s name and address; the patient’s name, address, telephone number, age and sex, race/ethnicity, if known; the employer’s name and location where the occupational exposure or injury reportedly occurred; the diagnosis of the disease or description of the injury; the patient’s occupation if known; and any other information as requested by the Department.

1. Occupational Lung Disease.
   (a) Asbestosis;
   (b) Silicosis;
   (c) Beryllium disease;
   (d) Chemical pneumonitis;
   (e) Asthma caused by or aggravated by workplace exposures;
   (f) Other work-related lung disease;

2. Work-related Heavy Metal Absorption.
   (a) Mercury (blood >15 mcg/L: urine > 35 mcg/grams creatinine);
   (b) Cadmium (blood > 5mcg/L: urine > 5 mcg/grams creatinine);
   (c) Other.

   (a) Carbon monoxide poisoning;
   (b) Pesticide poisoning;
   (c) Other;
   (d) Work-related Carpal Tunnel Syndrome.

(E) Reporting of Work-related Traumatic Injuries to a Person Younger than 18 Years Old

1. By Health Care Facilities. Work-related traumatic injuries to persons younger than 18 years old that are treated in a hospital or other health care facility shall be reported by the person in charge of the facility or their designee. Health care facilities shall report these cases through computer generated reports on a regular basis no less than once every six months. Said reports shall include similar information to that required under 105 CMR 300.180(D).

2. By Physicians and Other Health Care Providers. Serious work-related traumatic injuries to persons younger than 18 years old shall be reported to the Department by the physician or other health care provider who treats the minor, within ten days after the physician or health care provider initially treats the injury. Physicians and other health care providers may report all work-related traumatic injuries to persons younger than 18 years old. Said reports shall include similar information to that required under 105 CMR 300.180(D).

300.181: Reporting Work-related Disease Outbreaks

Any physician or other health care provider who shall have knowledge of a work-related disease outbreak, regardless of whether or not the disease is included on the reportable disease list, shall report it immediately by telephone, in writing, by facsimile, or other electronic means to the Department.

300.182: Joint Authority with Department of Labor and Workforce Development

The Department recognizes that the Department of Labor and Workforce Development also has the authority, pursuant to M.G.L. c.149, § 11, to require reporting of work-related diseases and conditions. In order to avoid duplicate reporting, the Department will, upon designation by the Department of Labor and Workforce Development, also serve as the agent of the Department of Labor and Workforce Development for collection of reports of work-related diseases and conditions required under M.G.L. c. 149, § 11.
300.190: Surveillance and Control of Diseases Dangerous to the Public Health

The Department and local boards of health are authorized to conduct surveillance activities necessary for the investigation, monitoring, control and prevention of diseases dangerous to the public health. Such activities shall include, but need not be limited to:

(A) Systematic collection and evaluation of morbidity and mortality reports.

(B) Investigation into the existence of diseases dangerous to the public health in order to determine the causes and extent of such diseases and to formulate prevention and control measures.

(C) Identification of cases and contacts.

(D) Counseling and interviewing individuals as appropriate to assist in positive identification of exposed individuals and to develop information relating to the source and spread of illness.

(E) Monitoring the medical condition of individuals diagnosed with or exposed to diseases dangerous to the public health.

(F) Collection and/or preparation of data concerning the availability and use of vaccines, immune globulins, insecticides and other substances used in disease prevention and control.

(G) Collection and/or preparation of data regarding immunity levels in segments of the population and other relevant epidemiological data.

(H) Ensuring that diseases dangerous to the public health are subject to the requirements of 105 CMR 300.200 and other proper control measures.

300.191: Access to Medical Records and Other Information

(A) The Department and local boards of health are authorized to obtain, upon request, from health care providers and other persons subject to the provisions of 105 CMR 300.000, medical records and other information that the Department or the local board of health deems necessary to carry out its responsibilities to investigate, monitor, prevent and control diseases dangerous to the public health.

(B) School nurses are authorized to obtain from health care providers the immunization records or other immunization related information required for school admission, without the authorization of the child's parent(s) or legal guardian(s), as necessary to carry out the immunization requirements of M.G.L. c. 76, § 15. Prior to requesting such records from the provider, school nurses shall make a good faith effort to obtain the information from the child's parent(s) or legal guardian(s) and shall notify them that the information will be obtained from the health care provider pursuant to 105 CMR 300.191 if it is not provided in a timely manner by the parent(s) or guardian(s). For purposes of the Health Insurance Portability and Accountability Act (HIPAA), school nurses are hereby designated as public health authorities and granted authority to obtain immunization information from health care providers in accordance with 105 CMR 300.000 in order to monitor and ensure compliance with the immunization requirements of M.G.L. c. 76, § 15.

300.192: Surveillance of Diseases Possibly Linked to Environmental Exposures

The Department is authorized to collect medical records and other identifiable information from health care providers and other persons subject to 105 CMR 300.000, and/or prepare data, as detailed in 105 CMR 300.190 and 300.191, on individuals evaluated for or diagnosed with the following diseases possibly linked to environmental exposures:

Amyotrophic lateral sclerosis (ALS);
Aplastic anemia;
Asthma;
Autism spectrum disorder (ASD);
Multiple sclerosis (MS);
Myelodysplastic syndrome (MDS);
Scleroderma;
Systemic lupus erythematosus.

300.193: Surveillance of Injuries Dangerous to Public Health

The Department is authorized to collect medical records and other identifiable information from health care providers and other persons subject to 105 CMR 300.000, and/or prepare data, as detailed in 105 CMR 300.190 and 300.191, related to the following types of injuries or causes of injuries:
Any mode of transportation;
Assaults or homicides;
Drownings;
Falls;
Fires;
Machinery;
Poisoning, including, but not limited to, drug overdose;
Spinal cord injuries;
 Strikes by/against another object or person;
Suffocation;
Suicides, attempted suicides, or self-inflicted wounds;
Traumatic amputations;
Traumatic brain injuries;
Weapons;
Work-related injuries.

300.200: Isolation and Quarantine Requirements

Upon the report of a case or suspected case of disease declared dangerous to the public health, the local board of health and the Department are authorized to implement and enforce the requirements outlined in 105 CMR 300.200. Minimum requirements for the isolation and quarantine of diseases dangerous to the public health are set forth in 105 CMR 300.200(A). Depending on the specific circumstances related to the exposure, case and/or contact with respect to any disease or condition listed in 105 CMR 300.200(A) or (B), additional control measures may be required.

(A) Diseases Reportable to Local Boards of Health.

<table>
<thead>
<tr>
<th>Disease</th>
<th>Minimum Period of Isolation of Patient</th>
<th>Minimum Period of Quarantine of Contacts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amebiasis</td>
<td>After diarrhea has resolved, food handlers may only return to food handling duties after producing one negative stool specimen. If a case has been treated with an antimicrobial, the stool specimen shall not be collected until at least 48 hours after cessation of therapy. In outbreak circumstances, two negative stool specimens produced at least 24 hours apart will be required prior to returning to food handling duties.</td>
<td>Contacts with diarrhea, who are food handlers, shall be considered the same as a case and handled in the same fashion. In outbreak circumstances, asymptomatic contacts who are food handlers shall be required to produce two negative stool specimens produced at least 24 hours apart prior to returning to food handling duties. Otherwise, no restrictions.</td>
</tr>
<tr>
<td>Anaplasmosis</td>
<td>No restrictions</td>
<td>No restrictions</td>
</tr>
<tr>
<td>Anthrax</td>
<td>For cutaneous anthrax, place on contact precautions until lesions are healed or free from anthrax bacilli.</td>
<td>No restrictions</td>
</tr>
<tr>
<td>Arbovirus infection</td>
<td>No restrictions</td>
<td>No restrictions</td>
</tr>
<tr>
<td>Babesiosis</td>
<td>No restrictions except for exclusion from blood donation.</td>
<td>No restrictions</td>
</tr>
<tr>
<td>B. miyamotoi</td>
<td>No restrictions</td>
<td>No restrictions</td>
</tr>
<tr>
<td>Disease</td>
<td>Minimum Period of Isolation of Patient</td>
<td>Minimum Period of Quarantine of Contacts</td>
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<tr>
<td>---------------------------------</td>
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</tr>
<tr>
<td>Botulism</td>
<td>No restrictions</td>
<td>No restrictions</td>
</tr>
<tr>
<td>Brucellosis</td>
<td>No restrictions</td>
<td>No restrictions</td>
</tr>
<tr>
<td>Campylobacteriosis</td>
<td>After diarrhea has resolved, food handlers may only return to food handling duties after producing one negative stool specimen. If a case has been treated with an antimicrobial, the stool specimen shall not be collected until at least 48 hours after cessation of therapy. In outbreak circumstances, two negative stool specimens produced at least 24 hours apart will be required prior to returning to food handling duties.</td>
<td>Contacts with diarrhea, who are food handlers, shall be considered the same as a case and handled in the same fashion. In outbreak circumstances, asymptomatic contacts who are food handlers shall be required to produce two negative stool specimens produced at least 24 hours apart prior to returning to food handling duties. Otherwise, no restrictions.</td>
</tr>
<tr>
<td>Cholera</td>
<td>After diarrhea has resolved, food handlers may only return to food handling duties after producing two negative stool specimens produced at least 24 hours apart. If a case has been treated with an antimicrobial, the stool specimen shall not be collected until at least 48 hours after cessation of therapy.</td>
<td>Contacts with diarrhea, who are food handlers, shall be considered the same as a case and handled in the same fashion. In outbreak circumstances, asymptomatic contacts who are food handlers shall be required to produce two negative stool specimens produced at least 24 hours apart prior to returning to food handling duties. Otherwise, no restrictions.</td>
</tr>
<tr>
<td>Clostridium difficile</td>
<td>No restrictions</td>
<td>No restrictions</td>
</tr>
<tr>
<td>Severe infection due to novel coronaviruses</td>
<td>Isolate for duration of illness. Isolation beyond the resolution of symptoms may be required and will be determined by the Department based on the most current recommendations by the Centers for Disease Control and Prevention.</td>
<td>Asymptomatic contacts should practice personal surveillance for symptoms and should any occur within 14 days of the individual’s last contact with the case, report them to their health care provider immediately. Febrile contacts or contacts with respiratory symptoms only, shall be treated the same as a case for 72 hours, after which further management shall be in consultation with the Department.</td>
</tr>
<tr>
<td>Creutzfeldt-Jakob disease or variant Creutzfeldt-Jakob disease</td>
<td>No restrictions</td>
<td>No restrictions</td>
</tr>
<tr>
<td>Cryptosporidiosis</td>
<td>After diarrhea has resolved, food handlers may only return to food handling duties after producing one negative stool specimen. If a case has been treated with an antimicrobial, the stool specimen shall not be collected until at least 48 hours after cessation of therapy. In outbreak circumstances, two negative stool specimens produced at least 24 hours apart will be required prior to returning to food handling duties.</td>
<td>Contacts with diarrhea, who are food handlers, shall be considered the same as a case and handled in the same fashion. In outbreak circumstances, asymptomatic contacts who are food handlers shall be required to produce two negative stool specimens produced at least 24 hours apart prior to returning to food handling duties. Otherwise, no restrictions.</td>
</tr>
<tr>
<td>Cyclosporiasis</td>
<td>Food handlers may return to food handling duties after diarrhea has resolved. In certain situations however, food handlers may be required to produce one or two negative stool specimens before returning to food handling duties. If a case has been treated with an antimicrobial, the stool specimen shall not be collected until at least 48 hours after cessation of therapy.</td>
<td>Contacts with diarrhea, who are food handlers, shall be considered the same as a case and handled in the same fashion. In certain outbreak situations, asymptomatic contacts who are food handlers may be required to produce one or two negative stool specimens prior to returning to food handling duties. Otherwise, no restrictions.</td>
</tr>
</tbody>
</table>
### Disease Minimum Period of Isolation of Patient Minimum Period of Quarantine of Contacts

<table>
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<tr>
<td>Diphtheria</td>
<td>Maintain isolation until two successive pairs of nose and throat cultures (and cultures of skin lesions in cutaneous diphtheria) obtained greater than 24 hours apart and at least 24 hours after completion of antimicrobial therapy are negative. If there was no antimicrobial therapy, these two sequential pairs of cultures shall be taken after symptoms resolve and greater than two weeks after their onset. If an avirulent (nontoxigenic) strain is documented, isolation is not necessary.</td>
<td>All contacts (both symptomatic and asymptomatic) who are food handlers must be excluded from work until two successive pairs of nose and throat cultures obtained greater than two weeks after completion of antimicrobial prophylaxis (if any) and greater than 24 hours apart are negative. Symptomatic contacts who are not food handlers shall be considered the same as a case until their culture results are negative and they are cleared by the appropriate public health authority. Asymptomatic contacts who are not food handlers must be on appropriate antibiotics and personal surveillance.</td>
</tr>
<tr>
<td>Ehrlichiosis</td>
<td>No restrictions</td>
<td>No restrictions</td>
</tr>
<tr>
<td>Encephalitis, any case</td>
<td>No restrictions</td>
<td>No restrictions</td>
</tr>
<tr>
<td>Food poisoning and toxicity</td>
<td>No restrictions</td>
<td>No restrictions</td>
</tr>
<tr>
<td>Giardiasis</td>
<td>After diarrhea has resolved, food handlers may only return to food handling duties after producing one negative stool specimen. If a case has been treated with an antimicrobial, the stool specimen shall not be collected until at least 48 hours after cessation of therapy. In outbreak circumstances, two negative stool specimens produced at least 24 hours apart will be required prior to returning to food handling duties.</td>
<td>Contacts with diarrhea, who are food handlers, shall be considered the same as a case and handled in the same fashion. In outbreak circumstances, asymptomatic contacts who are food handlers shall be required to produce two negative stool specimens produced at least 24 hours apart prior to returning to food handling duties. Otherwise, no restrictions.</td>
</tr>
<tr>
<td>Glanders</td>
<td>No restrictions</td>
<td>No restrictions</td>
</tr>
<tr>
<td>Group A streptococcus, invasive infection</td>
<td>Persons with streptococcal pharyngitis or skin infections, with or without invasive disease, shall not return to school or child care until at least 24 hours after initiating antimicrobial treatment.</td>
<td>Personal surveillance and prophylaxis with an antimicrobial when appropriate. Otherwise, no restrictions.</td>
</tr>
<tr>
<td>Group B streptococcus, invasive infection</td>
<td>No restrictions</td>
<td>No restrictions</td>
</tr>
<tr>
<td>Haemophilus influenzae, invasive infection</td>
<td>a) type B Until 24 hours after initiating antimicrobial treatment.</td>
<td>Personal surveillance and prophylaxis with an appropriate antimicrobial when indicated by clinical situation of the contact or by potential for transmission. Otherwise, no restrictions.</td>
</tr>
<tr>
<td></td>
<td>b) non type B</td>
<td>No restrictions</td>
</tr>
<tr>
<td>Hansen’s disease</td>
<td>No restrictions if under medical care.</td>
<td>No restrictions</td>
</tr>
<tr>
<td>Hantavirus infection</td>
<td>No restrictions</td>
<td>No restrictions</td>
</tr>
<tr>
<td>Hemolytic uremic syndrome</td>
<td>After diarrhea has resolved, food handlers may only return to food handling duties after producing two negative stool specimens, produced at least 24 hours apart. If a case was treated with an antimicrobial, the stool specimen shall not be collected until at least 48 hours after cessation of therapy.</td>
<td>Contacts with diarrhea, who are food handlers, shall be considered the same as a case and handled in the same fashion. In outbreak circumstances, asymptomatic contacts who are food handlers shall be required to produce two negative stool specimens produced at least 24 hours apart prior to returning to food handling duties. Otherwise, no restrictions.</td>
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<td>---------------------------------</td>
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</tr>
<tr>
<td>Hepatitis A</td>
<td>Isolation until one week after onset of symptoms or for cases where the onset date is not known, one week past the date the specimen positive for IgM antibody to HAV was provided.</td>
<td>No restrictions except for susceptible food handlers, who shall be excluded from their occupations for 28 days unless they receive a prophylactic dose of immune globulin (IG) and/or hepatitis A vaccine within 14 days of exposure, or in accordance with the latest recommendations from the Department.</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>No restrictions except for exclusion from organ and blood donation. Case shall receive counseling to modify activities in order to prevent transmission.</td>
<td>Personal surveillance for high-risk contacts who should receive hepatitis B immune globulin (HBIG) and vaccine. Infants born to infected women should also receive HBIG and vaccine. Otherwise, no restrictions.</td>
</tr>
<tr>
<td>Hepatitis C</td>
<td>No restrictions except for exclusion from organ and blood donation. Case shall receive counseling to modify activities in order to prevent transmission.</td>
<td>Personal surveillance for high-risk contacts. Otherwise, no restrictions.</td>
</tr>
<tr>
<td>Hepatitis D</td>
<td>Same as co-infecting hepatitis B</td>
<td>Same as co-infecting hepatitis B</td>
</tr>
<tr>
<td>Hepatitis E</td>
<td>Isolation until one week after onset of symptoms, or for cases where the onset date is not known, one week past the date the specimen positive for evidence of acute hepatitis E was provided.</td>
<td>No restrictions, except for susceptible food handlers, who shall be excluded from their occupations for 28 days.</td>
</tr>
<tr>
<td>Influenza</td>
<td>No restrictions</td>
<td>No restrictions</td>
</tr>
<tr>
<td>Legionellosis</td>
<td>No restrictions</td>
<td>No restrictions</td>
</tr>
<tr>
<td>Listeriosis</td>
<td>No restrictions</td>
<td>No restrictions</td>
</tr>
<tr>
<td>Lyme disease</td>
<td>No restrictions</td>
<td>No restrictions</td>
</tr>
<tr>
<td>Lymphocytic choriomeningitis virus infection</td>
<td>No restrictions, except for exclusion from organ and blood donation</td>
<td>No restrictions</td>
</tr>
<tr>
<td>Malaria</td>
<td>No restrictions except for exclusion from blood donation.</td>
<td>No restrictions</td>
</tr>
<tr>
<td>Measles</td>
<td>Through four days after onset of rash (counting the day of rash onset as day zero).</td>
<td>Contacts born in or after 1957, who are not appropriately immunized or do not have laboratory evidence of immunity, will be excluded from work, classes or other public activities from the fifth through the 21st day after their exposure even if they receive immune globulin. If exposure was continuous and/or if multiple cases occur, susceptibles will be excluded through the 21st day after rash onset in the last case. Health care workers and inpatients, regardless of year of birth, who are not appropriately immunized or do not have laboratory evidence of immunity, will be excluded from work (health care workers) or isolated with airborne precautions (inpatients) from the fifth day after their first exposure through the 21st day after their last exposure. These restrictions for health care workers and inpatients remain even if the contact received IG or was vaccinated post-exposure.</td>
</tr>
<tr>
<td>Melioidosis</td>
<td>No restrictions</td>
<td>No restrictions</td>
</tr>
</tbody>
</table>
### Disease | Minimum Period of Isolation of Patient | Minimum Period of Quarantine of Contacts
---|---|---
Meningitis  
a) bacterial, community-acquired  
b) viral (aseptic), and other non-bacterial | If infected with *H. influenzae* or *N. meningitidis*, droplet precautions until 24 hours after initiation of appropriate antibiotic therapy. Otherwise, no restrictions.  
No restrictions | Personal surveillance and antibiotic prophylaxis, where appropriate, if case has *H. influenzae* or *N. meningitidis*. Otherwise, no restrictions.  
No restrictions
Meningococcal disease, invasive infection | Droplet precautions until 24 hours after initiation of appropriate antibiotic therapy. Otherwise, no restrictions. | Personal surveillance and antibiotic prophylaxis, where appropriate. Otherwise no restrictions.
Monkeypox | Until lesions have dried and crusts have separated. If no lesions, until seven days after onset of fever. | Personal surveillance. Otherwise no restrictions.
Mumps | Through five days after onset of gland swelling (counting the initial day of gland swelling as day zero). | Contacts born in or after 1957, who are not appropriately immunized or do not have laboratory evidence of immunity, will be excluded from work, classes or other public activities from the 12th through the 25th day after their exposure. When multiple cases occur, susceptibles need to be excluded through 25 days after the onset of the last case. Health care workers, and inpatients, regardless of year of birth, who are not appropriately immunized or do not have laboratory evidence of immunity will be excluded from work (health care workers) or isolated with droplet precautions (inpatients) from the 12th through the 25th date after their exposure.
Noroviruses | Food handlers must be excluded from food handling duties for either 72 hours past the resolution of symptoms or 72 hours past the date the specimen positive for norovirus was produced, which ever occurs last. | Contacts with diarrhea or vomiting who are food handlers shall be excluded from food handling duties for 72 hours past the resolution of symptoms.
Pertussis | Until 21 days from onset of cough or five days after initiation of appropriate antibiotic therapy. | If the contact is symptomatic, use same restrictions as for cases. If the contact is an asymptomatic healthcare worker not receiving antibiotic prophylaxis, exclude from the workplace for 21 days after last exposure or, if unknown, for 21 days after the onset of the last case in the setting. If the contact is asymptomatic, not a healthcare worker, and exposed within the last 21 days, s/he should receive antibiotic prophylaxis but no exclusion is generally required. In certain situations deemed to be high-risk, the public health authority may require exclusion of asymptomatic contacts not receiving antibiotic prophylaxis and/or other contacts, and/or may extend the exclusion period beyond 21 days up to a maximum of 42 days.
<table>
<thead>
<tr>
<th>Disease</th>
<th>Minimum Period of Isolation of Patient</th>
<th>Minimum Period of Quarantine of Contacts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plague</td>
<td>For pneumonic plague, droplet precautions until 72 hours after initiation of appropriate antibiotic therapy. For bubonic plague, case shall be placed on contact precautions until 48 hours after initiation of effective therapy.</td>
<td>Contacts of cases of pneumonic plague should be provided prophylaxis and placed under personal surveillance for seven days; those who refuse prophylaxis shall be placed in quarantine and under personal surveillance for seven days.</td>
</tr>
<tr>
<td>Poliomyelitis</td>
<td>Place case on enteric precautions for six weeks after onset of symptoms or until poliovirus can no longer be recovered from feces (the number of negative specimens required will be determined by the Department on a case-by-case basis).</td>
<td>According to applicable Department guidelines, administer an appropriate preparation of poliovirus vaccine if the immune status is unknown or incomplete. Otherwise, no restrictions.</td>
</tr>
<tr>
<td>Powassan</td>
<td>No restrictions</td>
<td>No restrictions</td>
</tr>
<tr>
<td>Psittacosis</td>
<td>No restrictions</td>
<td>No restrictions</td>
</tr>
<tr>
<td>Q Fever</td>
<td>No restrictions</td>
<td>No restrictions</td>
</tr>
<tr>
<td>Rabies- human</td>
<td>For duration of illness</td>
<td>Post-exposure prophylaxis of contacts when appropriate, using recommendations of the Department. Otherwise, no restrictions.</td>
</tr>
<tr>
<td>Reye Syndrome</td>
<td>No restrictions</td>
<td>No restrictions</td>
</tr>
<tr>
<td>Rickettsialpox</td>
<td>No restrictions</td>
<td>No restrictions</td>
</tr>
<tr>
<td>Rocky Mountain spotted fever</td>
<td>No restrictions</td>
<td>No restrictions</td>
</tr>
<tr>
<td>Rubella</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a) Congenital</td>
<td>Isolation from susceptible persons for the first year of life or until two cultures of clinical specimens (nasopharyngeal secretions or urine) obtained one month apart after age three months are negative for rubella virus.</td>
<td>No restrictions except for susceptibles, then same as for non-congenital rubella.</td>
</tr>
<tr>
<td>b) Non-Congenital</td>
<td>Until seven days after onset of rash (counting the day of rash onset as day zero).</td>
<td>Contacts born in or after 1957, who are not appropriately immunized or do not have laboratory evidence of immunity, will be excluded from work, classes or other public activities from the seventh through the 23rd day after their last exposure. When multiple cases occur, susceptible need to be excluded until 23 days after the onset of the last case. Health care workers inpatients, regardless of year of birth, who are not appropriately immunized or do not have laboratory evidence of immunity, will be excluded from work (health care workers) or isolated with droplet precautions (inpatients) from the seventh day after first exposure through the 23rd day after their last exposure.</td>
</tr>
<tr>
<td>Disease</td>
<td>Minimum Period of Isolation of Patient</td>
<td>Minimum Period of Quarantine of Contacts</td>
</tr>
<tr>
<td>---------</td>
<td>---------------------------------------</td>
<td>------------------------------------------</td>
</tr>
</tbody>
</table>
| Salmonellosis  
  a) Not including typhoid fever | After diarrhea has resolved, food handlers may only return to food handling duties after producing one negative stool specimen. If a case was treated with an antimicrobial, the stool specimen shall not be collected until at least 48 hours after cessation of therapy. In outbreak circumstances, two negative stool specimens produced at least 24 hours apart will be required prior to returning to food handling duties. | Contacts with diarrhea, who are food handlers, shall be considered the same as a case and handled in the same fashion. In outbreak circumstances, asymptomatic contacts who are food handlers shall be required to produce two negative stool specimens produced at least 24 hours apart prior to returning to food handling duties. Otherwise, no restrictions. |
| b) S. typhi (typhoid fever) | Food handlers may only return to food handling duties after producing three consecutive negative stool specimens each produced no less than 48 hours apart and one month after onset of first symptoms. If one culture is positive, repeat cultures shall be collected at one month intervals until three consecutive negative cultures are obtained. If the case has been treated with an antimicrobial, the first stool specimen shall not be collected until 48 hours after cessation of therapy. | All food handlers, symptomatic or asymptomatic, who are contacts of a typhoid case shall be considered the same as a case and handled in the same fashion. |
| Shiga toxin-producing organisms, including E. coli O157:H7 | After diarrhea has resolved, food handlers may only return to food handling duties after producing two negative stool specimens, produced at least 24 hours apart. If a case was treated with an antimicrobial, the stool specimen shall not be collected until at least 48 hours after cessation of therapy. | Contacts with diarrhea, who are food handlers, shall be considered the same as a case and handled in the same fashion. In outbreak circumstances, asymptomatic contacts who are food handlers shall be required to produce two negative stool specimens produced at least 24 hours apart prior to returning to food handling duties. Otherwise, no restrictions. |
| Shigellosis | After diarrhea has resolved, food handlers may only return to food handling duties after producing two negative stool specimens produced at least 24 hours apart. If a case was treated with an antimicrobial, the stool specimen shall not be collected until at least 48 hours after cessation of therapy. | Contacts with diarrhea, who are food handlers, shall be considered the same as a case and handled in the same fashion. In outbreak circumstances, asymptomatic contacts who are food handlers shall be required to produce two negative stool specimens produced at least 24 hours apart prior to returning to food handling duties. Otherwise, no restrictions. |
| Smallpox | In conjunction with public health authorities, place case(s) on highest level of isolation to prevent direct contact, droplet contact and airbone exposure until lesions have dried and crusts have separated. | Afebrile contacts shall be placed under fever surveillance (quarantine) for 18 days from the last contact or 14 days from successful vaccination (which ever comes first), with monitoring and recording of temperature twice daily (morning and evening). Febrile contacts with or without rash shall be considered the same as a case and handled in the same fashion (isolation). If no rash develops after five days and the fever is diagnosed as being caused by recent vaccination or some other non-smallpox etiology, contact may be released from isolation to home to continue fever surveillance for 18 days following their last contact with a case or 14 days following successful vaccination (whichever comes first). |
### 105 CMR: DEPARTMENT OF PUBLIC HEALTH

**300.200: continued**

<table>
<thead>
<tr>
<th>Disease</th>
<th>Minimum Period of Isolation of Patient</th>
<th>Minimum Period of Quarantine of Contacts</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Streptococcus pneumoniae</em>, invasive infection</td>
<td>No restrictions</td>
<td>No restrictions</td>
</tr>
<tr>
<td>Tetanus</td>
<td>No restrictions</td>
<td>No restrictions</td>
</tr>
<tr>
<td>Toxic shock syndrome</td>
<td>No restrictions</td>
<td>No restrictions</td>
</tr>
<tr>
<td>Trichinosis</td>
<td>No restrictions</td>
<td>No restrictions</td>
</tr>
<tr>
<td>Tularemia</td>
<td>No restrictions</td>
<td>No restrictions</td>
</tr>
<tr>
<td>Typhus</td>
<td>No restrictions</td>
<td>No restrictions</td>
</tr>
<tr>
<td>Varicella (chickenpox)</td>
<td>If vesicles are present, until lesions have dried and crusted, or until no new lesions appear, usually by the fifth day (counting the day of rash onset as day zero). If no vesicles are present, until the lesions have faded (i.e. the skin lesions are in the process of resolving; lesions do not need to be completely resolved) or no new lesions appear within a 24-hour period, whichever is later.</td>
<td>Contacts in non-health care settings, who are not appropriately immunized or are without laboratory evidence of immunity or a reliable history of chickenpox, shall be excluded from school, work or other public activities from the eighth through the 21st days after their exposure to the case during the case's infectious period. If the exposure was continuous, contacts shall be excluded from the eighth through the 21st days after the case's rash onset. Neonates born to mothers with active varicella shall be isolated from susceptibles until 21 days of age. Health care workers who are not appropriately immunized or are without laboratory evidence of immunity shall be excluded from work (health care workers) or isolated with airborne precautions (inpatients) from the eighth day after their first exposure through the 21st day after the last exposure. In all settings, anyone receiving varicella zoster immune globulin (VZIG) or intravenous immune globulin (IVIG) shall extend their exclusion to 28 days post-exposure.</td>
</tr>
<tr>
<td>Vibriosis (non-Cholera)</td>
<td>Food handlers with diarrhea may return to work after diarrhea has resolved.</td>
<td>No restrictions</td>
</tr>
<tr>
<td>Viral hemorrhagic fevers</td>
<td>Place on hemorrhagic fever specific barrier precautions with airborne, contact, and droplet precautions, and double gloving, with strict hand hygiene, impermeable gowns, face shields, eye protection, and leg and shoe coverings until clinical illness has resolved.</td>
<td>Personal surveillance</td>
</tr>
<tr>
<td>Yersiniosis</td>
<td>After diarrhea has resolved, food handlers may only return to food handling duties after producing one negative stool specimen. If a case was treated with an antimicrobial, the stool specimen shall not be collected until at least 48 hours after cessation of therapy. In outbreak circumstances, two negative stool specimens produced at least 24 hours apart will be required prior to returning to food handling duties.</td>
<td>Contacts with diarrhea, who are food handlers, shall be considered the same as a case and handled in the same fashion. In outbreak circumstances, asymptomatic contacts who are food handlers shall be required to produce two negative stool specimens produced at least 24 hours apart prior to returning to food handling duties. Otherwise, no restrictions.</td>
</tr>
</tbody>
</table>
(B) Diseases Reportable Directly to the Department of Public Health.

<table>
<thead>
<tr>
<th>Disease</th>
<th>Minimum Period of Isolation of Patient</th>
<th>Minimum Period of Quarantine of Contacts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tuberculosis</td>
<td>Clearance from isolation in the community requires one or more of the following: three appropriately collected and processed sputum smears that are collected in eight – 24 hour intervals (one of which should be an early morning specimen); or other FDA cleared/approved or generally accepted laboratory tests indicating tuberculosis is unlikely or infectiousness is unlikely, as per guidelines such as those of the CDC, the Advisory Council of the Elimination of Tuberculosis (ACET) or the American Thoracic Society (ATS); or until the patient has undergone a period of effective chemotherapy in accordance with current treatment standards, such as those of CDC, ACET or ATS, and there is demonstration of clinical improvement (i.e. decreasing cough, reduced fever, resolving lung infiltrates).</td>
<td>No restrictions of asymptomatic contacts required.</td>
</tr>
<tr>
<td>a) Active tuberculosis:</td>
<td>No restrictions except for appropriate handling of infected fluids.</td>
<td>No restrictions</td>
</tr>
<tr>
<td>Pulmonary (also includes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>mediastinal, laryngeal,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>pleural, or miliary)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) Active tuberculosis:</td>
<td>No restrictions</td>
<td>No restrictions</td>
</tr>
<tr>
<td>Extra-pulmonary</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c) Latent TB infection</td>
<td>No restrictions</td>
<td>No restrictions</td>
</tr>
</tbody>
</table>

(C) Standard Precautions. In addition to the specific practices set out in 105 CMR 300.000, standard precautions should be followed when treating all patients and contacts. The Department adopts, by reference, as standard practice for infection control, the most current version of the guidelines on the prevention of transmission of infection published by the U.S. Centers for Disease Control and Prevention and its Healthcare Infection Control Practices Advisory Committee.

(D) Work-related Diseases and Injuries Reportable Directly to the Department of Public Health. As these diseases are not communicable, each case should be evaluated individually regarding a return to work.

300.210: Procedures for Isolation and Quarantine

(A) Scope.

(1) The Department through an authorized agent shall, and local boards of health are encouraged to strongly comply with the provisions of 105 CMR 300.210(B) through (I) when implementing isolation or quarantine.

(2) The procedures set forth in 105 CMR 300.210(B) through (I) are applicable to isolation and quarantine of persons in the population at large, but do not apply to persons in the custody of correctional facilities operated by the Department of Correction, persons in the custody of county houses of correction, persons in the custody of city or town jails, or to youth detained by or committed to the Department of Youth Services.

(3) Notwithstanding 105 CMR 300.210(A)(1) and (2), the Department and local boards of health shall follow the procedures set forth in M.G.L. c. 111, §§ 94A through 94H when isolating individuals with active tuberculosis who are unwilling or unable to accept proper medical treatment and who thereby pose a serious danger to public health.
300.210: continued

(B) General.
   (1) Voluntary Compliance.
      (a) Before using mandatory measures, the Department or local board of health shall
          educate the individual or group about the reasons and requirements for isolation or
          quarantine, and shall attempt to secure voluntary compliance.
      (b) When an individual or group agrees to comply voluntarily with isolation or
          quarantine, no written or oral order shall be necessary.
   (2) Least Restrictive Setting. Isolation or quarantine shall take place in the least restrictive
       setting that complies with the requirements of 105 CMR 300.200.
   (3) Types of Orders. Orders for isolation and quarantine may include, but are not limited
       to, restricting individuals or groups from being present in certain places including but not
       limited to school or workplace; restriction to residence and/or workplace; and confinement
       in other private or public premises. Such other premises shall not include a jail, prison, or
       other correctional facility.
   (4) Time Period of Order. An order that has not expired shall be rescinded when the
       individual or group no longer poses a serious danger to public health.

(C) Written Order.
   (1) The Department or local board of health may issue a written order of isolation or
       quarantine to an individual or group of individuals as authorized by 105 CMR 300.000.
   (2) A copy of the written order shall be provided to the individual to be isolated or
       quarantined. If the order applies to a group of individuals and it is impractical to provide
       individual copies, the order may be posted in a conspicuous place in the isolation or
       quarantine premises.

(D) Temporary Isolation or Quarantine through Oral Order.
   (1) The Department or local board of health may temporarily isolate or quarantine an
       individual or group of people as authorized by 105 CMR 300.000 through an oral order only
       if delay in imposing the isolation or quarantine would pose a serious, imminent danger to the
       public health.
   (2) The individual or group shall be orally informed that the order may be appealed by
       telephoning a specified health official issuing the order at a stated telephone number.
   (3) If an oral order is issued, a written order shall be issued as soon as is reasonably
       possible, but in no event later than 24 hours following the issuance of the oral order.
   (4) An individual or group subject to an oral order of isolation or quarantine may appeal the
       order by following the procedures specified in 105 CMR 300.210(F).

(E) Further Requirements.
   (1) Contents of Written or Oral Order. The written or oral order of isolation or quarantine
       shall include the following.
      (a) The identity of the individual or description of the group of individuals subject to
          isolation or quarantine;
      (b) The date and time at which isolation or quarantine will commence and the duration
          of the isolation or quarantine period;
      (c) The reason for which isolation or quarantine is being ordered;
      (d) The place of isolation or quarantine;
      (e) Any special instructions or precautions that should be taken;
      (f) The legal authority under which the order is issued; and
      (g) A statement advising the individual or group that the order may be appealed by
          contacting a designated health official at a telephone number stated in the order.
   (2) If an individual or group is isolated or quarantined in a location other than their
       residences, the Department or local board of health must obtain an order of the Superior
       Court authorizing the isolation or quarantine as soon as practicable, but in no event later than
       ten days following the commencement of isolation or quarantine.

(F) Appeal of Written or Oral Order.
   (1) An individual or group subject to an order of isolation or quarantine may appeal the
       order by contacting a specified health official at a telephone number stated on the written
       order or provided orally at the time that the oral order is issued.
300.210: continued

(2) An individual or group subject to an order of isolation or quarantine may file a petition in Superior Court challenging the order at any time.
(3) Unless rescinded by order of the Department or local board of health or a court, the order for isolation or quarantine shall remain in force and effect until any appeal is finally determined.

(G) Enforcement of Written or Oral Order.
(1) The Department or local board of health shall take all reasonable measures to minimize the risk of exposure to disease of police officers and others assisting with enforcement of an isolation or quarantine order.
(2) If an order for isolation or quarantine is violated, the Department or local board of health may apply to a judge of the Superior Court for an order to enforce the isolation or quarantine in a manner that will protect the public health.

(H) Requirements for Isolation or Quarantine.
(1) The Department or local board of health shall ensure that the following requirements are met, whether an individual or group is isolated or quarantined in their residences or in a place other than their residences.
   (a) The health status of isolated or quarantined individuals shall be monitored regularly to determine if they require continued isolation or quarantine.
   (b) The needs of individuals isolated or quarantined shall be addressed in a systematic and competent fashion, including, but not limited to, providing adequate food, medication, competent medical care, and crisis counseling or other mental health services when needed.
   (c) To the extent possible, cultural and religious beliefs and existing disabilities shall be considered in addressing the needs of individuals.
(2) The Department or local board of health shall ensure that the following requirements are met when an individual or group is isolated or quarantined in a place other than their residences.
   (a) Isolated individuals shall be confined separately from quarantined individuals.
   (b) If a quarantined individual subsequently acquires or is reasonably believed to have acquired a disease or condition for which isolation is necessary to protect the public health, he or she shall promptly be removed to isolation.
   (c) Individuals isolated or quarantined shall be provided adequate clothing, food, shelter, and means of communication with persons outside isolation or quarantine.
   (d) Premises used for isolation and quarantine shall be maintained in a safe and hygienic manner and shall be designed to minimize the likelihood of further transmission of infection or other harms to individuals isolated and quarantined.
   (e) The Department or local board of health may authorize physicians, health care workers, mental health workers, personal care attendants, parents or guardians of minor children, and others access to individuals in isolation or quarantine as necessary to meet the needs of isolated or quarantined individuals. Individuals who use service animals shall be allowed to bring them into the isolation or quarantine premises.
   (f) No individual other than an authorized individual shall enter isolation or quarantine premises. Any individual entering isolation or quarantine premises with or without authorization may be isolated or quarantined.

(I) Isolation or Quarantine of People in a Geographical Area.
(1) The Department or local board of health may order the isolation or quarantine of all people in a geographical area that poses a serious danger to public health, when such isolation or quarantine is reasonably believed to be necessary to prevent the immediate spread of a dangerous disease to people outside the area. Such isolation or quarantine shall be implemented by means of a written order as provided in 105 CMR 300.210(C).
(2) The Department or local board of health shall use all reasonable means of communication to inform individuals in the area of orders and instructions in effect during the period of isolation or quarantine of people in the area. At a minimum, such communication shall include posting notices in places where people in and approaching the area are reasonably likely to see them, and publishing a notice in a newspaper of general circulation in the area at least once each week during the isolation or quarantine period, which notices shall state the orders and instructions in force with a brief explanation of their meaning and effect.
300.210: continued

(3) The Department or local board of health shall terminate the isolation or quarantine of all people in an area when the area no longer poses a serious danger to public health.

(4) Any individual in the area subject to an order of isolation or quarantine may appeal the order as provided in 105 CMR 300.210(F).

REGULATORY AUTHORITY

105 CMR 300.000: M.G.L. c. 111, §§ 1, 3, 5, 6, 7, 94C, 109, 110, 110B, 111 and 112, and c. 111D, § 6.
Regulation Filing  To be completed by filing agency

CHAPTER NUMBER:  114.3 CMR 54.00

CHAPTER TITLE: Rates for Acquired Brain Injury Waiver and Related Services

AGENCY: Division of Health Care Finance and Policy

SUMMARY OF REGULATION: State the general requirements and purposes of this regulation.

The regulation at 114.3 CMR 54 establishes the rates to be paid for services provided under the Acquired Brain Injury Waivers. This regulation is being rescinded with rates to be promulgated in the regulation at 101 CMR 359 in accordance with M.G.L. Chapter 118E, Sections 13C and 13D.

REGULATORY AUTHORITY: M.G.L. c. 118E

AGENCY CONTACT: Deborah Briggs  PHONE: 617-847-3302

ADDRESS: 100 Hancock Street, Quincy, MA 02171

Compliance with M.G.L. c. 30A

EMERGENCY ADOPTION - if this regulation is adopted as an emergency, state the nature of the emergency.

PRIOR NOTIFICATION AND/OR APPROVAL - If prior notification to and/or approval of the Governor, Legislature or others was required, list each notification, and/or approval and date, including notice to the Local Government Advisory Commission.

Executive Order 562 approval: January 10, 2017
Executive Order 145 notification: October 7, 2016

PUBLIC REVIEW - M.G.L. c. 30A sections 2 and/or 3 requires notice of the hearing or comment period, including a small business impact statement, be filed with the Secretary of the Commonwealth, published in appropriate newspapers, and sent to persons to whom specific notice must be given at least 21 days prior to such hearing or comment period.

Date of public hearing or comment period: November 14, 2016
FISCAL EFFECT - Estimate the fiscal effect of the public and private sectors.
For the first and second year: FY17: $4,245,484.50; FY18: $8,490,969
For the first five years: ________________________________
No fiscal effect: ________________________________

SMALL BUSINESS IMPACT - M.G.L. c. 30A section 5 requires each agency to file an amended small business impact statement with the Secretary of the Commonwealth prior to the adoption of a proposed regulation. If the purpose of this regulation is to set rates for the state, this section does not apply.

Date amended small business impact statement was filed: N/A

CODE OF MASSACHUSETTS REGULATIONS INDEX - List key subjects that are relevant to this regulation:
Elders, Health Care, Housing, Persons with Disabilities

PROMULGATION - State the action taken by this regulation and its effect on existing provisions of the Code of Massachusetts Regulations (CMR) or repeal, replace or amend. List by CMR number:
114.3 CMR 54.00 is being repealed

ATTESTATION - The regulation described herein and attached hereto is a true copy of the regulation adopted by this agency. ATTEST:

SIGNATURE: ________________ SIGNATURE ON FILE ________________ DATE: Jan 13 2017

Publication - To be completed by the Regulations Division

MASSACHUSETTS REGISTER NUMBER: S1331 DATE: 01/27/2017

EFFECTIVE DATE: 01/27/2017

CODE OF MASSACHUSETTS REGULATIONS
Remove these pages: 17, 18 1556.29 - 1556.34
Insert these pages: 17, 18 1556.29, 1556.30

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(114.3 CMR 54.00: RESERVED)
Regulation Filing  To be completed by filing agency

CHAPTER NUMBER:  239 CMR 3.00

CHAPTER TITLE:  Registration Requirements; Standards of Business and Professional Practice

AGENCY:  Board of Registration in Embalming and Funeral Directing

SUMMARY OF REGULATION:  State the general requirements and purposes of this regulation.

The purpose of 239 CMR 3.00 is to provide the basic rules for funeral director and embalmer registration and practice in Massachusetts. Specifically, this section provides 1) personal and business registration/licensing rules, 2) rules for operating funeral establishments, 3) rules governing the conduct of funeral directing and embalming, including sanitation, 4) ethical requirements, and 5) rules governing advertising.

REGULATORY AUTHORITY:  M.G.L. c. 112, § 85

AGENCY CONTACT:  Charles Kilb  PHONE:  617-727-2707

ADDRESS:  Div. of Prof. Licensure, 1000 Washington St., 7th Fl., Boston, MA 02118

Compliance with M.G.L. c. 30A

EMERGENCY ADOPTION -  if this regulation is adopted as an emergency, state the nature of the emergency.

PRIOR NOTIFICATION AND/OR APPROVAL -  If prior notification to and/or approval of the Governor, Legislature or others was required, list each notification, and/or approval and date, including notice to the Local Government Advisory Commission.

Local Government Advisory Committee - July 22, 2016
Massachusetts Register Publication - September 9, 2016
Boston Globe and Springfield Republican - August 29, 2016

PUBLIC REVIEW -  M.G.L. c. 30A sections 2 and/or 3 requires notice of the hearing or comment period, including a small business impact statement, be filed with the Secretary of the Commonwealth, published in appropriate newspapers, and sent to persons to whom specific notice must be given at least 21 days prior to such hearing or comment period.

Date of public hearing or comment period:  September 20, 2016

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FISCAL EFFECT -  

Estimate the fiscal effect of the public and private sectors.

For the first and second year:  No fiscal effect anticipated

For the first five years:  No fiscal effect anticipated

No fiscal effect:  No fiscal effect anticipated

SMALL BUSINESS IMPACT -  

M.G.L. c. 30A section 5 requires each agency to file an amended small business impact statement with the Secretary of the Commonwealth prior to the adoption of a proposed regulation. If the purpose of this regulation is to set rates for the state, this section does not apply.

Date amended small business impact statement was filed:  January 11, 2017

CODE OF MASSACHUSETTS REGULATIONS INDEX -  

List key subjects that are relevant to this regulation:
embalming, funeral directing, funeral homes, registration

PROMULGATION -  

State the action taken by this regulation and its effect on existing provisions of the Code of Massachusetts Regulations (CMR) or repeal, replace or amend. List by CMR number:
239 CMR 3.00 (amend)

ATTESTATION -  

The regulation described herein and attached hereto is a true copy of the regulation adopted by this agency.  

ATTEST:

SIGNATURE:  SIGNATURE ON FILE  DATE:  Jan 12 2017

Publication -  

To be completed by the Regulations Division

MASSACHUSETTS REGISTER NUMBER:  S1331  DATE:  01/27/2017

EFFECTIVE DATE:  01/27/2017

CODE OF MASSACHUSETTS REGULATIONS

Remove these pages:  1, 2  9 - 18.12
Insert these pages:  1, 2  9 - 30

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239 CMR 3.00: REGISTRATION REQUIREMENTS; STANDARDS OF BUSINESS AND PROFESSIONAL PRACTICE

Section

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3.01: Definitions

For purposes of 239 CMR, the following terms shall have the following meanings:

Advertising. The use of any marketing or public relations materials including but not limited to all print or electronic media, letters, signs, business cards, and stationery to promote the availability of services of a registrant of the Board or Licensed Funeral Establishment.

Apprentice Embalmer. Any individual engaged in learning the practice of embalming and funeral directing who is duly registered by the Board and who is registered to a Licensed Funeral Establishment and working under the instruction and Personal Supervision of a Type 3 or a Type 6 employed by the Type 3; provided that no individual shall begin to serve as an Apprentice Embalmer unless he or she has been registered as such by the Board pursuant to 239 CMR 3.02. An Apprentice Embalmer registration shall not be renewed after six years from the date the registration was initially granted unless given special Board approval.

Board. The Massachusetts Board of Registration in Embalming and Funeral Directing established pursuant to M.G.L. c. 13, § 29.

Embalmer. Any individual engaged, or holding himself or herself out as engaged, in the Profession and Business of Embalming and Funeral Directing, whether on his or her own behalf or in the employ of a Type 3.

Funeral Director. Any individual engaged, or holding himself or herself out as engaged, in the Profession and Business of Embalming and Funeral Directing.

Funeral Home Assistant. Any individual duly registered as a Funeral Home Assistant by the Board who is registered to and working under the Personal Supervision of a Type 3 (that Type 3 may delegate such supervision to an employed Type 6); provided that no individual shall begin to serve as a Funeral Home Assistant unless he or she has been registered as such by the Board pursuant to 239 CMR 3.02. A Funeral Home Assistant may perform only the services outlined in 239 CMR 3.18.
3.01: continued

Licensed Funeral Establishment. A fixed place or establishment privately owned or maintained by a person, partnership, corporation, association or other organization which has been duly registered by the Board pursuant to M.G.L. c. 112, § 83 and which is located, constructed, equipped and operated for the purpose of providing sanitary handling, preparation, disposition and care of dead human bodies.

LLC. Any "limited liability company" or "foreign limited liability company", as defined by M.G.L. c. 156C, § 2.

LLP. Any "registered limited liability partnership" or "foreign registered limited liability partnership", as defined in M.G.L. c. 108A, § 1.

Person. An individual; a corporation; a partnership; a limited liability company or foreign limited liability company as defined in M.G.L. c. 156C, § 1; a registered limited liability partnership or foreign registered limited liability partnership as defined in M.G.L. c. 108A, § 1; a society; an association; an organization; or any other business entity, however named.

Personal Supervision. Being supervised by an individual in the same building unless the only activity being performed is removing human remains under the orders of a supervisor and performed within the scope of the registration held. For purposes of conferences with consumers for the purposes of making funeral or pre-need arrangements, Personal Supervision of Apprentice Embalmers must be provided within the same room. For purposes of embalming, an Apprentice Embalmer must have same room supervision only for the first 25 dead human bodies.

Profession and Business of Embalming and Funeral Directing. Includes, but shall not be limited to, the sale or provision of any of the following goods or services:
(a) consulting with members of the general public about, and/or making arrangements concerning the disposition of human remains, including arrangements for cremation for compensation;
(b) removing a human body from the place of death;
(c) transporting human remains;
(d) embalming;
(e) performing restorative and cosmetic work on human remains, including hairdressing;
(f) dressing, and retail sale of clothing for use in dressing, human remains;
(g) casketing of human remains;
(h) the sale of caskets, either at retail or at wholesale, and/or rental of caskets to the general public;
(i) arranging for disposition of flowers used in funerals or funeral services;
(j) making arrangements for obituaries and death notices in newspapers, the internet, radio and television;
(k) making cemetery, cremation and/or anatomical gift arrangements at the request of the decedent or the decedent's family;
(l) providing hearses, flower vehicles, limousines and sedans in connection with a funeral;
(m) arranging for services and officiant at the interment of human remains;
(n) providing assistants during visiting hours and at the funeral service, and for other funeral service related functions and responsibilities;
(o) securing and processing required documents, including but not limited to death certificates, burial/transfer permits, certified copies of death certificates, and visas for foreign shipment of human remains;
(p) making arrangements with medical examiners;
(q) providing acknowledgement cards, register books, local and long distance telephone messages and telegrams in connection with a funeral;
(r) preparing, negotiating or executing any pre-need funeral contract, or receiving, controlling or managing any funds tendered as payment for the Funeral Goods and/or Services identified in such a pre-need funeral contract, as defined in 239 CMR 4.00: Pre-need Funeral Contracts and Arrangements;
(s) disposition of ashes or cremated remains; and
3.01: continued

(i) The Profession and Business of Embalming and Funeral Directing shall also include engaging in such other activities, including Advertising, as are considered to be a part of the business, practice, science or profession of embalming or funeral directing, as commonly practiced.

Type 3. A Funeral Director and Embalmer who is duly registered as a Type 3 by the Board pursuant to M.G.L. c. 112, § 83 and licensed by a city or town pursuant to M.G.L. c. 114, § 49, who meets the qualifications outlined in 239 CMR 3.02(3)(a).

Type 6. A Funeral Director and Embalmer who is duly registered as a Type 6 by the Board pursuant to M.G.L. c. 112, § 83, who meets the qualifications outlined in 239 CMR 3.02(2) and who has been sworn in by the Board. A Type 6 may practice embalming, but may otherwise practice funeral directing only when holding a license issued by a city or town pursuant to M.G.L. c. 114, § 49 and when working as an employee in a Licensed Funeral Establishment. A Type 6 who performs funeral services when not so employed shall be considered acting outside the scope of his or her registration and shall face disciplinary action. Said registrants may not sign death certificates and may utilize only stationary, or other funeral related contracts or documents on behalf of his or her employing Licensed Funeral Establishment and Type 3. Type 6s may conduct pre-need funeral arrangements only pursuant to 239 CMR 3.04(5).

3.02: Registration Requirements and Examinations

(1) Registration as an Apprentice Embalmer. Any individual desiring to become an Apprentice Embalmer shall make application to the Board on a form provided for that purpose and pay any applicable fees. Said application shall contain the following:

(a) satisfactory written proof that the applicant is of good moral character;
(b) satisfactory written proof that the applicant holds a high school diploma or its equivalent;
(c) satisfactory written proof that the applicant is or will be employed on a full-time basis (at least 30 hours per week, up to half of which may be on call hours) by only one business entity which operates one or more Licensed Funeral Establishments in Massachusetts;
(d) the name and address of the business entity which employs or will employ the applicant;
(e) the name(s) and registration number(s) of the Type 3(s) to whom the Licensed Funeral Establishment's certificate was issued; and
(f) satisfactory written proof that the applicant has completed OSHA training related to biohazards/blood borne pathogens within 30 days prior to applying for this registration and for each year so registered.

(2) Registration as a Type 6. Any individual desiring to become a Type 6 shall make application to the Board on a form provided for that purpose and pay any applicable fees. Said application shall contain the following:

(a) satisfactory written proof that the applicant is 18 years of age or older;
(b) satisfactory written proof that the applicant is of good moral character;
(c) satisfactory written proof that the applicant holds a high school diploma or its equivalent;
(d) satisfactory written proof that the applicant has served as an Apprentice Embalmer for a period of not less than two years under the instruction and Personal Supervision of a Type 3;
(e) satisfactory written proof that the applicant has, during the period of service as an Apprentice Embalmer, as required under 239 CMR 3.02(2)(e), personally embalmed not less than 50 dead human bodies;
(f) satisfactory written proof that the applicant has attended at least 25 funeral or pre-need conferences with consumers;
(g) satisfactory written proof that the applicant has achieved an associate's degree in mortuary science from a program meeting the accreditation requirements of the American Board of Funeral Service Education, or the equivalent thereof as determined by the Board;
(h) satisfactory written proof that the applicant has achieved a passing grade on the examination prescribed by the Board; and
(i) a certification that said applicant will act as a Funeral Director only in the employ of a Type 3 in a Licensed Funeral Establishment where the applicant shall be conducting, directing, and keeping up said establishment. Applicants must also agree to notify the Board at all times where they are employed utilizing a certification approved by the Board.

(3) Registration as a Type 3. Any Type 6 desiring to become a Type 3 shall make application to the Board on a form provided for that purpose and pay any applicable fees. Said application shall contain satisfactory written proof that the applicant holds an ownership interest of at least 10% in the business entity which holds the funeral establishment certificate for, and operates, the Licensed Funeral Establishment to which he or she will be registered. Where such business entity is a corporation, the applicant must show that he or she owns at least 10% of the authorized and issued stock of that corporation. Where the Licensed Funeral Establishment is operated by a partnership, the applicant must show that he or she owns at least a 10% share of that partnership.

(4) Registration as a Funeral Home Assistant. Any individual desiring to become a Funeral Home Assistant shall make application to the Board on a form provided for that purpose and pay any applicable fees. Said application shall contain the following:

(a) satisfactory written proof that the applicant is of good moral character;

(b) satisfactory written proof that the applicant holds a high school diploma or its equivalent;

(c) satisfactory written proof that the applicant is or will be employed by only one sole proprietorship, partnership, corporation, association, limited liability partnership, limited liability company, or other business entity which operates one or more Licensed Funeral Establishments in Massachusetts;

(d) the name and address of the business entity which employs or will employ the applicant;

(e) the name and registration number of the Type 3 to whom the applicant will be registered, and who will be responsible for providing supervision of the applicant's activities as Funeral Home Assistant;

(f) satisfactory written proof that the applicant has completed OSHA training related to biohazards/blood borne pathogens within 30 days prior to applying for the registration; and

(g) satisfactory written proof that the applicant meets one of the following educational criteria:

1. holds an associate's degree in mortuary science from a program meeting the accreditation requirements of the American Board of Funeral Service Education;

2. has completed Board approved training in the following areas:
   a. General Public Health;
   b. Ergonomics; and
   c. Funeral Service Law and Ethics.

3. Applicants who have funeral related experience or education that do not fall within the specific provisions of 239 CMR 3.02(6)(g)1. or 2. may submit to the Board a written request that such experience or education be considered for approval as the equivalent of the education requirements.

(5) Inactive Status Registrations. A Type 3 or Type 6 who does not engage in the Profession and Business of Embalming and Funeral Directing in the Commonwealth may have his or her registration placed on inactive status by requesting such status in writing in a form prescribed by the Board. To maintain an inactive status registration, the Type 3 or Type 6 must annually renew his or her registration under inactive status and complete normally required continuing education. While registered under inactive status, the Type 3 or Type 6 shall no longer be eligible to engage in the Profession and Business of Embalming and Funeral Directing in the Commonwealth. Engaging in the Profession and Business of Embalming and Funeral Directing while registered under inactive status shall constitute unregistered practice under M.G.L. c. 112, § 65(b).
3.02: continued

(6) **Reinstatement of a Lapsed Registration.** Pursuant to M.G.L. c. 112, § 84, where a registrant fails or is unable to renew his or her registration within one year of its expiration, the former registrant shall be required to provide satisfactory proof of the completion of continuing education Contact Hours required for each year of lapsed registration status and meet the provisions of M.G.L. c. 112, § 83 relative to original registration in order to reinstate his or her registration which includes payment of applicable fees and examination.

(7) **Registration by Endorsement.** An individual who holds out of state credentials may be permitted to take the Massachusetts examination without further apprentice requirements upon written petition to the Board showing the following:
   
   (a) The applicant holds a license/certificate/registration in another state in funeral directing and embalming which is valid and in good standing and is substantially equivalent to the Massachusetts Funeral Director Registration; 
   
   (b) The applicant holds an associate's degree in mortuary sciences; and 
   
   (c) Evidence that the applicant is of good moral character.

3.03: Employment of Apprentice Embalmers

A Licensed Funeral Establishment may employ Apprentice Embalmers to prepare or assist in the preparation of dead human bodies for burial, cremation or other final disposition, provided that all of the following conditions are met:

(1) Each Apprentice Embalmer so employed is duly registered with the Board pursuant to 239 CMR 3.02.

(2) Each Apprentice Embalmer is employed on a full-time basis (at least 30 hours per week, up to half of which may be on call hours) by only one business entity which operates one or more Licensed Funeral Establishments in the Commonwealth of Massachusetts.

(3) Each Apprentice Embalmer so employed is registered to a Licensed Funeral Establishment operated by the business organization which employs that Apprentice Embalmer. The Apprentice Embalmer shall work at all times under the instruction and Personal Supervision of a Type 3 employed by the business organization which operates said Licensed Funeral Establishment and/or a Type 6 employed by the Type 3.

(4) The Type 3(s) to whom the funeral establishment certificate was issued for the Licensed Funeral Establishment under which that Apprentice Embalmer is registered as well as any supervising Type 6(s) shall also be held responsible for all acts or omissions of that Apprentice Embalmer which occur in the course of that Apprentice Embalmer's employment with that entity.

(5) Each Apprentice Embalmer so employed complies with any and all applicable requirements of M.G.L. c. 112, §§ 61 through 65A, 82 through 87, and 239 CMR;

(6) The business entity which employs an Apprentice Embalmer notifies the Board, in writing, within seven business days of any change in the name and address of the Licensed Funeral Establishment(s) in which each such Apprentice Embalmer works.

(7) If there is a change in the employment status of any such Apprentice Embalmer, the business entity which employed that Apprentice Embalmer submits to the Board a written affidavit indicating the length of time that the Apprentice Embalmer was employed as such.

(8) The total number of Apprentice Embalmers employed by any one entity does not exceed one Apprentice Embalmer for each 50 cases, or fraction thereof, for which funeral goods or services were provided by that entity during the preceding two calendar years.

(9) The address of the license for an Apprentice Embalmer shall be the Licensed Funeral Establishment where the Apprentice Embalmer is employed.
3.03: continued

(10) Upon termination of employment, an Apprentice Embalmer registration shall become null and void within 30 days, unless the Apprentice Embalmer secures employment with another Licensed Funeral Establishment.

(11) Apprentice Embalmers may perform the removal or transfer of a dead human body in a vehicle registered as a hearse after requisite permission for such a removal has been obtained by the supervisor (Type 3 or Type 6) so long as said supervisor has personally accompanied the registrant for the first 20 removals/transfers performed during the course of their employment as an Apprentice Embalmer.

(12) Upon the request of the Board, or a duly authorized representative thereof, a Licensed Funeral Establishment shall furnish to the Board satisfactory written proof of employment for any Apprentice Embalmer employed by said Licensed Funeral Establishment and registered under 239 CMR 3.03.

3.04: Ownership of Licensed Funeral Establishments; Disclosure of Ownership

(1) A business entity may engage in the Profession and Business of Embalming and Funeral only if:

(a) a controlling interest, reflected by a majority of authorized stock in said entity, is held by one or more Type 3(s);

(b) the business of that entity is under the direction and control of a Type 3, who shall be held responsible for ensuring that the entity complies with all applicable laws and regulations governing embalming and funeral directing; and

(c) that entity meets the insurance requirements of 239 CMR 3.17.

(2) Display of Ownership Information.

(a) Every Licensed Funeral Establishment shall display on a sign, located either immediately outside or immediately inside the main entrance, all of the following ownership information:

1. the name of every individual who holds at least a 10% ownership interest in the corporation, limited liability company, partnership, limited liability partnership, association, organization, or other business entity which operates said Licensed Funeral Establishment;

2. the names of any and all corporations, limited liability companies, partnerships, or limited liability partnerships which either directly or indirectly hold an ownership interest of 10% or more in the corporation, limited liability company, partnership, limited liability partnership, association or other business entity which operates that Licensed Funeral Establishment; and

3. The lettering on said signs shall be readily legible.

(b) Where an ownership interest of 10% or more in a Licensed Funeral Establishment is held, either directly or indirectly, by one or more corporations, limited liability companies, partnerships or limited liability partnerships, the name, complete headquarters address and telephone number of each such corporation, limited liability company, partnership or limited liability partnership shall also be listed on the business letterhead, invoices, and all Advertising used by said Licensed Funeral Establishment.

(3) Changes in Name, Ownership, or Location of a Licensed Funeral Establishment.

(a) Whenever the ownership of a Licensed Funeral Establishment changes, the establishment registration shall be deemed cancelled pursuant to M.G.L. c. 112, § 83.

(b) A change of ownership shall be deemed to occur whenever the Type(s) originally owning or holding more than a 50% stake in an entity owning the establishment are transferring ownership in the funeral home or entity owning the funeral home such that he/she/they no longer hold more than a 50% controlling interest in the home/entity. For purposes of changes of ownership, a Type 3 registered to a Licensed Funeral Establishment for ten years or more at the time of a transfer in ownership shall be deemed to be an original owner by the Board.

(c) A Licensed Funeral Establishment must obtain a new establishment certificate from the Board whenever the name or location of the establishment is changing.
3.04: continued

(d) A Type 3 and the Licensed Funeral Establishment to which he or she is registered shall notify the Board where said Type 3 no longer maintains at least a 10% ownership interest as required under 239 CMR 3.02. Said notice to the Board shall be made within 30 days of the date in which the Type 3 no longer maintains at least a 10% ownership interest.

(e) At least 30 days prior to a closure or change of ownership, a Licensed Funeral Establishment must submit to the Board a closure or change of ownership form which includes but is not limited to information relative to pre-need accounts and cremated remains held by the Licensed Funeral Establishment. Said form shall be prescribed by the Board.

(f) For purposes of 239 CMR 3.04(3)(a) through (f), should a registered Type 3 pass away, the direct passage of their ownership interest in a funeral establishment to a widow or widower shall not be deemed a change of ownership. However, if said widow or widower does not hold a Funeral Director registration, and no other original owners of the establishment are so registered, the widow/widower must obtain the services of a validly registered Type 3 to continue operating the funeral establishment.

(4) Temporary Absence of a Type 3.

(a) A Type 6 may operate a funeral home during the limited absence of a Type 3 for up to 90 days so long as the funeral home is still subject to the direction and ownership of the Type 3.

(b) The Board must be notified in writing by the Type 3 whenever he or she will have a Type 6 fill in for him or her in excess of 30 days.

(c) Notwithstanding any other restrictions in 239 CMR 3.00, the Board may, after a majority vote, allow a Type 6 to fill in for a Type 3 for a period in excess of 90 days for good cause shown.

(5) Pre-need Funeral Arrangements. A Type 6 may conduct pre-need funeral arrangements at any Licensed Funeral Establishment owned by their employer(s) under the following conditions:

(a) The Type 6 has been employed by the Type 3 at the subject Licensed Funeral Establishment for at least 30 days; and

(b) The Type 6 has written authorization from the employing Type 3 that they have been employed for at least 30 days and may conduct pre-need funeral arrangements. A copy of this authorization must be available for Board review upon request. Notwithstanding this authorization, the employing Type 3 shall remain obligated to review all pre-need contracts entered into by a Type 6.

(6) Closing of a Funeral Establishment.

(a) The Type 3(s) owning a Licensed Funeral Establishment must notify the Board within ten calendar days upon the closure of that funeral establishment.

(b) With regards to pre-need funeral arrangements, a closing Licensed Funeral Establishment must meet the requirements of 239 CMR 4.03(1).

(c) All signage must be removed or covered upon closure of the Licensed Funeral Establishment or cancellation of the establishment registration.

(d) All advertisements for a Licensed Funeral Establishment, including websites, must cease and/or be taken down upon the closure of said establishment.

3.05: Inspections; Powers and Duties of Investigators

(1) A Board investigator shall have the right to enter into and inspect any Licensed Funeral Establishment at any time for the purpose of inspecting such records and conducting such investigations as may reasonably be necessary to ensure that the Licensed Funeral Establishment, and its agents or employees, are in compliance with all applicable requirements of M.G.L. c. 112, §§ 61 through 65A, 82 through 87, and 239 CMR.

(2) A Board investigator may visit any place where the operation of embalming is being conducted or where a funeral is in process of being directed, provided, however, that such visitation shall be made in a respectful and decorous manner.

(3) A Board investigator shall in no way be connected with the work or business of Type 3 or Type 6 in any Licensed Funeral Establishment.
3.05: continued

(4) Interference with or obstruction of the Board or any investigator authorized by the Board in the performance of their respective duties by a registered person, shall be considered sufficient cause for suspension or revocation of such registration.

3.06: Establishments

(1) Every Licensed Funeral Establishment shall:

(a) be accessible to individuals with disabilities to the extent required by all applicable provisions of 521 CMR: Architectural Access Board, M.G.L. c. 112, §§ 61 through 65A, 82 through 87, and 239 CMR;

(b) include a chapel sufficiently large and sufficiently equipped for the conduct of an average funeral service; such chapel shall contain a minimum of 300 square feet of floor space;

(c) not contain any living quarters on the floor used for the Licensed Funeral Establishment without the prior written permission of the Board. Said permission shall not be granted unless the applicant provides satisfactory written assurances that such living quarters will not be used for the conduct of any funeral or visitation;

(d) include a preparation room equipped with sanitary flooring, a flush rim sink, floor drain and ventilation, a reduced pressure backflow preventer or air gap separation at the meter or property line, and the necessary equipment, instruments and supplies for the preparation and embalming of dead human bodies for burial and transportation. Such preparation room and equipment shall comply with all applicable requirements of 239 CMR 3.07 and 3.12, and all applicable requirements of other federal, state and local laws, including but not limited to all applicable regulations of the United States Occupational Safety and Health Administration;

(e) contain such toilets, lavatories and other sanitary facilities for men and women as may be required by applicable federal, state and local laws and regulations;

(f) where the Licensed Funeral Establishment consists of more than one building or more than one lot of land, ensure that said buildings and/or lots shall be adjoining and connecting (239 CMR 3.06(1)(f) shall not apply to any Licensed Funeral Establishment opened prior to December 3, 1943 unless there has been a change of address for said establishment since that date);

(g) where the Licensed Funeral Establishment was established after December 1, 1949, make removals of dead human bodies into the Licensed Funeral Establishment completely concealed from public view; and

(h) meet the insurance requirements of 239 CMR 3.17.

(2) No funeral establishment certificate shall be granted to any Licensed Funeral Establishment unless the owners of said establishment certify, in writing and under the pains and penalties of perjury, that said Licensed Funeral Establishment is in compliance with all applicable requirements of 521 CMR: Architectural Access Board and all applicable requirements of the United States Occupational Safety and Health Administration. The Board may require proof of such compliance by building officials, licensed engineers, or licensed architects. Adherence to this section may be waived if the establishment obtains a variance from the Architectural Access Board or if the establishment enters into a compliance plan agreed to by the Board.

(3) Existing Licensed Funeral Establishments not meeting the rules and regulations of 521 CMR: Architectural Access Board because they are grandfathered under old rules do not need to conform to the newer accessibility rules adopted by 239 CMR 3.00 unless:

(a) the funeral home needs a new establishment certificate due to a change in ownership or location (name changes alone do not trigger this requirement);

(b) compliance is mandated by the Architectural Access Board or some other local, state, or federal authority; or

(c) other changes are made to the laws applicable to the establishment ending said grandfathering.

(4) Funeral Establishments that require renovations creating a violation of 239 CMR 3.06 may continue operating if first entering into a written compliance agreement with the Board. Such agreements are fully discretionary on the part of the Board, the ability to grant such an agreement shall not be deemed to grant funeral establishments any right or entitlement to such an agreement.
3.07: Preparation Room

(1) Every Licensed Funeral Establishment shall have at least one preparation room for the preparation for burial or other disposition of all dead human bodies. Said preparation room shall be at least 12’ x 14’ in size for any new construction after January 1, 2008. Preparation rooms shall be locked at all times.

(2) No person shall be allowed in the preparation room while a dead human body is being prepared for burial or other final disposition except persons duly registered or licensed by the Board pursuant to M.G.L. c. 112, §§ 82 through 87, public officials engaged in the discharge of their official duties, students who are duly enrolled in a recognized mortuary school, and members of the decedent's immediate family or persons authorized by them in writing. The provisions of 239 CMR 3.07(2) shall be printed on a placard and conspicuously displayed or posted on the exterior of each door to each preparation room in the Licensed Funeral Establishment. Failure to post said placards shall constitute grounds for disciplinary action by the Board.

(3) Each preparation room in a Licensed Funeral Establishment shall be equipped with a tile or cement floor. Rubber tile, rubber matting or linoleum may be used provided that it is not less than 3/16” thick, and that, if it is used as a floor covering, it is laid over a floor constructed of cement or other waterproof substance. Wooden floors overlaid with metal or other waterproof materials may be accepted in lieu of cement floors.

(4) Each preparation room shall also contain the following: one standard-type sanitary operating table; one flush-rim sink, one floor drain; one reduced pressure or air gap separation backflow prevention device located at the water meter or property line; one sanitary waste receptacle which is opened by a foot pedal; and a standard-type instrument sterilizer.

(5) Every preparation room shall comply with all applicable federal, state and local laws, regulations and ordinances regarding ventilation and, in the absence of such laws, shall be ventilated so as to ensure that no deleterious odors are allowed to remain therein and that the odors there from are not permitted to enter into any other part of the Licensed Funeral Establishment or any part of any adjoining premises.

(6) An embalmer's kit shall contain, at a minimum, all items which are reasonably necessary for proper embalming and/or preparation of a dead human body for burial, cremation or other final disposition in light of currently accepted standards of professional practice.

(7) All equipment which is used to aspirate or remove blood or other potentially infectious materials, as defined in 239 CMR 3.12, or which comes into contact with blood or other potentially infectious materials, shall be maintained and used in a manner which prevents conversion of blood or other potentially infectious materials to aerosol or airborne particles.

3.08: Office of the Chief Medical Examiner

(1) Every Type 3 and Type 6 shall report to the medical examiner all deaths which he or she, as an authorized public official, should investigate pursuant to the reporting requirements in M.G.L. c. 38. Persons registered by the Board shall consult the medical examiner of the district prior to making any removal when in doubt.

(2) No embalming fluid or any preparation substitute therefore shall be injected into the body of any person unless the requirements of M.G.L. c. 38, § 12 are met.

3.09: Control Over Arrangements and Disposition of Human Remains

(1) Every registrant and Licensed Funeral Establishment shall comply with 239 CMR 3.09(1)(a) through (c) with respect to control over funeral arrangements and disposition of human remains:
3.09: continued

(a) If a Licensed Funeral Establishment is a party to a pre-need funeral services contract, as defined in 239 CMR 4.01: Definitions, for the benefit of the deceased person, and said contract is still in effect at the time of that person's death, the terms of that contract shall control the nature of the funeral goods and services to be provided, the manner in which funeral services are to be conducted for the deceased, and the final disposition of the deceased person's remains to the full extent provided in that contract. No Licensed Funeral Establishment, nor any of its agents or employees, may cancel or materially alter any of the arrangements specified in that contract, even if requested to do so by a member of the deceased person's family or any other person, unless:

1. compliance with the terms of the original contract would result in a violation of any applicable federal, state or local law or regulation; or
2. the Licensed Funeral Establishment is ordered to do so by a court of competent jurisdiction.

(b) Where there is no pre-need funeral services contract with the Licensed Funeral Establishment in effect at the time of death for the benefit of the deceased person, or to the extent that any such contract does not fully specify the nature of the funeral arrangements to be provided, said License Funeral Establishment and its agents or employees shall give effect first to any wishes of the deceased person regarding the nature of the funeral goods and services to be provided, the manner in which funeral services are to be conducted, and/or the final disposition of the deceased person's remains, which have been expressed in any written document which was signed by the deceased person in the presence of a witness. In the absence of an order from a court of competent jurisdiction to the contrary, said written document shall be sufficient legal authorization for implementation of the arrangements specified therein.

(c) To the extent that there is no pre-need funeral services contract in effect at the time of death for the benefit of the deceased person, and no other valid written document indicating the wishes of the deceased person with respect to the nature of the funeral goods and services to be provided, the manner in which funeral services are to be conducted, or the final disposition of the deceased person's remains, the Licensed Funeral Establishment and its agents or employees shall follow the directions of the deceased person's surviving kin, in the following order of priority:

1. the surviving spouse of the deceased;
2. the surviving adult children of the deceased;
3. the surviving parent(s) of the deceased;
4. the surviving brother(s) or sister(s) of the deceased;
5. the guardian of the person of the deceased at the time of his or her death;
6. any other person authorized or obligated by law to dispose of the remains of the deceased.

If there is more than one member of a class, the directions of a majority shall prevail; in the event of a tie, the decision of a court of competent jurisdiction will be necessary. Provided, however, that with respect to receiving authorizations to release a decedent from the Office of the Chief Medical Examiner, the Office of the Chief Medical Examiner may require different or additional signatures for release.

3.10: Removal, Preparation and Transportation - Other General Requirements

(1) For purposes of 239 CMR 3.10, the following terms shall have the following meanings:

**Remove or Removal.** The moving of a dead human body from a home, hospital, or other place of death to a Licensed Funeral Establishment for the purpose of preparing it for burial or cremation.

**Ship or Shipment.** To convey a dead human body by train, boat, airplane, express or motor freight, or other means of transportation, either within, into, or out of the Commonwealth of Massachusetts after said body has been prepared for burial or cremation.

**Transport.** To convey a dead human body in a closed hearse or other vehicle registered as a hearse used exclusively for the purpose of transporting dead human bodies or funeral equipment, either within, into or out of Massachusetts for any purpose other than that referred to in the definition of remove or ship in 239 CMR 3.10(1)(a).
3.10: continued

(2) In order to recognize the inherent dignity of the human body and protect the public health, sufficient preservation and/or disinfection and refrigeration shall be applied to each dead human body to guarantee temporary protection against excessive decomposition.

(3) Removals shall not be made from any place of death unless a death certificate or other appropriate death pronouncement form, signed by a duly licensed physician, a medical examiner or another person duly authorized by law, is in the possession of the Type 3. In the absence of such a pronouncement, removal may take place with the verbal approval by authorized/legally appropriate government authorities unless otherwise prohibited by M.G.L. c. 114, § 45. Such approval should be documented, in writing thereafter, with the details of said approval.

(4) No Licensed Funeral Establishment, nor any agent or employee thereof, shall handle, move or transport any dead human body except under the supervision of, and with the personal attendance in the vehicle of, a person registered by the Board.

(5) No person registered by this Board or his or her agent or employee shall remove, transport or otherwise convey a dead human body except in a closed hearse or other vehicle used exclusively for the purpose of transporting dead human bodies within the Commonwealth of Massachusetts. Said vehicles shall be designed or equipped in such a manner as to ensure that any dead human body transported therein is concealed from public view. Said vehicles shall be registered and designated as hearses by the Registry of Motor Vehicles. A person duly registered by this Board shall be in personal attendance in the vehicle during any removal, transportation or conveyance of a dead human body.

(6) Vehicles registered and equipped as hearses and bearing hearse plates may be used only for removal or transportation of dead human bodies, transportation of flowers, transportation of funeral equipment, transportation of a clergyperson or other funeral service officiant if such is the custom of the deceased, and/or transportation of other Licensed Funeral Establishment personnel.

(7) If a body has not been embalmed, and the body is to be buried or cremated within the Commonwealth of Massachusetts within 50 hours after death, said body shall be prepared by a Type 3, Type 6, or Apprentice Embalmer. Said registrant shall thoroughly wash, disinfect and sanitize said body; close all orifices with treated absorbent cotton; envelop the entire body with clean sheeting or with provided clothing; and take any other appropriate steps necessary to ensure that there will be no offensive leakage or odors from the body prior to burial, cremation or other final disposition. If a body has not been embalmed, and said body is to be buried or cremated within the Commonwealth of Massachusetts, but said burial or cremation will not occur within 50 hours after death, said body shall be prepared by Type 3, Type 6, or Apprentice Embalmer, and shall also be maintained at a temperature between 34°F and 39°F. If the body cannot be maintained at these temperatures, the body must be embalmed unless directed by the client not to in writing. In cases of advanced decomposition where public health may be an issue, a local board of health may direct a funeral director to embalm a body notwithstanding the direction of a client.

(8) A body, once interred or placed in a cemetery receiving vault, shall not be transported or shipped from the cemetery where it lies unless it is encased in a hermetically sealed or air-tight casket, box or container. A body embalmed by a Type 3, Type 6, or Apprentice Embalmer and placed in a receiving vault for not over 30 days shall not be subject to the requirements of 239 CMR 3.10.

(9) In all cases of cremation, a suitable casket or alternative container shall be used. If a casket is used, that casket may later be re-used as long as:

(a) the casket is equipped with a removable liner or insert;
(b) the removable liner or insert is completely removed and replaced with a new liner or insert after each use;
(c) no such casket is used or re-used after any non-removable portion of that casket has been soiled, stained or otherwise contaminated by or from any human remains placed therein, or has been placed within a rental casket insert;
3.10: continued

(d) the customer who rents or re-uses that casket has been informed, in writing, that the casket may have been used previously and that it will be reclaimed by the Licensed Funeral Establishment from which he or she has rented or obtained it immediately prior to final disposition of the deceased; and

(e) the customer who rents or re-uses that casket has signed a written disclosure or authorization form verifying that he or she has received all of the information required by 239 CMR 3.10(10) in writing and that he or she authorizes the Licensed Funeral Establishment to use the removable liner or insert selected by him or her for the final disposition of the deceased.

3.11: Conduct of Funerals

(1) All funerals conducted by a Licensed Funeral Establishment shall be conducted under the direct supervision of a Type 3 or Type 6.

(2) Removal, Viewing, Identification and Embalming Procedures.

(a) When a Licensed Funeral Establishment is called upon to remove a body and accept responsibility for it, said body shall be held at said Licensed Funeral Establishment, or at such other location as the Medical Examiner may direct, until such time as the body can be buried or cremated in accordance with applicable state or local laws.

(b) A Licensed Funeral Establishment which has accepted responsibility for the care of any dead human body may properly require that said body be viewed and identified by the next of kin or duly authorized legal representative of the deceased at said Licensed Funeral Establishment prior to any cremation, burial, medical school donation or anatomical gift donation, if said body has not previously been viewed and identified by said next of kin or duly authorized legal representative elsewhere.

(c) Required Forms. Licensed Funeral Establishments must develop and utilize written disclosure/authorization forms to be obtained by Type 3s and Type 6s as follows:

1. A Licensed Funeral Establishment shall obtain written permission to embalm, or a written acknowledgment of the decision not to embalm, from the next of kin or the duly authorized legal representative of the deceased, for each dead human body which is placed under its care and for which it has accepted responsibility.

2. Where a dead human body is under the care of a Licensed Funeral Establishment which has accepted responsibility for it, and said body is to be cremated, said Licensed Funeral Establishment shall also obtain written authorization for cremation of said body from the medical examiner or similarly authorized person, in addition to the normally-required physician certifications, prior to cremation of said body.

(d) All arrangements for a funeral, including obtaining any required permissions or authorizations, must be made by Type 3s or Type 6s, provided, however, that Apprentice Embalmers and Funeral Home Assistants may obtain removal and embalming authorization forms.

(e) For purposes of 239 CMR 3.11(2)(a) through (d) all identifications, authorizations and permissions shall be obtained first from the decedent's next of kin, in the order of priority specified under 239 CMR 3.09(1)(c). If none of the next of kin are available, said identifications, authorizations or permissions may then be obtained from the duly authorized legal representative of the deceased, the individual designated as the health care proxy for the deceased pursuant to M.G.L. c. 201D, or the individual possessing a power of attorney for health care executed by the decedent.

(3) Refreshments.

(a) No alcoholic beverages may be served in a Licensed Funeral Establishment.

(b) No individual registered with the Board, or other agent or employee of any Licensed Funeral Establishment, shall prepare any food or beverages to be served in connection with any burial or funeral.

(c) No individual registered with the Board, or other agent or employee of any Licensed Funeral Establishment, shall serve any food or beverages in connection with any burial or funeral unless all of the following conditions are met:
3.11: continued

1. any food and beverages served in connection with any burial or funeral must be provided by a third party vendor or supplier meeting the requirements of 105 CMR 590.000: State Sanitary Code Chapter X – Minimum Sanitation Standards for Food Establishments;
2. the provision of food and beverages served in connection with any burial or funeral must be treated as a "cash advance item" and no Licensed Funeral Establishment shall bill or cause to be billed, the cost for the food and beverages unless the net amount billed for it by the Licensed Funeral Establishment is the same amount as is billed the Licensed Funeral Establishment by the third party vendor or supplier, this shall not bar Funeral Establishments from directly charging for facility usage and cleaning;
3. there shall be no direct opening between the preparation room and any room where food or beverages are stored or served;
4. food and beverages shall be served in an area separate and apart from where dead human bodies are displayed and in a manner that does not interfere with public health; and
5. the Licensed Funeral Establishment shall be in compliance with all other applicable local, state, and federal laws.

(4) Disposition of Cremated Human Remains. Licensed Funeral Establishments shall dispose of cremated human remains as follows:
(a) Upon receipt of any cremated human remains, the Licensed Funeral Establishment receiving such cremated remains shall contact the next of kin or duly authorized representative of the decedent who made the cremation arrangements.
(b) The Licensed Funeral Establishment shall deliver such cremated remains only to the next of kin or duly authorized representative of the decedent who made the cremation arrangements and obtain a signed acknowledgment of receipt from said next of kin or duly authorized representative.
(c) If, after a period of at least ten months from the date of cremation, the cremated remains of a deceased person have not been claimed by the next of kin or the duly authorized representative of the decedent, the Licensed Funeral Establishment shall send written notice, by certified mail, return receipt requested, to the next of kin or duly authorized representative of the decedent at their last known address as shown in the records of the Licensed Funeral Establishment. If, after an additional period of two months from the date on which that notice was mailed, the cremated remains still have not been claimed, the Licensed Funeral Establishment may dispose of the cremated remains as provided in M.G.L. c. 114, § 43M. The Licensed Funeral Establishment shall maintain a permanent written record of this final disposition.
(d) All cremated human remains in the possession of a Licensed Funeral Establishment shall be stored on the premises of the Licensed Funeral Establishment until disposition is made in accordance with 239 CMR 3.11(4).

3.12: Required Precautions Against Bloodborne and Other Pathogens

(1) For purposes of 239 CMR 3.12, the following terms shall have the following meanings:

Blood. Human blood, human blood components, and products made from human blood.

Bloodborne Pathogens. Pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV).

Contaminated. The presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.

Contaminated Laundry. Laundry which has been soiled with blood or other potentially infectious materials.

Occupational Exposure. Actual or reasonably anticipated skin, eye, mucous membrane or parenteral contact with blood or other potentially infectious materials which results or may result from the performance of an employee's duties.
Other Potentially Infectious Materials:
(a) the following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva, urine, feces, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids;
(b) any unfixed tissue or organ (other than intact skin) from a human (living or dead); and
(c) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions, and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

Personal Protective Equipment. Specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes not intended to function as protection against a hazard are not considered to be personal protective equipment.

Remove. The moving of a dead human body from a home, hospital, or other place of death to a Licensed Funeral Establishment for the purpose of preparing it for burial or cremation.

Ship or Shipment. To convey a dead human body by train, boat, airplane, express or motor freight or other means of transportation either within, into or out of Massachusetts after said body has been prepared for burial or cremation.

Source Individual. Any individual, living or dead, whose blood or other potentially infectious materials may be a source of occupational exposure to the employee. Examples include, but are not limited to, hospital or clinic patients, clients in institutions for the developmentally disabled, trauma victims, clients of drug and alcohol treatment facilities, residents of hospices and nursing homes, human remains, and individuals who donate or sell blood or blood components.

Sterilize. The use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospores.

Transport. To convey a dead human body in a closed hearse or other appropriately registered vehicle used exclusively for the purpose of transporting dead human bodies and/or funeral equipment, either within, into or out of Massachusetts for any purpose other than that referred to in the definitions of 239 CMR 3.12: Remove and Ship or Shipment;

Universal Precautions. An approach to infection control in which all human blood and certain human body fluids are to be treated as if known to be infectious.

(2) As part of their function of being health care responsible, every Type 3 and Type 6 shall adopt all proper means to safeguard the public health, including but not limited to the use of universal precautions during the embalming or preparation of a body, as set forth in 239 CMR 3.12.

(3) Every person, while engaged in removal of a dead human body from the place of death to a Licensed Funeral Establishment, shall be provided with and shall use personal protective clothing and equipment to protect against exposure to bloodborne pathogens.
(a) Disposable OSHA approved gloves shall be worn for barrier protection against contact with blood or other potentially infectious materials. Non-disposable autopsy, kevlar or rubber gloves shall be worn for additional protection if warranted. Non-disposable gloves shall be cleaned and carefully inspected for punctures, tears or other damage after each use. Damaged gloves, whether disposable or non-disposable, shall be replaced immediately. Other soiled clothing shall be removed before the removal of gloves. Gloves shall be carefully removed to avoid skin contact with the exterior of the gloves.
(b) The body being removed shall be enclosed in a body bag or other suitable, sealed container which will prevent leakage or escape of blood or other potentially infectious materials during removal from the place of death to the Licensed Funeral Establishment accepting responsibility for the care and preparation of said body.
3.12: continued

(4) Every person, while engaged in actually preparing a dead human body for burial or cremation, shall be provided with and shall use personal protective clothing and equipment to protect against exposure to bloodborne pathogens.
   
   (a) Disposable OSHA approved gloves shall be worn for barrier protection against contact with blood or other potentially infectious materials. Other soiled clothing or equipment shall be removed before the removal of gloves. Gloves shall be carefully removed to avoid skin contact with the exterior of the gloves.

   (b) Non-disposable autopsy, kevlar or rubber gloves shall be worn for additional protection if warranted. If non-disposable gloves are used, they shall be cleaned and carefully inspected for punctures, tears or other damage after each use. Damaged gloves shall be replaced immediately. Other soiled clothing or equipment shall be removed before the removal of gloves. Gloves shall be carefully removed to avoid skin contact with the exterior of the gloves.

   (c) Disposable face masks shall be worn for barrier protection against sprays of blood or other potentially infectious materials to the mouth or nose. Soiled masks shall be replaced immediately.

   (d) Goggles shall be worn for barrier protection against sprays of blood or other potentially infectious materials to the eyes and for vapor protection against exposure to formaldehyde.

   (e) Face shields shall be worn for barrier protection against sprays of blood or other potentially infectious materials to the face.

   (f) Gowns which are impervious to moisture, are washable or disposable, and are long-sleeved shall be worn for barrier protection against skin contact with chemicals, blood or other potentially infectious materials. Soiled gowns shall be replaced immediately.

   (g) Disposable head and shoe covers shall be worn for barrier protection against blood or other potentially infectious materials.

(5) All instruments, appliances and equipment used in the preparation of a dead human body shall be used and maintained in a manner which prevents, insofar as is reasonably possible, conversion of blood or other potentially infectious bodily fluids or materials into aerosols or airborne particles.

(6) Every Licensed Funeral Establishment shall ensure proper disposal of personal protective clothing and equipment. Disposable items contaminated with blood or other potentially infectious materials shall be placed immediately in an appropriately labeled disposal container and removed in accordance with applicable federal, state and local laws and regulations governing hazardous waste disposal. Non-disposable items contaminated with blood or other potentially infectious materials shall be placed immediately in an appropriately labeled laundry container.

(7) No sheets or linens which have come in contact with a dead human body shall be re-used unless they have first been thoroughly laundered and disinfected. No other materials or supplies of any kind which have come in contact with a dead human body shall be used more than once. Contaminated laundry shall be handled as little as possible with a minimum of agitation, shall be bagged or containerized at the location where it was used, and shall not be sorted or rinsed at the location of use. Contaminated laundry shall be placed and transported in bags or containers which are labeled or color-coded in accordance with the applicable requirements of the United States Occupational Safety and Health Administration.

(8) All instruments, appliances and equipment used in the preparation of a dead human body shall be thoroughly cleansed and sterilized in accordance with all applicable state and federal laws and regulations, including but not limited to all applicable regulations of the United States Occupational Safety and Health Administration and the Massachusetts Department of Public Health, immediately at the conclusion of each individual case.

(9) Each preparation room in a Licensed Funeral Establishment shall be equipped with proper and convenient receptacles for refuse, bandages, cotton and other waste materials and supplies, and all such refuse, bandages, cotton and other waste materials shall be disposed of in accordance with all applicable federal, state and local laws governing disposal of hazardous waste.
3.12: continued

(10) Whenever a dead human body is transported within, into or out of Massachusetts prior to being embalmed or otherwise prepared for burial or cremation, all persons engaged in the transportation of said body or who may come into physical contact with that body during transportation shall follow the precautions required by 239 CMR 3.12(3).

(11) Whenever a dead human body is transported or shipped within, into or out of Massachusetts after being embalmed or otherwise prepared for burial or cremation, the use of disposable gloves shall be required only for persons who come into actual physical contact with the body itself. Said body shall be transported or shipped in a sealed casket, body bag or other appropriate sealed container which will prevent leakage or escape of blood or other potentially infectious materials during such shipment or transportation.

(12) Notwithstanding the provisions of 239 CMR 3.12(1) through (11), where a body is dead of a disease which has been identified by the Massachusetts Department of Public Health or the Center for Disease Control as one which requires precautions above and beyond those required by 239 CMR 3.12(1) through (11), a Licensed Funeral Establishment and its agents and employees shall follow such additional precautions as may be required or recommended by the Center for Disease Control with respect to said body.

(13) In accordance with the regulations of the United States Occupational Safety and Health Administration (29 CFR 1910.1030), every Type 3 and Type 6 shall inform all workers performing tasks in and for any Licensed Funeral Establishment, including any trade Type 6s or other workers who are not directly employed by that establishment, about bloodborne pathogen exposure risks associated with specific tasks, how to protect themselves and others from exposure, and the actions to be taken in the event of an exposure incident.

3.13: Code of Conduct and Professional Ethics

(1) No person who is registered with the Board, nor any person who holds an ownership interest in or is employed by any Licensed Funeral Establishment, shall engage in, or hold any ownership interest in, any other business which is related to the disposition of human remains, including but not limited to any cemetery; crematorium; retail or wholesale casket, urn or vault sales or rental enterprise; monument sales enterprise; or other similar business; provided, however, that 3.13(1) shall not apply to registrants duly registered with the Board in inactive status pursuant to 239 CMR 3.02(5).

(2) All functions or services which fall within the scope of the Profession and Business of Embalming and Funeral Directing, as defined in 239 CMR 3.01 must be provided by or through one or more Licensed Funeral Establishments.

(3) No person who is registered with the Board, nor any person who holds an ownership interest in or is employed by a Licensed Funeral Establishment, shall establish, maintain, own or operate any corporation, partnership, limited liability company, limited liability partnership, society, association or other business entity, however named, for the purpose of referring members of the general public to Licensed Funeral Establishments in which he or she holds an ownership interest or is employed.

(4) No person who is registered with the Board, nor any person who holds an ownership interest in or is employed by a Licensed Funeral Establishment, shall make or cause to be made any representation which indicates that an organization or other entity which performs any function or service which falls within the scope of the “Profession and Business of Embalming and Funeral Directing” as defined in 239 CMR 3.01 is a not-for-profit organization or entity unless such organization or entity is, in fact, a not-for-profit organization or entity.

(5) A person who is registered with the Board, or who holds an ownership interest in or is employed by any Licensed Funeral Establishment, shall not, either directly or through any other person acting with his or her express or implied knowledge or consent:
3.13: continued

(a) solicit for human remains (except through general advertising), or give anything of value to anyone who solicits or refers any business to him or her or to the Licensed Funeral Establishment in which he or she holds an ownership interest or is employed; or
(b) solicit or accept anything of value in exchange for recommending, referring any person to, or employing any business or service related to the disposition of human remains.

(6) A person who is registered with the Board, or who holds an ownership interest in or is employed by any Licensed Funeral Establishment, shall not, either directly or through another person acting with his or her express or implied knowledge or consent, recommend, refer any person to, or employ any business or service related to the disposition of human remains if that business or service is owned, operated or controlled by one or more of his or her relatives. For purposes of 239 CMR 3.13(6), a relative is a person's spouse, parent, grandparent, step-parent, child, grandchild, step-child, brother, sister, half-brother, half-sister, son-in-law, daughter-in-law, father-in-law, mother-in-law, brother-in-law, sister-in-law, niece, nephew, aunt or uncle.

(7) A person who is registered with the Board, or who holds an ownership interest in or is employed by any Licensed Funeral Establishment, shall not disclose confidential or private information, such as causes of death, financial information, or other such personal information about a client or any member of any household or family which he or she serves, comment on the condition of any dead human body entrusted to his or her care, or engage in any other conduct adverse to the interests of that client based on information obtained in confidence. Notwithstanding the above, 239 CMR 3.13(7) shall not be interpreted to bar cooperation with a Board investigation or from making other disclosures as required by law or for purposes of insurance and debt collection activities.

(8) No person who is registered with the Board, nor any person who holds an ownership interest in or is employed by any Licensed Funeral Establishment, shall engage in any unfair or deceptive business practice, misrepresent merchandise in any manner, deceptively alter merchandise labels, or knowingly attempt to induce any person to spend more money on funeral arrangements than is commensurate with the means of the person liable for such expense.

(9) No person who is registered with the Board, nor any person who holds an ownership interest in or is employed by any Licensed Funeral Establishment, shall engage in any false, deceptive or misleading Advertising or marketing practices.

(10) No person who is registered with the Board, nor any person who holds an ownership interest in or is employed by any Licensed Funeral Establishment, shall:
(a) fail or refuse to give a general price list containing all information required by 16 CFR Part 453 to any person who requests one in person; or
(b) fail or refuse to give out accurate information from that general price list, and any other readily available information requested, to any person who contacts that person or Licensed Funeral Establishment by telephone, to the extent required by 16 CFR Part 453.

(11) No Type 3 or Type 6 who is employed in a Licensed Funeral Establishment shall fail or refuse to give an itemized written statement of funeral costs to any person making funeral arrangements or arranging for the shipment, transportation or other disposition of a deceased person, in accordance with the requirements of M.G.L. c. 112, § 84B.

(12) No person who is registered with the Board, nor any person who holds an ownership interest in or is employed by any Licensed Funeral Establishment, shall discriminate in any way against employees or present or prospective customers on the basis of race, color, religious creed, national origin, sex, sexual orientation, age, ancestry, marital status, status as a veteran or member of the armed forces, blindness, hearing impairment, or any physical or mental disability with respect to terms or conditions of employment or the availability, provision or performance of any function or service.

(13) No person who is registered with the Board, nor any person who holds an ownership interest in or is employed by any Licensed Funeral Establishment, shall provide or offer to provide grief or bereavement counseling services unless:
3.13: continued

(a) the person actually providing such grief or bereavement counseling services is a Type 3 or Type 6; or
(b) the person actually providing such grief or bereavement counseling services is an independent contractor providing such services through an arms-length contractual agreement with one or more Licensed Funeral Establishments, and is duly licensed by the Commonwealth as a psychiatrist, clinical psychologist, social worker, psychiatric nurse mental health specialist, or allied mental health professional.

(14) No person who is registered with the Board, nor any person who holds an ownership interest in or is employed by any Licensed Funeral Establishment, shall solicit, receive or agree to receive any fee, monetary compensation or other valuable consideration in exchange for referring a customer or member of a deceased person's family to any person who provides grief and bereavement counseling services.

(15) Persons registered with the Board, and persons who hold an ownership interest in or are employed by any funeral establishment licensed by the Board, shall be fair with present or prospective customers with respect to quality of merchandise, freedom of choice, quality of service, and reasonableness of price, and shall not misrepresent any material fact with respect to such matters.

(16) Persons registered with the Board, and persons who hold an ownership interest in or are employed by any Licensed Funeral Establishment, shall be fair with competitors; shall respect contractual arrangements which those competitors have made with consumers; shall act equitably in forwarding or transferring cases; shall respect customary or contractual arrangements with employees of such competitors; and shall refrain from disparaging or defaming competitors with respect to price, service, merchandise or professional reputation.

(17) Persons registered with the Board, and persons who hold an ownership interest in any Licensed Funeral Establishment, shall provide safe and healthful working conditions for all employees; and shall comply with M.G.L. c. 112, §§ 61 through 65A, 82 through 87, and 239 CMR.

(18) No person registered with the Board, nor any person who holds an ownership interest in or is employed by any Licensed Funeral Establishment, shall engage in, authorize, or aid or abet fraud, deceit, misrepresentation of any material fact, provision of any false or forged evidence, or bribery.

(19) The Board may take disciplinary action against any person registered with the Board who has been subjected to disciplinary action or denial of licensure by another jurisdiction.

(20) The Board may take disciplinary action against any person registered with the Board who has been convicted of, or who has pleaded guilty or no lo contendere to, any criminal offense.

(21) Violation of any provision of 239 CMR 3.14, any other provision of 239 CMR, any provision of M.G.L. c. 112, §§ 61 through 65A or 82 through 87, by any person registered with the Board shall be grounds for disciplinary action by the Board.

(22) The Type 3(s) to whom a funeral establishment certificate is issued shall be responsible for any and all acts or omissions of any person who holds an ownership interest in, or is employed by, that Licensed Funeral Establishment, and may be disciplined by the Board for any such acts or omissions which constitute violations of 239 CMR, M.G.L. c. 112, §§ 61 through 65A or 82 through 87.

(23) The Board may also, after hearing, suspend, revoke, or take other disciplinary action against, the funeral establishment certificate of any Licensed Funeral Establishment for any acts or omissions of any person who holds an ownership interest in, or is employed by, that Licensed Funeral Establishment if such acts or omissions constitute violations of 239 CMR 3.00, and M.G.L. c. 112, §§ 61 through 65A, 82 through 87.
3.13: continued

(24) As described in M.G.L. c. 112, § 84, the Board may take disciplinary action against any person registered with the Board who engages in unprofessional conduct. Unprofessional conduct shall include, but not be limited to, failing to cooperate with a Board investigation, practicing or offering to practice beyond the scope of the Board issued license, accepting and performing professional responsibilities which the licensee knows or has reason to know that he or she is not competent to perform, and engaging in any course of conduct which constitutes a failure to conform to generally accepted standard(s) of professional conduct in the funeral industry.

(25) It shall be deemed outside the scope of registration and considered unregistered practice for an individual who is not a Type 3 or Type 6 to register a hearse with the Registry of Motor Vehicles. 239 CMR 3.13(25) shall not apply to non-funeral businesses that register hearses for the sole purpose of leasing the vehicles to properly Licensed Funeral Establishments.

(26) All Type 3s, Type 6s, and Apprentice Embalmers shall maintain complete embalming reports for all embalming performed by him or her. Said reports shall be retained as part of the consumer's record.

3.14: Price Disclosure to Consumer

(1) A Licensed Funeral Establishment, and/or its agents or employees, shall give, or cause to be given to the person or persons making funeral arrangements, or otherwise arranging for shipment, transportation or other disposition of a deceased person, at the time such arrangements are completed or prior to the time of rendering the service, including the selected merchandise, a written statement showing to the extent then known:
   (a) the price of the merchandise and service that the person or persons making such arrangements have selected and what is included therein;
   (b) the price of each of the supplemental items of service and/or merchandise agreed upon by the parties involved; and
   (c) the estimated amount involved for each of the items for which the Licensed Funeral Establishment will advance monies as an accommodation to the person or persons making such funeral arrangements.

(2) No Licensed Funeral Establishment in the Commonwealth of Massachusetts shall bill or cause to be billed, any item that is referred to as a "Cash Advanced" item unless the net amount billed for such item or items by the Licensed Funeral Establishment is the same amount as is billed the Licensed Funeral Establishment by the third party vendor or supplier.

3.15: Advisory Ruling

Any interested person or his or her attorney may at any time request an advisory ruling with respect to the applicability to any person, property or factual situation of any statute or regulation enforced or administered by the Board. The request shall be addressed to the Board and sent to the secretary by certified mail or delivered in person. All requests shall be signed by the person making it or his or her attorney, contain his or her address or the address of his or her attorney, and state clearly and concisely the substance or nature of the request. The request may be accompanied by any supporting data, views or arguments. Upon receipt of the request, the Board shall consider it and render its opinion in writing. The Board may at any time rescind an advisory ruling. When an advisory ruling is rendered, a copy of the ruling shall be sent to the person requesting it or his or her attorney.

3.16: Corporations, LLCs, LLPs, and Other Entities

(1) A corporation, LLC, LLP, or other such entities may engage in the Profession and Business of Embalming and Funeral Directing only if:
   (a) a controlling interest in that entity is held by one or more individuals holding a Type 3. This shall be determined based on the distribution of authorized stock or other such evidence of ownership;
3.16: continued

(b) the business of that entity is under the direction and control of one or more Type 3s, who shall be held responsible for ensuring that that the entity complies with M.G.L. c. 112, §§ 61 through 65A, 82 through 87, and 239 CMR; 
(c) the entity meets the professional liability insurance requirements set forth in 239 CMR 3.17; and 
(d) the entity does not hold an ownership interest in, or engage in, any business other than the Profession and Business of Embalming and Funeral Directing as defined in 239 CMR 3.01.

(2) Changes in the controlling interest held by a Type 3 in a corporation, LLC, LLP, or other such entity operating a Licensed Funeral Establishment which causes the individual(s) holding the controlling interest to change shall be construed as a change in ownership in the Licensed Funeral Establishment itself as described in 239 CMR 3.04 and 3.06.

3.17: Required Insurance and Capital Program

(1) A Licensed Funeral Establishment which engages in the Profession and Business of Embalming and Funeral Directing in Massachusetts shall maintain in good standing professional liability insurance which meets the following minimum standards:
   (a) The insurance shall cover negligence, wrongful acts, and errors and omissions.
   (b) The insurance shall be in an amount of at least $50,000, plus the product of $15,000 multiplied by the number of owners and employees of the Licensed Funeral Establishment who are Type 3(s), but does not need to be in excess of $500,000 in the aggregate.
   (c) The requirements of 239 CMR 3.17(1)(c) shall be considered satisfied if the Licensed Funeral Establishment maintains insurance sufficient to provide coverage at a level of at least $300,000 for each claim with an aggregate top limit of liability for all claims during any one year of at least $1,000,000.
   (d) Such insurance policies may contain reasonable provisions with respect to policy periods, territory, claims, conditions and other usual matters.

(2) A Licensed Funeral Establishment which engages in the Profession and Business of Embalming and Funeral Directing in Massachusetts is not required to maintain the insurance required by 239 CMR 3.17(2) if:
   (a) that Licensed Funeral Establishment maintains a designated and segregated capital fund equal to the amount of insurance required by 239 CMR 3.17(2); and
   (b) such funds are specifically designated and segregated for the satisfaction of judgments against the Licensed Funeral Establishment and/or its owners, based on negligence, wrongful acts, or errors and omissions, by means of:
      1. Deposit in trust, or in bank escrow, of such funds in the form of cash, bank certificates of deposit, or United States Treasury obligations; or
      2. A bank letter of credit or insurance company bond.

(3) Upon any cancellation or other interruption in the insurance coverage required by 239 CMR 3.17(3), or any failure to maintain the designated and segregated capital required by 239 CMR 3.17(3) shall immediately cease engaging in the Profession and Business of Embalming and Funeral Directing until such time as the Licensed Funeral Establishment is in compliance with 239 CMR 3.17.

(4) A Licensed Funeral Establishment shall notify the Board in writing, within five business days, if the insurance coverage required by this section is cancelled or otherwise interrupted, or if the designated and segregated capital falls below the amount required. Failure to provide such notice to the Board shall subject the Licensed Funeral Establishment and its related Type 3(s), to disciplinary action by the Board pursuant to M.G.L. c. 112, § 84(j).

(5) A Licensed Funeral Establishment may be required to provide verification of compliance with this section, satisfactory to the Board, at the time it applies for a new funeral establishment certificate, or at any other time upon request by the Board.
3.18: Employment of Funeral Home Assistants

(1) A Licensed Funeral Establishment may employ Funeral Home Assistants, provided that all of the following conditions are met:
   (a) Each Funeral Home Assistant so employed is duly registered with the Board pursuant to 239 CMR 3.02.
   (b) Each Funeral Home Assistant so employed is registered to a Type 3 employed by the same entity which employs that Funeral Home Assistant. The Funeral Home Assistant shall work at all times under the instruction and supervision of that Type 3, who shall be held responsible for all acts or omissions of that Funeral Home Assistant which occur while that person is acting within the scope of said employment.
   (c) Each Funeral Home Assistant so employed complies with any and all applicable requirements of M.G.L. c. 112, §§ 61 through 65A, 82 through 87, and 239 CMR.
   (d) The entity which employs a Funeral Home Assistant shall promptly inform the Board, in writing, of any change in the identity of the Type 3 to whom that Funeral Home Assistant is registered, and of any change in the name and address of the Licensed Funeral Establishment(s) in which each Funeral Home Assistant works.
   (e) If there is a change in the employment status of any such Funeral Home Assistant, the Funeral Home Assistant as well as the Type 3 to whom he or she is registered must notify the Board in writing within seven business days.
   (f) The address of the license for a Funeral Home Assistant shall be the Licensed Funeral Establishment where the Funeral Home Assistant is employed.
   (g) Upon termination of employment, a Funeral Home Assistant registration shall become null and void, a new registration must be sought for new employment.

(2) Upon the request of the Board, or a duly authorized representative thereof, a Licensed Funeral Establishment shall furnish to the Board satisfactory written proof of employment for any Funeral Home Assistant employed by said Licensed Funeral Establishment and registered under 239 CMR 3.18.

(3) For purposes of upgrading to a Type 3 or Type 6, a Funeral Home Assistant shall not be deemed an Apprentice Embalmer and shall not be granted credit for a higher level registration based on that experience without special board approval.

(4) Scope of Practice of Funeral Home Assistants.
   (a) Funeral Home Assistants may, while under the supervision of a Type 3 (that Type 3 may delegate such supervision to a Type 6):
      1. perform the removal or transfer of a dead human body in a vehicle registered as a hearse. With permission of a supervisor (Type 3 or Type 6), Funeral Home Assistants may perform removals without the presence of a supervisor so long as a supervisor has personally accompanied the Funeral Home Assistant on the first 20 removals/transfers performed during the course of their licensure;
      2. assist in dressing, casketing, and general handling of human remains; and
      3. assist in all other funeral related tasks otherwise not requiring a license/registration.
   (b) Funeral Home Assistants may not:
      1. participate in embalming;
      2. arrange or direct any funeral, memorial, or cremation service; or
      3. arrange, handle, or have any other duties regarding pre-need funds.

3.19: Advertisements

(1) Business cards may be used by any registrant so long as they include the name of a Licensed Funeral Establishment and includes their registration type.

(2) A Type 3 or Type 6 may properly advertise the services offered so long as said advertising is not false, deceptive, misleading or unfair as prohibited by 239 CMR 3.13(9). Advertising not meeting 239 CMR 3.19(2) includes, but is not limited to:
   (a) advertisements for a service that cannot be legally provided by a Licensed Funeral Establishment;
   (b) the listing of services of an Apprentice Embalmer or Funeral Home Assistant;
3.19: continued

(c) advertisements that state or imply that, with regards to pre-need arrangements, a Type 6, Apprentice Embalmer, or Funeral Home Assistant is a specialist, certified, an expert, or other similar terms.
(d) advertisements referring to unregistered individuals or unlicensed funeral establishments. However, unregistered owners may utilize their names on signs as required by 239 CMR 3.04(2); and
(e) services provided by a Type 6 that do not fall within the employment of said registrant at a Licensed Funeral Establishment.

(3) All Advertising for a function or service that must be provided through a Licensed Funeral Establishment must include the name of a Licensed Funeral Establishment.

3.20: Regulation Review

The Board shall regularly review its regulations in compliance with M.G.L. c. 30A, § 5A.

REGULATORY AUTHORITY

239 CMR 3.00: M.G.L. c. 112, § 85.
Regulation Filing  To be completed by filing agency

CHAPTER NUMBER: 239 CMR 4.00
CHAPTER TITLE: Pre-Need Funeral Contracts and Arrangements
AGENCY: Board of Registration in Embalming and Funeral Directing

SUMMARY OF REGULATION: State the general requirements and purposes of this regulation.
The purpose of 239 CMR 4.00 is to provide the basic rules for funeral establishments which choose to offer pre-need funeral contracts, in which consumers pre-pay for funeral arrangements. Specifically, this section provides basic rules for the handling of such funds, mandatory contractual requirements, and rules when funeral establishments are closing or changing ownership.

REGULATORY AUTHORITY: M.G.L. c. 112, § 85

AGENCY CONTACT: Charles Kilb  PHONE: 617-727-2707
ADDRESS: Div. of Prof. Licensure, 1000 Washington St., 7th Fl., Boston, MA 02118

Compliance with M.G.L. c. 30A

EMERGENCY ADOPTION - if this regulation is adopted as an emergency, state the nature of the emergency.

PRIOR NOTIFICATION AND/OR APPROVAL - If prior notification to and/or approval of the Governor, Legislature or others was required, list each notification, and/or approval and date, including notice to the Local Government Advisory Commission.
Local Government Advisory Committee - July 22, 2016
Massachusetts Register Publication - September 9, 2016
Boston Globe and Springfield Republican - August 29, 2016

PUBLIC REVIEW - M.G.L. c. 30A sections 2 and/or 3 requires notice of the hearing or comment period, including a small business impact statement, be filed with the Secretary of the Commonwealth, published in appropriate newspapers, and sent to persons to whom specific notice must be given at least 21 days prior to such hearing or comment period.

Date of public hearing or comment period: September 20, 2016
FISCAL EFFECT -  

Estimate the fiscal effect of the public and private sectors.

For the first and second year:  No fiscal effect anticipated

For the first five years:  No fiscal effect anticipated

No fiscal effect:

SMALL BUSINESS IMPACT -  

M.G.L. c. 30A section 5 requires each agency to file an amended small business impact statement with the Secretary of the Commonwealth prior to the adoption of a proposed regulation. If the purpose of this regulation is to set rates for the state, this section does not apply.

Date amended small business impact statement was filed:  January 11, 2017

CODE OF MASSACHUSETTS REGULATIONS INDEX -  

List key subjects that are relevant to this regulation:

- embalming, funeral directing, funeral homes, pre-need funeral contracts

PROMULGATION -  

State the action taken by this regulation and its effect on existing provisions of the Code of Massachusetts Regulations (CMR) or repeal, replace or amend. List by CMR number:

239 CMR 4.00 (amend)

ATTESTATION -  

The regulation described herein and attached hereto is a true copy of the regulation adopted by this agency.  

ATTEST:

SIGNATURE:  SIGNATURE ON FILE  DATE:  Jan 12 2017

Publication -  

To be completed by the Regulations Division

MASSACHUSETTS REGISTER NUMBER:  S1331  DATE:  01/27/2017

EFFECTIVE DATE:  01/27/2017

CODE OF MASSACHUSETTS REGULATIONS

Remove these pages:  19 - 30.2  Insert these pages:  31 - 46

The text of the regulations published in the electronic version of the Massachusetts Register is unofficial and for informational purposes only. The official version is the printed copy which is available from the State Bookstore at http://www.sec.state.ma.us/spr/sprcat/catidx.htm.
For purposes of 239 CMR 4.00, the following terms shall have the following meanings unless the context in which they are used clearly indicates otherwise:

**Beneficiary.** The individual for whom funeral goods and services are to be provided under the terms of a Pre-need Funeral Contract.

**Buyer.** The person entering into a Pre-need Funeral Contract with a Licensed Funeral Establishment.

**Cost-protected Pre-need Funeral Contract.** A Pre-need Funeral Contract in which:

(a) a Licensed Funeral Establishment agrees to provide a specifically-identified set of Funeral Goods and/or Services for a named Beneficiary upon his or her death;
(b) the Beneficiary has established a Funeral Trust Account, or purchased a Pre-need Insurance Policy or Annuity, which is to be used to pay for those funeral goods and services;

(3) the Beneficiary has fully funded the Funeral Trust Account, or fully paid for the Pre-need Insurance Policy or Annuity, within a specified period of time after the Pre-need Funeral Contract is made; and

(4) the Licensed Funeral Establishment has agreed to accept the funds available in the Beneficiary's Funeral Trust Account or Pre-need Insurance Policy or Annuity at the time of the Beneficiary's death as payment in full for all funeral goods and services provided by the funeral establishment, and, to the extent specifically provided in the contract, for Non-funeral Establishment Charges or "Cash Advance Item" Charges as well, so that there will be no additional cost to the Beneficiary or his or her estate for those goods, services and charges at the time of the Beneficiary's death.

**Funeral Goods and/or Services.** Those goods and services which are customarily provided in the business of embalming and funeral directing, as commonly practiced, including but not limited to usage of facilities and those goods and services identified in 239 CMR 3.01: Definitions.

**Funeral Trust Account.** An account established in any federal or state-chartered banking institution having trust powers, or any trust company, located in the Commonwealth of Massachusetts, in which funds are deposited or invested pursuant to the terms of a Pre-need Funeral Contract for the purpose of paying for Funeral Goods and/or Services at a future time.

**Irrevocable.** After any cooling off period, that the Pre-need Funeral Contract may not be terminated by any party or beneficiary of the contract except by order of a court of competent jurisdiction. Irrevocable may apply to the Pre-need Funeral Contract as a whole, or may apply to specific portions of the contract.
Itemized Statement of Funeral Goods and Services. A written itemized statement showing to the extent then known the price of Funeral Goods and/or Services selected by a person, the price of each supplemental item of goods and/or services to be provided, the estimated amount for each item for which the funeral establishment will advance monies as an accommodation to the person or persons making the funeral arrangements, and all other information required by M.G.L. c. 112, § 84B, 239 CMR 3.14: Price Disclosure to Consumer, and 16 CFR 453.2.

Non-funeral Establishment Charges or "Cash Advance Item" Charges. The costs of goods or services which are provided for a Beneficiary in connection with his or her funeral by a supplier or vendor other than a funeral establishment licensed in Massachusetts, but which are partially or fully paid for by a Massachusetts Licensed Funeral Establishment with funds in a Funeral Trust Account or Pre-need Insurance Policy or Annuity on behalf of, and as an accommodation to, that Beneficiary.

Pre-need Funeral Contract. Any written agreement between a Buyer and a Licensed Funeral Establishment in which:
(a) the Licensed Funeral Establishment agrees, prior to the death of a named Beneficiary, to furnish Funeral Goods and/or Services for that named Beneficiary upon his or her death, and
(b) the Buyer, pursuant to that agreement, tenders funds made payable to a banking institution or insurance company to the Licensed Funeral Establishment for the purpose of paying all or part of the cost of those Funeral Goods and/or Services at the time they are actually provided.

Pre-need Insurance Policy or Annuity. Any policy, certificate, agreement or contract of insurance issued by an insurance company, the proceeds of which are to be utilized to pay for Funeral Goods and/or Services furnished to a named Beneficiary.

Revocable. The Pre-need Funeral Contract may be terminated at any time, with or without cause, by the Beneficiary of the contract, or, if the Beneficiary is deceased, his or her estate. Revocable may apply to the Pre-need Funeral Contract as a whole, or may apply to specific portions of the contract, such as specific goods and services.

Trustee. A federal or state-chartered banking institution within the Commonwealth of Massachusetts having trust powers, or a trust company within the Commonwealth of Massachusetts, to which funds have been transferred in trust for the purpose of paying for Funeral Goods and/or Services for a named Beneficiary, and which is charged with the fiduciary duty of managing and administering those funds for the benefit for that named Beneficiary.

4.02: Creation and Content of Pre-need Funeral Contracts

(1) Parties to Pre-need Funeral Contracts. All Pre-need Funeral Contracts shall be between a Buyer and a Licensed Funeral Establishment. The Licensed Funeral Establishment may not accept cash or checks made payable to the Licensed Funeral Establishment or individual registrants for purposes of funding the Pre-need Funeral Contract unless said checks are endorsed and sent to the banking institution or insurance company within one business day. Such funds must be made payable directly to the banking institution or insurance company.

(2) Who May Prepare Pre-need Funeral Contracts. No person shall prepare, negotiate or execute a Pre-need Funeral Contract with a Buyer or potential Buyer; or receive, or manage any funds made payable to a banking institution or insurance company as payment for the Funeral Goods and/or Services identified in such a Pre-need Funeral Contract unless:
(a) he or she is a Type 3; or
(b) he or she is a Type 6 and meets the conditions outlined in 239 CMR 3.04(5): Pre-need Funeral Arrangements.

(3) Location of Offices in Which Pre-need Funeral Contracts May Be Prepared. All Pre-need centers or offices which engage in the preparation, negotiation or execution of Pre-need Funeral Contracts or arrangements shall be located within a duly Licensed Funeral Establishment.
4.02: continued

(4) Provision of Buyer's Guide Required. A copy of a Buyer's Guide to Pre-need Funeral Contracts, approved by the Board, shall be furnished to every person or identifiable group of persons who enter into negotiations or discussions with a Type 3 or Type 6 regarding a Pre-need Funeral Contract prior to the signing of any such contract by the parties. A Buyer's Guide to Pre-need Funeral Contracts shall, at a minimum, inform the consumer that:
   (a) A consumer can pre-plan his or her funeral arrangements without paying for such arrangements in advance;
   (b) The cost of the funeral goods and services purchased through a Pre-need Funeral Contract may be higher or lower at the time of the Beneficiary's death than the amounts set forth in the contract, and the Beneficiary's rights and obligations with respect to such changes in price are determined by the contract;
   (c) There are various methods of financing Pre-need Funeral Contracts, including but not limited to trusts, Pre-need insurance policies, funeral insurance, traditional life insurance policies, annuities, and separately-created Medicaid-compliant burial accounts;
   (d) Each such financing method has certain briefly-described tax, Medicare and Medicaid eligibility, and cancellation consequences;
   (e) The consumer has a legal right to cancel such a Pre-need Funeral Contract within ten days of its execution without penalty;
   (f) Cancellation or revocation of a Pre-need Funeral Contract after the expiration of the ten-day "cooling-off" period may have adverse consequences in terms of eligibility for Medicaid or other government benefits programs;
   (g) A Licensed Funeral Establishment may not impose any surcharge, fee, or other penalty upon any person who seeks to exercise his or her rights to cancel or transfer a Pre-need Funeral Contract.
   (h) The funeral establishment will report any changes in the Pre-need Funeral Contract, or withdrawals of funds which were originally received in connection with that contract, to the applicable governmental authority responsible for the administration of Medicaid or other governmental benefits programs to the extent that such reporting is required by law.
   (i) The Licensed Funeral Establishment must:
      1. deposit any Pre-need funds received from the consumer into a Funeral Trust Account not later than five business days after the ten-day "cooling-off" period; or
      2. pay any Pre-need funds received from the consumer to an insurance company not later than five business days after the ten-day "cooling-off period".
   (j) The Licensed Funeral Establishment must send the consumer and the Beneficiary (if different) written confirmation that the Pre-need funds have been deposited in a Funeral Trust Account or used to purchase a Pre-need Insurance Policy or Annuity not later than ten days after the funds are deposited or paid. Such written confirmation must bear the signature of a duly-authorized representative of the insurance company which issued the Pre-need Insurance Policy or Annuity, whichever applies.
   (k) The consumer may transfer his or her Pre-need Funeral Contract to another Licensed Funeral Establishment at any time.
   (l) The Licensed Funeral Establishment may not accept cash or check made payable to the Licensed Funeral Establishment for purposes of funding the Pre-need Funeral Contract unless said checks are endorsed and sent to the banking institution or insurance company within one business day. Such funds must be made payable directly to the banking institution or insurance company.

(5) Required Form and Contents of Pre-need Funeral Contracts.
   (a) All Pre-need Funeral Contracts shall be in writing and shall be prepared and executed on one of the Pre-need Funeral Contract forms prescribed by the Board.
   (b) Each Pre-need Funeral Contract shall be complete and shall contain all information specified on the form used, including but not limited to:
      1. The signature of the Buyer; and
      2. The signature of the Type 3 or Type 6 who is acting as the authorized representative of the contracting funeral establishment.
   (c) Each Pre-need Funeral Contract shall:
      1. State conspicuously on the first page of the contract, in a manner reasonably calculated to attract the attention of a reasonable person, whether or not the Buyer has selected specific Funeral Goods and/or Services;
2. Be accompanied by an Itemized Statement of Funeral Goods and Services which meets the requirements of the Federal Trade Commission Funeral Rule (16 CFR Part 453), M.G.L. c. 112, § 84B and 239 CMR 3.14: Price Disclosure to Consumer, which shall be attached to that Pre-need Funeral Contract and incorporated by reference into that contract;

3. If the Buyer has selected specific Funeral Goods and/or Services, the Itemized Statement of Funeral Goods and Services shall specify the prices for each identified funeral good or service selected by the Buyer to the extent known at the time the Pre-need Funeral Contract is prepared;

4. If the Buyer has not selected any specific Funeral Goods and/or Services, the Itemized Statement of Funeral Goods and Services shall have the words "No Goods or Services Selected" clearly and conspicuously marked thereon; and

5. Permit the buyer to specify if the selected Funeral Goods and/or Services may be deemed Revocable or Irrevocable, subject to any attachments by Medicaid or other government benefit programs. With regards to specific goods and services, the Pre-need Funeral Contract may specify the selections become irrevocable upon death of the Beneficiary. If the Pre-need Funeral Contract itself is irrevocable, the substitution or removal of specific goods and services may not be utilized to provide a refund for any monies paid for the Pre-need Funeral Contract back to the Beneficiary's estate.

(d) Each Pre-need Funeral Contract shall indicate, in the spaces designated for such information on the Board-prescribed Pre-need Funeral Contract form:

1. The percentage of the total cost of the funeral which is attributable to the goods and services which are being provided directly by the Licensed Funeral Establishment itself, which shall be calculated by dividing the total cost of the goods and services being provided by the funeral establishment itself, as set forth in the Itemized Statement of Funeral Goods and Services required by 239 CMR 4.02(5)(c), by the total cost of the funeral as set forth in that Itemized Statement of Funeral Goods and Services; and

2. The percentage of the total cost of the funeral which is attributable to goods and services provided by suppliers or vendors other than the Licensed Funeral Establishment (the Non-funeral Establishment Charges or "Cash Advance Item" Charges), which shall be calculated by dividing the total cost of the goods and services being provided by suppliers or vendors other than the Licensed Funeral Establishment (the Non-funeral Establishment Charges or "Cash Advance Item" Charges), as set forth in the "cash advance items" section of the Itemized Statement of Funeral Goods and Services required by 239 CMR 4.02(5)(c), by the total cost of the funeral as set forth in that itemized statement.

The percentages so calculated for preneed arrangements shall be rounded off to the nearest whole number (e.g., 75.28% = 75%, 75.67% = 76%) and the sum of such percentages shall in all cases equal 100%.

(e) Each Pre-need Funeral Contract shall contain the initials or signature of the Buyer acknowledging receipt of the Board-approved Buyer's Guide to Pre-need Funeral Contracts required under 239 CMR 4.02(4).

(f) Each Pre-need Funeral Contract shall recite:

1. The amount of money which the Buyer has tendered and made payable to a banking institution or insurance company in connection with that contract at the time the contract was made;

2. The amount(s) of any future payment(s) which are to be made by the Buyer in order to fully fund that contract and the date(s) on which such payments are due;

3. Whether the money tendered and made payable to a banking institution or insurance company in connection with that contract was placed in a Funeral Trust Account or used to pay for a Pre-need Insurance Policy or Annuity; and

5. The identity of the banking institution which serves as Trustee of the Funeral Trust Account established pursuant to 239 CMR 4.09, or the insurance company which issued the Pre-need Insurance Policy or Annuity pursuant to 239 CMR 4.10, whichever applies.

(g) Each Pre-need Funeral Contract shall recite conspicuously on its face whether it is Revocable or Irrevocable, and that an attempt to revoke or cancel an Irrevocable Pre-need Funeral Contract after the expiration of the ten-day "cooling-off" period described in 239 CMR 4.07(1) may have adverse consequences in terms of eligibility for Medicaid or other government benefit programs.
(h) If the Buyer has not tendered funds made payable to a banking institution or insurance company to the funeral establishment in connection with a proposed Pre-need Funeral Contract, any document which sets forth the terms and provisions of a proposed Pre-need Funeral Contract shall be treated as a non-binding Pre-need Funeral Contract estimate pursuant to 239 CMR 4.02(6).

(i) A proposed or attempted Pre-need Funeral Contract shall be deemed null and void and unenforceable by either party if:

1. The parties fail to prepare and execute the Pre-need Funeral Contract on one of the Pre-need Funeral Contract forms prescribed by the Board;
2. The parties fail to fully and properly complete any portion of the prescribed Pre-need Funeral Contract Form used; or
3. The parties fail to comply with any other applicable provision of 239 CMR 4.02(5) with respect to the preparation or execution of the proposed or attempted Pre-need Funeral Contract.

(j) In the event a proposed or attempted Pre-need Funeral Contract is to be deemed null and void and unenforceable, any and all monies tendered and made payable to a banking institution or insurance company to the funeral establishment by the Buyer in connection with the proposed Pre-need Funeral Contract shall be returned to the Buyer immediately, without penalty or deduction of any kind.

(k) Notwithstanding the provisions of 239 CMR 4.02(5)(h), a proposed or attempted Pre-need Funeral Contract which has not been signed by one or both parties shall be treated as a non-binding Pre-need funeral estimate pursuant to 239 CMR 4.02(6).

(l) The Licensed Funeral Establishment shall furnish a complete, fully-executed copy of the Pre-need Funeral Contract to the Buyer at the time the Pre-need Funeral Contract is made. In the event that the Beneficiary of the Pre-need Funeral Contract is someone other than the Buyer, the funeral establishment shall furnish an additional fully-executed copy of the Pre-need Funeral Contract to the Beneficiary not later than five business days after the Pre-need Funeral Contract is made.

(6) Non-binding Pre-need Funeral Estimates. A Licensed Funeral Establishment may issue a non-binding estimate or proposal for a Pre-need Funeral Contract to a Buyer or potential Buyer, as long as:

(a) The estimate or proposal is prepared and issued on the Pre-need Funeral Contract Form prescribed by the Board;
(b) The estimate or proposal specifies the funeral goods or services which the issuing funeral establishment proposes to provide; and
(c) The estimate or proposal contains, or is accompanied by, an Itemized Statement of Funeral Goods and Services which meets the requirements of 239 CMR 4.02(5) and which specifies the prices for each identified funeral good or service which the funeral establishment proposes to provide to the extent known at the time the estimate is prepared.
(d) Any such estimate or proposal expires and becomes null and void after a specified period of time, not to exceed 30 days from the date of its issuance, unless the Buyer or potential Buyer, prior to that expiration date, enters into a Pre-need Funeral Contract which meets the requirements of 239 CMR 4.02(5) and tenders full or partial payment made payable to a banking institution or insurance company of the specified price for the identified funeral goods and services to the funeral establishment which issued the estimate.

(7) Sale of Monuments or Interment Space Prohibited. Type 3s and Type 6s who prepare, negotiate and/or execute Pre-need Funeral Contracts shall arrange only for Funeral Goods and/or Services, and shall not sell interment space or monuments in such contracts. Nothing in 239 CMR 4.02(7) shall be construed to prohibit a Licensed Funeral Establishment from contracting with a vendor or supplier which is not a Licensed Funeral Establishment for the purchase of a monument or interment space on behalf of the Beneficiary pursuant to the terms of a Pre-need Funeral Contract which specifically identifies that monument or interment space as one of the cash-advance items selected by the Buyer.
4.03: Notice of Changes Affecting Pre-need Funeral Contracts Required

(1) A Licensed Funeral Establishment shall send written notice of any proposed cessation of the funeral establishment's operation to the Buyer (and Beneficiary, if different) of each Pre-need Funeral Contract, via certified mail, return receipt requested, at least ten days prior to the effective date of that proposed cessation of operations. Such notice shall inform the Buyer (and Beneficiary, if different) of their right to:
   (a) Transfer that Pre-need Funeral Contract and all funds connected with that contract to another Licensed Funeral Establishment of their choice, or
   (b) Cancel that Pre-need Funeral Contract, if it is Revocable, and receive a refund of all funds connected with that contract pursuant to 239 CMR 4.07(3).
   (c) In the event that the Buyer does not respond to this notice within 30 days after the date on which the notice was sent, there shall be a rebuttable presumption that the Pre-need Funeral Contract and all funds connected with that contract have been transferred to the transferee funeral establishment of which the Buyer (and Beneficiary, if different) was notified of in the written notice required under 239 CMR 4.03(1).

(2) A Licensed Funeral Establishment shall send written notice of any transfer of ownership of that funeral establishment, or sale of any portion of its assets, to the Buyer (and Beneficiary, if different) of every Pre-need Funeral Contract to which it is a party, via certified mail, return receipt requested, not later than ten days after the effective date of said transfer or sale. Such notice shall request that the Buyer inform the funeral establishment, in writing, whether the Buyer wishes to:
   (a) Transfer that Pre-need Funeral Contract, and assign all funds paid in connection with that contract, to the new owner(s) of that funeral establishment;
   (b) Transfer that Pre-need Funeral Contract, and assign all funds paid in connection with that contract, to another Licensed Funeral Establishment of their choice;
   (c) Cancel that Pre-need Funeral Contract, if it is Revocable, and receive a refund of all funds paid in connection with that contract pursuant to 239 CMR 4.07(3);
   (d) In the event that the Buyer does not respond to this notice within 30 days after the date on which the notice was sent, there shall be a rebuttable presumption that the Pre-need Funeral Contract and all funds connected with that contract have been transferred to the new owner(s) of the transferee funeral establishment.

(3) In the event that a Licensed Funeral Establishment enters into an assignment for the benefit of creditors or other debt reorganization plan, or institutes bankruptcy or receivership proceedings under state or federal law, the funeral establishment shall send to the Buyer (and Beneficiary, if different) of each Pre-need Funeral Contract to which it is a party, via certified mail, return receipt requested, a written explanation of how their rights and obligations under the Pre-need Funeral Contract will be affected by that event.

4.04: Amendment of Pre-need Funeral Contracts

(1) Except as provided in 239 CMR 4.04(2), a Pre-need Funeral Contract may be amended by the Licensed Funeral Establishment, the Buyer, or the Buyer's legal representative, at any time prior to the death of the Beneficiary of that contract. The party proposing the change shall give written notice of the proposed change to the other party at least ten days prior to the effective date of the proposed change. All such amendments shall be in writing, and no such amendment shall be effective unless signed by both parties to the contract.

(2) A Pre-need Funeral Contract shall not be amended or modified, except by order of a court of competent jurisdiction, if:
   (a) The amendment or modification would convert a Pre-need Funeral Contract which was Irrevocable at the time it was originally made into a Revocable contract, and such an amendment or modification would adversely affect the eligibility of the contract Beneficiary for Medicaid or any other government benefits program; or
   (b) The amendment or modification would modify or eliminate any price-protection provision which was included in a price-protected Pre-need Funeral Contract at the time it was originally made.
4.05: Substitution of Goods or Services

If any funeral good or service which was selected by the Buyer and identified in a Pre-need Funeral Contract at the time that contract was created is unavailable at the time of the death of the Beneficiary of that contract, the Licensed Funeral Establishment which is responsible for performing that Pre-need Funeral Contract shall provide the Beneficiary of the contract with a good or service selected by the Buyer, or if the Buyer is unavailable, the Beneficiary's next-of-kin, whose fair market value is equal to or greater than the value of the good or service which is now unavailable. Where the Pre-need Funeral Contract was a Cost-protected Pre-need Funeral Contract, as defined in 239 CMR 4.01, the substituted good or service shall be provided to the contract Beneficiary at no additional cost. Where a Pre-need Funeral Contract is not cost protected, the goods and services selected were identified by the Buyer as being Irrevocable, and the costs of the goods and services exceeds funds provided by the Pre-need Funeral Contract, the estate of the Beneficiary may elect to cancel excess goods and services in lieu of providing additional funding.

4.06: Transfer of Pre-need Funeral Contracts

(1) Upon receipt of written authorization to do so from the Buyer of a Pre-need Funeral Contract, or the Buyer's legal representative, a Licensed Funeral Establishment shall transfer or assign that Pre-need Funeral Contract to another Licensed Funeral Establishment designated by that Buyer or legal representative, provided that the funeral establishment to whom the contract is to be transferred or assigned has indicated in writing that it will agree to honor that contract. The terms of the contract shall not be modified at the time of the transfer, but may be amended by means of a written agreement between the Buyer and the transferee funeral establishment after the transfer of the contract and all funds connected with that contract has been completed. All such amendments shall be subject to the limitations on amendments of Pre-need Funeral Contracts, as set forth in 239 CMR 4.04.

(2) In the event of any transfer or assignment of a Pre-need Funeral Contract pursuant to 239 CMR 4.06(1):

(a) If any funds received by the transferor funeral establishment from the Buyer in connection with that Pre-need Funeral Contract are being held in a Funeral Trust Account pursuant to 239 CMR 4.09, all such funds shall be transferred to the transferee funeral establishment within ten business days, as provided in 239 CMR 4.09(5). The transferee funeral establishment shall furnish written confirmation to the Buyer, and the Beneficiary (if different), that these funds have been received by the transferee funeral establishment and deposited in a Funeral Trust Account which meets the requirements of 239 CMR 4.09 not later than 30 days after the transfer or assignment of the Pre-need Funeral Contract occurs. The transferee funeral establishment shall notify the Buyer, in writing, of the identity and location of the banking institution in which the funds were deposited and which will serve as the Trustee of the new Funeral Trust Account.

(b) If any funds in connection with that Pre-need Funeral Contract were used to purchase a Pre-need Insurance Policy or Annuity pursuant to 239 CMR 4.10, the transferor funeral establishment shall send a copy of the Buyer's written authorization for transfer of that Pre-need Funeral Contract to the insurance company which issued the Pre-need Insurance Policy or Annuity and request that the insurance company take all necessary and appropriate steps to modify the insurance policy so that the transferee funeral establishment may receive payment for any funeral goods and services it provides to the Beneficiary of that policy. The transferor funeral establishment shall furnish written confirmation to the Buyer, and the Beneficiary (if different), that the request for transfer of the Pre-need Funeral Contract and appropriate modification of the insurance policy have been sent to the insurance company which issued the Pre-need Insurance Policy or Annuity not later than 30 days after the transfer or assignment of the Pre-need Funeral Contract occurs.

4.07: Cancellation of Pre-need Funeral Contracts

(1) Any Buyer of a Pre-need Funeral Contract may cancel that contract and receive a full refund of all monies paid connected with that contract, without penalty, at any time within ten days after signing said contract. After the expiration of this ten-day "cooling off period" a Pre-need Funeral Contract may be canceled in accordance with 239 CMR 4.07(3).
4.07: continued

(2) Where an application by the Buyer or contract Beneficiary of a Pre-need Funeral Contract for government benefits is pending, the Buyer may waive his or her right to cancel said contract within this ten-day "cooling off" period, but only by signing a written waiver of that right. Said waiver shall not affect the Buyer's right to transfer that Pre-need Funeral Contract pursuant to 239 CMR 4.06.

(3) If a Pre-need Funeral Contract was Revocable at the time it was originally created, the Buyer who signed that Pre-need Funeral Contract, or his or her legal representative, may cancel that Pre-need Funeral Contract at any time after the expiration of the ten-day "cooling off" period specified in 239 CMR 4.07(1) by sending written notice of such cancellation, via certified mail, return receipt requested, to the Licensed Funeral Establishment.

(a) If a Funeral Trust Account has been established to fund that Pre-need Funeral Contract, the funeral establishment shall forward a copy of said notice of cancellation to the named Trustee of said Funeral Trust Account, and take all steps necessary to ensure that all funds contained in that Funeral Trust Account are refunded to the Buyer, without penalty, within ten days after the notice of cancellation is received by the Trustee of the Funeral Trust Account.

(b) If a Pre-need Insurance Policy or Annuity was purchased to fund that Pre-need Funeral Contract, the Licensed Funeral Establishment shall forward a copy of the notice of cancellation of that Pre-need Funeral Contract to the insurance company which issued the Pre-need Insurance Policy or Annuity.

(4) If a Pre-need Funeral Contract was Irrevocable at the time it was originally created, such a contract shall not be cancelled by either party except by order of a court of competent jurisdiction. Such a contract may, however, be transferred to another Licensed Funeral Establishment in accordance with 239 CMR 4.06.

(5) No Licensed Funeral Establishment, or agent or employee thereof, shall impose any surcharge, fee or other penalty (monetary or otherwise) upon any person who seeks to exercise his or her rights to cancel a Pre-need Funeral Contract under 239 CMR 4.07.

4.08: Restrictions on Use or Disposition of Funds Received in Connection with Pre-need Funeral Contracts

(1) Prohibition Against Personal or Business Uses. No Licensed Funeral Establishment, nor any agent or employee thereof, shall receive funds in connection with any Pre-need Funeral Contract for any personal use, payment of the operating expenses of any funeral establishment, issuance of a loan to any person, as collateral for any loan, or for any purpose.

(2) Funeral Trust Account or Pre-need Insurance Policy or Annuity Required. All funds made payable to a banking institution or insurance company received from a Buyer by a Licensed Funeral Establishment, or by any employee or agent thereof, in connection with any Pre-need Funeral Contract shall be:

(a) Deposited in a Funeral Trust Account which meets the requirements of 239 CMR 4.09 not later than five business days after the expiration of the "cooling-off" period described in 239 CMR 4.07(1); or

(b) Paid to an insurance company for the purchase of a Pre-need Insurance Policy or Annuity pursuant to 239 CMR 4.10 not later than five business days after the expiration of the "cooling-off" period described in 239 CMR 4.07(1).

(c) Each time a Licensed Funeral Establishment receives any funds made payable to a banking institution or insurance company in connection with any Pre-need Funeral Contract to which it is a party, that funeral establishment shall furnish the Buyer, and the Beneficiary (if different), with written confirmation that such funds have been deposited in a Funeral Trust Account or used to purchase a Pre-need Insurance Policy or Annuity, as required by this section, not later than 14 days after such funds are deposited or paid. Such written confirmation shall bear the signature of a duly-authorized representative of the banking institution in which the Funeral Trust Account has been established, or a duly-authorized representative of the insurance company which issued the Pre-need Insurance Policy or Annuity, whichever applies.
4.08: continued

(3) Reimbursement for Newly Imposed Taxes or Governmental Fees Permitted. Notwithstanding the provisions of 239 CMR 4.08(1), a Licensed Funeral Establishment may require a customer to reimburse said funeral establishment for any local, state or federal taxes or fees imposed after the execution of the Pre-need Funeral Contract, including but not limited to any value-added or sales taxes, for which the funeral establishment is held responsible by the taxing authority or governmental entity. In cases where the Pre-need Funeral Contract is funded in full or in part, said reimbursement shall be considered an additional sum to be paid by the customer, and the funeral establishment shall not be required to deduct it from any income which accrues on the amount initially placed with the funeral establishment for investment in a Pre-need Funeral Trust Account or Pre-need Insurance Policy or Annuity.

(4) Access to Pre-need Funeral Contract Funds. Neither a Licensed Funeral Establishment, nor any agent or employee thereof, shall have access to any of the funds made payable to a banking institution or insurance company which are received by that funeral establishment in connection with any Pre-need Funeral Contract for any purpose other than:

(a) Obtaining payment for the actual costs of Funeral Goods and/or Services provided to the Beneficiary, or for Non-funeral Establishment Charges or "Cash Advance Item" Charges connected with the funeral of that Beneficiary, upon presentation of the documentation required by 239 CMR 4.08(5);

(b) Transferring those funds to another Funeral Trust Account, or to a Pre-need Insurance Policy or Annuity, upon written authorization to do so from the Buyer, the Beneficiary of the Pre-need Funeral Contract (if different from the Buyer), or the duly authorized legal representative of the Buyer or Beneficiary;

(c) Transferring those funds to another Licensed Funeral Establishment in connection with a transfer of the underlying Pre-need Funeral Contract, pursuant to and in accordance with the requirements of 239 CMR 4.06;

(d) Refunding those funds to the Buyer or the Beneficiary upon receipt of a written notice of cancellation of the Pre-need Funeral Contract from the Buyer, the Beneficiary of the Pre-need Funeral Contract (if different from the Buyer) or the duly authorized legal representative of the Buyer or Beneficiary, to the extent permitted by 239 CMR 4.07.

(5) Documentation Required for Payment for Services Rendered. Before obtaining or receiving payment for Funeral Goods and/or Services rendered to the Beneficiary of any Pre-need Funeral Contract pursuant to 239 CMR 4.08(4)(a), the Licensed Funeral Establishment shall present both of the following to the named Trustee of the Funeral Trust Account, or the duly authorized representative of the insurer which issued the Pre-need Insurance Policy or Annuity, which was used to fund that Pre-need Funeral Contract:

(a) a certified copy of the death certificate for the Beneficiary; and

(b) a written statement, signed by a Type 3, certifying that the Pre-need Funeral Contract has been performed in full.

(6) Allocation and Disposition of Pre-need Funeral Contract Funds. At the time of the contract Beneficiary's death, the funds available in any Funeral Trust Account established in connection with that Pre-need Funeral Contract pursuant to 239 CMR 4.09, and/or in any Pre-need insurance policies purchased in connection with that Pre-need Funeral Contract pursuant to 239 CMR 4.10, shall be apportioned between the cost of the goods and services provided directly by the Licensed Funeral Establishment and the cost of the goods and services provided by vendors other than the Licensed Funeral Establishment (the Non-Funeral Establishment Charges or "Cash Advance Item" Charges) in accordance with the percentages calculated pursuant to 239 CMR 4.02(5)(d).

(a) If the Pre-need Funeral Contract contained cost-protection provisions pertaining to the costs of the goods and services provided directly by the Licensed Funeral Establishment, and the amount of funds to be applied to the costs of those goods and services pursuant to this section exceeds the actual cost of those goods and services at the time of the contract Beneficiary's death, the Licensed Funeral Establishment may retain the resulting surplus funds.
4.08: continued

(b) If the Pre-need Funeral Contract contained cost-protection provisions pertaining to the costs of the goods and services provided directly by the Licensed Funeral Establishment, and the amount of funds to be applied to the costs of those goods and services pursuant to 239 CMR 4.08(6) is not sufficient to cover the actual cost of those goods and services at the time of the contract Beneficiary's death, the Licensed Funeral Establishment shall bear the resulting loss and shall not bill the estate of the contract Beneficiary, or any other person, for the deficiency.

(c) If the Pre-need Funeral Contract contained cost-protection provisions pertaining to the costs of the goods and services provided by vendors other than the Licensed Funeral Establishment, and the amount of funds to be applied to the costs of those goods and services pursuant to 239 CMR 4.08(6) exceeds the actual cost of those goods and services at the time of the contract Beneficiary's death, the Licensed Funeral Establishment may retain the resulting surplus funds.

(d) If the Pre-need Funeral Contract contained cost-protection provisions pertaining to the costs of the goods and services provided by vendors other than the Licensed Funeral Establishment, and the amount of funds to be applied to the costs of those goods and services pursuant to 239 CMR 4.08(6) is not sufficient to cover the actual cost of those goods and services at the time of the contract Beneficiary's death, the Licensed Funeral Establishment shall bear the resulting loss and shall not bill the estate of the contract Beneficiary, or any other person, for the deficiency.

(e) If the Pre-need Funeral Contract did not contain cost-protection provisions pertaining to the costs of the goods and services provided directly by the Licensed Funeral Establishment, and the amount of funds to be applied to the costs of those goods and services pursuant to 239 CMR 4.08(6) exceeds the actual cost of those goods and services at the time of the contract Beneficiary's death, the Licensed Funeral Establishment shall refund the resulting surplus to the estate of the contract Beneficiary. In such event, the amount refunded may be subject to claims of the Commonwealth or the United States.

(f) If the Pre-need Funeral Contract did not contain cost-protection provisions pertaining to the costs of the goods and services provided directly by the Licensed Funeral Establishment, and the amount of funds to be applied to the costs of those goods and services pursuant to 239 CMR 4.08(6) is not sufficient to cover the actual cost of those goods and services at the time of the contract Beneficiary's death, the Licensed Funeral Establishment may bill the estate of the contract Beneficiary for the deficiency.

(g) If the Pre-need Funeral Contract did not contain cost-protection provisions pertaining to the costs of the goods and services provided by vendors other than the Licensed Funeral Establishment, and the amount of funds to be applied to the costs of those goods and services pursuant to 239 CMR 4.08(6) exceeds the actual cost of those goods and services at the time of the contract Beneficiary's death, the Licensed Funeral Establishment shall refund the resulting surplus to the estate of the contract Beneficiary. In such event, the amount refunded may be subject to claims of the Commonwealth or the United States.

(h) If the Pre-need Funeral Contract did not contain cost-protection provisions pertaining to the costs of the goods and services provided by vendors other than the Licensed Funeral Establishment, and the amount of funds to be applied to the costs of those goods and services pursuant to 239 CMR 4.08(6) is not sufficient to cover the actual cost of those goods and services at the time of the contract Beneficiary's death, the Licensed Funeral Establishment may bill the estate of the contract Beneficiary for the deficiency.

(7) Final Statement of Allocation of Funds to Be Furnished to Beneficiary's Estate in Certain Cases. If a Pre-need Funeral Contract is not a Cost-protected Pre-need Funeral Contract with respect to all of the funeral goods and services identified in that contract, the Licensed Funeral Establishment shall prepare, and furnish to the estate of the contract Beneficiary at the time of the contract Beneficiary's death, an addendum to the written Itemized Statement of Funeral Goods and Services required by 16 CFR Part 453 and M.G.L. c. 112, § 84B which shows:

(a) The total amount of funds in the Pre-need Funeral Trust Account(s) and/or Pre-need insurance policies for that Beneficiary which were available at the time of the contract Beneficiary's death;

(b) The amount of funds available in the Pre-need Funeral Trust Account(s) and/or Pre-need insurance policies which was applied to the costs of the goods and services which were provided directly by the Licensed Funeral Establishment itself; and
4.08: continued

(c) The amount of funds available in the Pre-need Funeral Trust Account(s) and/or Pre-need insurance policies which was applied to the costs of the goods and services provided by vendors other than the Licensed Funeral Establishment (the Non-funeral Establishment Charges or "Cash Advance Item" Charges).

(d) Failure to provide such information accurately and completely in writing to the estate of the contract Beneficiary shall constitute a violation of 239 CMR 4.00.

4.09: Funeral Trust Accounts

(1) All Funeral Trust Accounts shall be established and administered in compliance with the requirements of 239 CMR 4.09.

(2) Creation of Funeral Trust Accounts. Where a Pre-need Funeral Contract will be funded through a Funeral Trust Account, the Licensed Funeral Establishment shall deposit all funds made payable to a banking institution received in connection with that Pre-need Funeral Contract in a Funeral Trust Account within five business days after the expiration of the "cooling-off" period described in 239 CMR 4.07(1). Every such Funeral Trust Account shall:
   (a) Designate a federal or state-chartered banking institution which has trust powers, or a trust company, within the Commonwealth of Massachusetts as the Trustee of said Funeral Trust Account;
   (b) Designate the person for whom the Funeral Goods and/or Services are to be provided as the Beneficiary of said Funeral Trust Account;
   (c) Indicate that the funds are to be used solely for the purpose of paying for Funeral Goods and/or Services and Non-funeral Establishment Charges or "Cash Advance Item" Charges as indicated in the Itemized Statement of Funeral Goods and Services required by 239 CMR 4.02(5); and
   (d) Provide that the entire account balance shall be payable to the Licensed Funeral Establishment which provides the specified Funeral Goods and/or Services to the Beneficiary at time of death in accordance with 239 CMR 4.00.

(3) Investment Requirements. The funds placed in a Funeral Trust Account may be invested in any form of investment which may lawfully be established or maintained by the trust department of the banking institution or trust company which is serving as the Trustee of that Funeral Trust Account. All funds deposited in that Funeral Trust Account shall be invested and managed in accordance with M.G.L. c. 203C.

(4) Common or Commingled Trust Accounts. Funds made payable to a banking institution received in connection with more than one Pre-need Funeral Contract may be deposited in a single common or commingled Funeral Trust Account under the terms of a single trust instrument, provided that:
   (a) The common or commingled Funeral Trust Account is established and administered in accordance with all applicable requirements of 239 CMR 4.09; and
   (b) Separate records, which meet the requirements of 239 CMR 4.12(1)(e), are maintained for each customer whose funds are deposited in the common or commingled Funeral Trust Account.

(5) Obligations to Locate Trust Beneficiary.
   (a) If a Licensed Funeral Establishment which is a party to a Pre-need Funeral Contract does not provide the Funeral Goods and/or Services for the Beneficiary of that contract upon his or her death, then, upon receipt of a certified copy of the death certificate of such Beneficiary, the Trustee of any Funeral Trust Account established to fund said Pre-need Funeral Contract shall pay the assets of said Funeral Trust Account to the estate or legal representative of the named Beneficiary in accordance with the applicable requirements of 239 CMR 4.09.
4.09: continued

(b) If a Licensed Funeral Establishment has not received notice of the death of the named Beneficiary of a Pre-need Funeral Contract for whom a Funeral Trust Account has been established under 239 CMR 4.09 within 110 years of the Beneficiary's date of birth, said funeral establishment shall take all reasonable steps to contact that Beneficiary or his or her legal representative to inform them of the existence of said Funeral Trust Account. A written notice of the existence of said Funeral Trust Account, sent via certified mail, return receipt requested, to the last known address of the trust Beneficiary and his or her legal representative shall be sufficient to satisfy the requirements of 239 CMR 4.09(5)(b).

(c) If, after a reasonable search, a Licensed Funeral Establishment is unable to locate the Beneficiary of said Funeral Trust Account, the funeral establishment shall notify the Trustee of the account, and the Trustee shall turn over all funds in the Funeral Trust Account to the Treasurer of the Commonwealth, in accordance with the laws of the Commonwealth. Any such transfer of funds to the Treasurer of the Commonwealth shall constitute a complete release of all obligations of such Licensed Funeral Establishment pursuant to the Pre-need Funeral Contract.

4.10: Pre-need Insurance Policies and Annuities

(1) Any agent or employee of any Licensed Funeral Establishment who sells or otherwise provides insurance policies or annuities as a method for funding Pre-need Funeral Contracts shall comply with all applicable state and federal laws and regulations pertaining to the conduct of the business of insurance, including but not limited to all licensing requirements of the Massachusetts Division of Insurance.

(2) Any agent or employee of any Licensed Funeral Establishment who sells or otherwise provides insurance policies or annuities as a method for funding Pre-need Funeral Contracts shall, prior to accepting any funds as payment for the issuance of any such insurance policy or annuity, make all of the disclosures required by the Massachusetts Division of Insurance to the prospective purchaser of said insurance policy or annuity. In addition to the disclosures required by the Massachusetts Division of Insurance, the agent or employee of the funeral establishment shall also disclose:

(a) That the amount to be refunded to the Buyer if the insurance policy is cancelled prior to the death of the Beneficiary will be determined by the cash surrender value provisions of the insurance policy; and

(b) That the funeral establishment, or its agent or employee, will be paid a commission on the sale of the insurance policy.

(3) No Licensed Funeral Establishment, nor any agent or employee thereof, shall require any Buyer to purchase any insurance policy or annuity as a condition for entering into any Pre-need Funeral Contract.

(4) Any person who purchases a Pre-need Insurance Policy or Annuity from any agent or employee of any Licensed Funeral Establishment who is duly licensed as an insurance agent by the Massachusetts Division of Insurance, may cancel said policy or annuity without penalty any time within ten days after said policy or annuity contract is delivered to him or her by surrendering the policy or annuity contract to either the insurance company which issued said policy or annuity or the agent from whom it was purchased. Upon surrender of such policy or annuity, the purchaser shall be entitled to a full refund of all payments made in connection with said policy or annuity. No Licensed Funeral Establishment, nor any agent or employee thereof, shall impose any penalty or surcharge (monetary or otherwise) on any person exercising said right of cancellation.

(5) The requirements of 239 CMR 4.10 shall apply to any and all forms of insurance which are sold or utilized for the purpose of providing funding for a Pre-need Funeral Contract, regardless of how named.
4.11: Marketing of Pre-need Funeral Products

(1) No agent or employee of any Licensed Funeral Establishment shall visit or call upon any patient in a hospital, convalescent or nursing home, rest home, charitable home for the aged, infirmary maintained in a town, intermediate care facility for the mentally retarded, or other health care facility, for the purpose of soliciting or inducing such patient to enter into any Pre-need Funeral Contract, or for the purpose of soliciting or inducing such patient to establish a Funeral Trust Account or purchase a Pre-need Insurance Policy or Annuity, unless said agent or employee has been authorized to do so by the patient or his or her legal representative to do so prior to the visit.

(2) A Licensed Funeral Establishment, or any agent or employee thereof, may utilize telephonic communications for the purpose of soliciting or inducing any person to enter into a Pre-need Funeral Contract, establish a Funeral Trust Account, or purchase any Pre-need Insurance Policy or Annuity, provided that:

(a) The prospective customer is informed at the beginning of the telephonic communication that the telephonic communication is being made for the purpose of inducing him or her to enter into a Pre-need Funeral Contract, establish a Funeral Trust Account, or purchase a Pre-need Insurance Policy or Annuity; and

(b) The telephonic communication is terminated immediately upon any request to do so from the prospective customer.

(3) No agent or employee of any Licensed Funeral Establishment shall solicit or attempt to induce any person to enter into a Pre-need Funeral Contract, establish any Funeral Trust Account, or purchase any Pre-need Insurance Policy or Annuity by any method or means which is false, deceptive, misleading, coercive, intimidating or threatening.

(4) No Licensed Funeral Establishment, nor any agent or employee thereof, shall knowingly induce or attempt to induce any person to cancel or revoke any pre-existing Pre-need Funeral Contract, Funeral Trust Account, or Pre-need Insurance Policy or Annuity.

(5) Advertising of Pre-need Funeral Products.

(a) Advertising of Pre-need Funeral Contracts, Funeral Trust Accounts and/or Pre-need insurance policies or annuities by any Licensed Funeral Establishment, or agent or employee thereof, shall not be false, deceptive or misleading.

(b) All advertising of Pre-need Funeral Contracts, Funeral Trust Accounts and/or Pre-need insurance policies or annuities shall disclose all of the following information:

1. The type of product (e.g., Funeral Trust Account or Pre-need Insurance Policy or Annuity) which is to be, or may be, used to fund the Pre-need Funeral Contract; and

2. The nature of the relationship between the agent who solicits the purchase of the product, the funeral establishment which is to provide the Funeral Goods and/or Services, the Buyer, and the individual or institution which will receive and/or hold any funds paid by the Buyer in connection with the purchase of the product.

(c) All advertising of Pre-need Funeral Contracts, Funeral Trust Accounts, and/or Pre-need insurance policies or annuities by a Licensed Funeral Establishment, or any agent or employee thereof, shall comply with all other applicable state and federal laws and regulations pertaining to such advertising.

4.12: Recordkeeping Requirements

(1) Each Licensed Funeral Establishment shall maintain a separate, legible written record for each Pre-need Funeral Contract to which that funeral establishment is a party. Said records shall be maintained at all times on the premises of that funeral establishment, or on the premises of another specifically-identified Licensed Funeral Establishment within the Commonwealth which is owned and operated by the same proprietor, corporation, partnership, association, limited liability company, limited liability partnership or other business entity. At a minimum, such records shall contain all of the following information:

(a) A fully-executed copy of the Pre-need Funeral Contract;

(b) A fully-executed copy of each amendment or modification of the terms of that Pre-need Funeral Contract;
4.12: continued

(c) In the case of any Pre-need Funeral Contract which was transferred to another funeral establishment after its original execution, the name and address of the funeral establishment to which that Pre-need Funeral Contract was transferred and written documentation that the Buyer and/or Beneficiary has authorized that transfer;

(d) In the case of any Pre-need Funeral Contract which has been performed (i.e., the funeral goods and services specified in that contract have been provided to the Beneficiary of that contract), a copy of the death certificate for the Beneficiary of that Pre-need Funeral Contract and written documentation that the funeral goods and services specified in that contract were provided;

(e) Where the funding source for the funeral goods and services to be provided pursuant to that Pre-need Funeral Contract is a Funeral Trust Account:
   1. The name, address, date of birth and social security number of the named trust Beneficiary;
   2. Copies of bank statements and deposit slips from the bank or financial institution which is holding the funds deposited in the Funeral Trust Account which show the date on which the funeral trust was originally established, the amount of money originally deposited in the Funeral Trust Account at the time the Funeral Trust Account was originally established, and the date and amount of each subsequent deposit in the Funeral Trust Account, if any;
   3. The name and address of the bank or financial institution which is holding the funds deposited in the Funeral Trust Account;
   4. The balance in the Funeral Trust Account, on a monthly basis;
   5. A description of the form and manner in which the trust funds are invested;
   6. A copy of the individual trust agreement, or, in the case of a common or commingled Funeral Trust Account established pursuant to 239 CMR 4.09(4), a copy of the Master Trust Agreement for the common account; and
   7. Written documentation sufficient to demonstrate compliance with all applicable requirements of 239 CMR 4.00 with respect to all changes in the terms or provisions of the Funeral Trust Account.

(f) Where the funding source for the funeral goods and services to be provided pursuant to that Pre-need Funeral Contract is a Pre-need Insurance Policy or Annuity:
   1. the name and address of the insurance company which issued the policy or annuity;
   2. the amount of money originally paid to that insurance company for the issuance of that policy or annuity; and
   3. the face value of that insurance policy or annuity.

(2) In the case of any common or commingled Funeral Trust Account established pursuant to 239 CMR 4.09(4), a separate written record which complies with the requirements of 239 CMR 4.12(1) shall be maintained for each separate trust Beneficiary.

(3) Any and all records established and maintained pursuant to 239 CMR 4.12 shall be available upon request, at any time during regular business hours, to any duly authorized representative of the Board for inspection.

(4) Any and all records required by 239 CMR 4.12 shall be made available by the Licensed Funeral Establishment during regular business hours, to the Buyer of the Pre-need Funeral Contract to whom those records pertain, the Beneficiary of the Pre-need Funeral Contract to whom those records pertain, or the legal representative of either, for inspection within ten days after receipt of any written request from any such person to examine such records. Upon the written request of the Buyer, the contract Beneficiary, or the legal representative of either, the Licensed Funeral Establishment shall furnish copies of all such records to the requesting party. The Licensed Funeral Establishment may charge a reasonable fee, not to exceed the actual costs of reproduction, for such copies.

(5) Every Licensed Funeral Establishment shall file with the Board, on or before January 31st of each calendar year, a written report setting forth the following information:
   (a) The number of Pre-need Funeral Contracts entered into during the preceding calendar year;
4.12: continued

(b) The total number of Pre-need Funeral Contracts to which the funeral establishment is a party;
(c) The funding method used to finance each Pre-need Funeral Contract to which the Licensed Funeral Establishment is a party;
(d) The names and addresses of all banks, trust companies, and insurance companies holding any funds received in connection with any such Pre-need Funeral Contracts during the preceding calendar year;
(e) The location within the Commonwealth of Massachusetts where its records pertaining to Pre-need Funeral Contracts are maintained; and
(f) The number of Pre-need Funeral Contracts and amount of funds transferred to the Treasurer of the Commonwealth in accordance with 239 CMR 4.09(5)(c).

(6) Said report shall be made in such form and manner as the Board may direct.

(7) Upon request by any authorized representative of the Board in connection with any official inquiry, a Licensed Funeral Establishment shall furnish complete written information regarding the total amount of assets being held in connection with Pre-need Funeral Contracts by each institution or company identified pursuant to 239 CMR 4.12(6) which is holding any such funds.

4.13: Penalties

Violation of any provision of 239 CMR 4.00 shall be considered a violation of M.G.L. c. 112, § 84A(j), and may also be considered "gross misconduct in the practice of the profession" within the meaning of M.G.L. c. 112, § 61, and shall constitute grounds for disciplinary action by the Board.

4.14: Effective Date

(1) The provisions of 239 CMR 4.00 shall apply in full to all Pre-need Funeral Contracts which are established on or after July 27, 2017.

(2) With respect to any and all Pre-need Funeral Contracts established prior to July 27, 2017:
   (a) Such Pre-need Funeral Contracts shall be in compliance with the record-keeping requirements of 239 CMR 4.12 no later than July 27, 2017; and
   (b) All other requirements of 239 CMR 4.00 shall apply to the administration and performance of such Pre-need Funeral Contracts as of July 27, 2017.

(3) For the purposes of 239 CMR 4.12(5), the report otherwise due January 31, 2017 may be submitted to the Board no later than June 30, 2017.

REGULATORY AUTHORITY

239 CMR 4.00: M.G.L. c. 112, § 85.
Regulation Filing  

To be completed by filing agency

CHAPTER NUMBER: 239 CMR 5.00

CHAPTER TITLE: Continuing Education

AGENCY: Board of Registration in Embalming and Funeral Directing

SUMMARY OF REGULATION: State the general requirements and purposes of this regulation.

The purpose of 239 CMR 5.00 is to provide the basic rules for continuing education mandated for funeral directors and embalmers. Specifically, this section mandates the amount of continuing education required, rules governing providers, and explains how the requirement is enforced.

REGULATORY AUTHORITY: M.G.L. c. 112, § 85

AGENCY CONTACT: Charles Kilb  PHONE: 617-727-2707

ADDRESS: Div. of Prof. Licensure, 1000 Washington St., 7th Fl., Boston, MA 02118

Compliance with M.G.L. c. 30A

EMERGENCY ADOPTION - if this regulation is adopted as an emergency, state the nature of the emergency.

PRIOR NOTIFICATION AND/OR APPROVAL - If prior notification to and/or approval of the Governor, Legislature or others was required, list each notification, and/or approval and date, including notice to the Local Government Advisory Commission.

Local Government Advisory Committee - July 22, 2016
Massachusetts Register Publication - September 9, 2016
Boston Globe and Springfield Republican - August 29, 2016

PUBLIC REVIEW - M.G.L. c. 30A sections 2 and/or 3 requires notice of the hearing or comment period, including a small business impact statement, be filed with the Secretary of the Commonwealth, published in appropriate newspapers, and sent to persons to whom specific notice must be given at least 21 days prior to such hearing or comment period.

Date of public hearing or comment period: September 20, 2016
FISCAL EFFECT -  

Estimate the fiscal effect of the public and private sectors.

For the first and second year:  
No fiscal effect anticipated

For the first five years:  
No fiscal effect anticipated

No fiscal effect:  
No fiscal effect anticipated

SMALL BUSINESS IMPACT -  

M.G.L. c. 30A section 5 requires each agency to file an amended small business impact statement with the Secretary of the Commonwealth prior to the adoption of a proposed regulation. If the purpose of this regulation is to set rates for the state, this section does not apply.

Date amended small business impact statement was filed:  
January 11, 2017

CODE OF MASSACHUSETTS REGULATIONS INDEX -  

List key subjects that are relevant to this regulation:
continuing education, embalming, funeral directing, funeral homes

PROMULGATION -  

State the action taken by this regulation and its effect on existing provisions of the Code of Massachusetts Regulations (CMR) or repeal, replace or amend. List by CMR number:

239 CMR 5.00 (amend)

ATTESTATION -  

The regulation described herein and attached hereto is a true copy of the regulation adopted by this agency.  
ATTEST:

SIGNATURE:  
SIGNATURE ON FILE  
DATE:  
Jan 12 2017

Publication -  
To be completed by the Regulations Division

MASSACHUSETTS REGISTER NUMBER:  
S1331  
DATE:  
01/27/2017

EFFECTIVE DATE:  
01/27/2017

The text of the regulations published in the electronic version of the Massachusetts Register is unofficial and for informational purposes only. The official version is the printed copy which is available from the State Bookstore at http://www.sec.state.ma.us/spr/sprcat/catidx.htm.
The purpose of 239 CMR 5.00 is to require all registrants to obtain continuing education as a condition for renewal of their licenses in order to maintain the high standards of the profession and business of funeral directing, and to establish criteria for approval of continuing education programs to be used in fulfilling such continuing education requirements.

For purposes of 239 CMR 5.00, the following terms shall have the following meanings:

**Contact Hour.** A unit of measurement of organized learning experience lasting 50 consecutive minutes.

**Registration Period.** The one-year period between registration renewals beginning on November 1st of each calendar year and ending on October 31st of the next calendar year.

(1) Every registrant shall complete a minimum of eight hours of continuing education prior to the end of each Registration Period in courses or programs approved by the Board as a condition for renewal of his or her registration.

(2) All continuing education courses or programs approved by the Board shall require Board registrants to complete and pass an examination on the material presented in the course or program as a condition to receiving continuing education credit for the course or program.

(3) As part of the continuing education required by 239 CMR 5.03(1), every registrant shall obtain at least one hour of continuing education to be in compliance with the regulations of the United States Occupational Safety and Health Administration regarding information on bloodborne pathogen exposure risks and protection from such risks, as delineated in 239 CMR 3.12(13) and 29 CFR 1910.1030.

(4) The Board may extend the deadline for completion of the continuing education requirements upon a showing by the registrant that such requirements impose an undue hardship due to unforeseen circumstances. Such a request must be in writing, under oath, and accompanied by a letter addressed to the Board written and signed by a licensed medical doctor stating the nature of the registrant's medical condition and the correlation between that condition and the registrant's inability both to complete the required continuing education within the required period as well as the registrant's inability to work. A registrant shall also be eligible for a waiver of mandatory continuing education deadlines if the registrant can provide adequate documentation to show that another individual under the care of the registrant is suffering from an illness or disability and that said care prevented the registrant both from completing continuing education as well as preventing the registrant from working.
5.03: continued

(5) A registrant shall not be required to complete the continuing education required by 239 CMR 5.03(1) for the Registration Period in which he or she obtains his or her initial registration in order to obtain renewal of said registration for the following Registration Period, but shall be required to obtain such continuing education for all subsequent renewals. Nothing in 239 CMR 5.03(5) shall exempt a registrant from having to obtain the continuing education in bloodborne pathogen risks required by 239 CMR 3.12(13) and 5.03(2).

5.04: Qualifying Continuing Education Programs

A continuing education course or program may be used to satisfy the continuing education requirements set forth in 239 CMR 5.03 only if it is a formally organized course of program which is primarily instructional in nature and contributes directly to professional competence in the profession and business of funeral directing. Such courses or programs must meet the following criteria in order to be approved for continuing education credit:

(1) The course or program shall be given by a sponsor approved by the Board, or approved for an individual registrant by the Board;

(2) An outline of the course shall be prepared and distributed to all attendees. Said outline shall state the number of continuing education contact hours provided;

(3) The course or program shall be at least 50 consecutive minutes in length;

(4) The course or program shall be conducted by a qualified instructor;

(5) The number of continuing education contact hours to be awarded to attendees shall be determined by the sponsor or, in the case of a course or program approved for an individual registrant, approved by the Board;

(6) The course or program shall cover appropriate subject matter, which shall include but shall not be limited to:
   (a) Business administration;
   (b) Religious customs and traditions relating to funerals;
   (c) Natural sciences including first aid and CPR;
   (d) Pre-need services;
   (e) Embalming and restorative arts;
   (f) Massachusetts laws and regulations governing funeral service;
   (g) Funeral service counseling;
   (h) Funeral service merchandising; and
   (i) Sanitation and infection control.

(7) The following are generally not acceptable subject matters:
   (a) Services falling outside the scope of Board issued registrations; and
   (b) Non-Massachusetts laws and regulations.

(8) The course or program shall be available to all registrants.

5.05: Sponsor Requirements

(1) A sponsor of a continuing education course or program shall be recognized and approved by the Board upon submission of a completed application for approval of said course or program, provided that said sponsor meets all of the following requirements:
   (a) The sponsor establishes and maintains an accurate record of course attendance showing the date of the program or course, the location at which the program or course was given, the name of each person who attended, and the license or registration number of each person who attended;
   (b) The sponsor issues certificates or other written evidence of completion of the course or program to each person who attends the entire course or program;
5.05: continued

(c) The sponsor does not issue certificates or other written evidence of completion of the course or program until the course or program is completed;
(d) The course or program meets all applicable requirements of 239 CMR 5.04; and
(e) The sponsor maintains a copy of the course or program outline, and all records required by 239 CMR 5.04 and 5.05(1)(a) for a period of at least four years from the date on which the course or program is presented.

(2) The Board may grant approval to sponsors and/or individual continuing education courses or programs by resolution, and may likewise withdraw or rescind such approval for good cause shown.

(3) In general, the Board shall not approve as sponsors a registrant or licensed funeral establishment seeking to provide continuing education to its own employees.

5.06: Responsibilities of Individual Registrants

(1) Each registrant shall maintain a record of all continuing education courses or programs he or she has completed for a period of not less than four consecutive Registration Periods, inclusive of the Registration Period during which the course or program was completed.

(2) Each registrant, as part of his or her application for renewal of his or her registration, shall attest under the pains and penalties of perjury that he or she has completed the number of continuing education hours required by 239 CMR 5.03. Such attestation shall be made on a form prescribed and provided by the Board.

(3) Upon written request by the Board, a registrant shall furnish to the Board such information as the Board may reasonably require about any or all continuing education courses or programs completed by said registrant. A registrant who is requested to submit such verification of his or her continuing education activities shall submit written verification of all of the following:
   (a) the name of the school, institution, organization or other sponsor conducting the course or program in question;
   (b) the location at which the course or program in question was presented;
   (c) the title of the course or program in question;
   (d) the date on which the course or program in question was presented;
   (e) the number of hours of continuing education credit being claimed for the course or program in question; and
   (f) the name of the individual authorizing the award of continuing education credit for the course or program in question.

(4) Failure or refusal to provide timely proof of completion of the number of continuing education hours required by 239 CMR 5.03 upon the request of the Board shall constitute grounds for disciplinary action by the Board.

5.07: Continuing Education Requirements for License Reinstatement

In order to reinstate a registration after expiration, cancellation, or suspension, a registrant shall submit proof of completion of all continuing education hours normally required under 239 CMR 5.03 for the period from the date of his or her last registration renewal to the date of his or her application for reinstatement. In the event that such an application for reinstatement is submitted prior to the expiration date of a particular Registration Period, the continuing education required for that Registration Period shall be prorated appropriately.

5.08: Board Responsibilities

It shall be the responsibility of the Board to:

(1) Establish a system for verifying continuing education information submitted by applicants for renewal of registration;
5.08: continued

(2) Establish deadlines for the submission of documentation of completion of continuing education hours;

(3) Establish and maintain a record of current registrants;

(4) Review, and approve or deny, applications for approval of continuing education courses, programs and sponsors;

(5) Conduct ongoing evaluations of the continuing education process; and

(6) Supervise related continuing education activities as necessary and appropriate.

REGULATORY AUTHORITY:

239 CMR 5.00: M.G.L. c. 112, § 85.
Regulation Filing  To be completed by filing agency

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</table>

**SUMMARY OF REGULATION:**  State the general requirements and purposes of this regulation.

These regulations govern how MassDEP selects and oversees local governments' waste water infrastructure projects which voluntarily receive state-subsidized financing under the State Revolving Fund program. These changes are an update required by state statute and conform to federal law. Specifically, the Massachusetts General Court enacted "An Act improving drinking water and waste water infrastructure" (2014), authorizing the appropriation of enhanced loan subsidies. This regulatory revision is required to codify the eligibility criteria for the enhanced subsidies outlined in the statute.

**REGULATORY AUTHORITY:**  M.G.L c.29C

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<thead>
<tr>
<th>AGENCY CONTACT:</th>
<th>Steve McCurdy  PHONE: 617-292-5779</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADDRESS:</td>
<td>1 Winter Street 5th floor, Boston, MA 02108</td>
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**Compliance with M.G.L. c. 30A**

**EMERGENCY ADOPTION** -  if this regulation is adopted as an emergency, state the nature of the emergency.

**PRIOR NOTIFICATION AND/OR APPROVAL** -  If prior notification to and/or approval of the Governor, Legislature or others was required, list each notification, and/or approval and date, including notice to the Local Government Advisory Commission.

- Mass Municipal Association  2-12-2016
- Local Government Advisory Commission  2-12-2016
- Mass Dept. of Housing and Community Development  2-16-2016

**PUBLIC REVIEW** -  M.G.L. c. 30A sections 2 and/or 3 requires notice of the hearing or comment period, including a small business impact statement, be filed with the Secretary of the Commonwealth, published in appropriate newspapers, and sent to persons to whom specific notice must be given at least 21 days prior to such hearing or comment period.

| Date of public hearing or comment period: | April 14, 2016 |
FISCAL EFFECT -  Estimate the fiscal effect of the public and private sectors.

For the first and second year: 

For the first five years: 

No fiscal effect: 

SMALL BUSINESS IMPACT -  M.G.L. c. 30A section 5 requires each agency to file an amended small business impact statement with the Secretary of the Commonwealth prior to the adoption of a proposed regulation. If the purpose of this regulation is to set rates for the state, this section does not apply.

Date amended small business impact statement was filed: 1/4/2017

CODE OF MASSACHUSETTS REGULATIONS INDEX -  List key subjects that are relevant to this regulation:

PROMULGATION -  State the action taken by this regulation and its effect on existing provisions of the Code of Massachusetts Regulations (CMR) or repeal, replace or amend. List by CMR number:

Amend 310 CMR 44

ATTESTATION -  The regulation described herein and attached hereto is a true copy of the regulation adopted by this agency.  ATTEST:

SIGNATURE:  SIGNATURE ON FILE  DATE:  Jan 6 2017

Publication -  To be completed by the Regulations Division

MASSACHUSETTS REGISTER NUMBER:  S1331  DATE:  01/27/2017

EFFECTIVE DATE:  01/27/2017

CODE OF MASSACHUSETTS REGULATIONS

Remove these pages:  Insert these pages:

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2169 - 2180  2169 - 2188
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44.01: Introduction

The federal Clean Water Act amendments of 1987 authorized the Clean Water State Revolving Fund program to finance protection and improvement of water quality. The Massachusetts Clean Water State Revolving Fund (CWSRF) Program is a federal-state partnership that provides below-market-rate financing to assist municipalities in complying with federal and state water quality requirements. The CWSRF Program is jointly administered through the Clean Water Trust by the Commissioner of the Department of Environmental Protection (Department), the State Treasurer, and the Secretary of Energy and Environmental Affairs pursuant to M.G.L. c. 29C, § 2. Every summer, the Department solicits projects from Massachusetts municipalities and wastewater districts for consideration for subsidized State Revolving Fund (SRF) loans. The current standard subsidy is provided via a 2% interest, 20-year loan, but there are opportunities for some projects to receive 30 year loans, or lower interest rates. The SRF Program continues to emphasize public health needs and watershed management priorities. A major goal is to provide incentives to communities to undertake projects with meaningful water quality and public health benefits and which address the needs of the communities and the watersheds. After evaluating the project requests submitted in response to the annual solicitation, the Department develops a list of projects eligible to receive financial assistance. From this annual list, and on the basis of projects’ readiness to proceed and priority rating, the Department assigns projects to a fundable list called the Intended Use Plan Project Listing (IUP). Projects placed on the IUP are eligible to apply for financing in the coming year, with the total cost of all projects on the IUP not to exceed the amount of funding available for that year. To qualify for placement on the IUP, a project must have a high enough ranking, have received a local funding appropriation or be scheduled for funding appropriation by June 30th of the coming year, and the applicant must be able to file a complete loan application no later than October 15th of the coming year.

44.02: Purpose

310 CMR 44.00 implements the CWSRF Program. Under federal and state law, the primary purpose of the CWSRF Program is to provide financing for eligible projects to protect and promote the health, safety, and welfare of the inhabitants of the state. 310 CMR 44.00 sets forth the Department’s authority and responsibilities to select, approve and regulate water pollution abatement projects receiving financial assistance under the SRF Program. The Department may issue supplemental policies, guidelines, guidance documents and/or administrative procedures to assist in the implementation and administration of 310 CMR 44.00.

44.03: Definitions

For the purposes of 310 CMR 44.00, the following terms shall have the meaning set forth in 310 CMR 44.00 unless the context clearly requires otherwise.

208 Plan. An Areawide Waste Treatment Management Plan certified by the Governor or his or her designee and approved by EPA pursuant to § 208 of the Clean Water Act (CWA), 33 U.S.C. § 1288.
Best Management Practices (BMPs). A method, measure or practice in water management, or a combination thereof, established and published by the Trust pursuant to St. 2014, c. 259, § 55. The Trust's BMPs can be found on the Official Website of the Treasurer and Receiver General of Massachusetts.


Collection System Projects. Projects for the construction of a collection system or its related components. Collection systems generally consist of each and all of the common lateral sewers and appurtenances of publicly owned treatment works which are primarily installed to receive wastewaters from individual structures or from private property, and which include service connection “Y” fittings and service connections within the boundary of the public way or easement.

Community Septic Management Program. As authorized by St. 1996, c. 15, § 2, or by any other applicable law, a loan program to Local Governmental Units administered within the Fund and under 310 CMR 44.00 to assist eligible homeowners to upgrade failed septic systems in compliance with 310 CMR 15.000: The State Environmental Code, Title 5: Standard Requirements for the Siting, Construction, Inspection, Upgrade and Expansion of On-site Sewage Treatment and Disposal Systems and for the Transport and Disposal of Septage through underlying betterment agreements between the Local Governmental Unit and such homeowners pursuant to M.G.L. c. 111, § 127B½.

Comprehensive Water Resource Management Plan (CWMP). In accordance with the Department's Guide to Water Resource Management Planning, a CWMP identifies all of a community's needs/problems in one sector of its water resource structure, evaluates alternative means of meeting those needs, selects the most cost-effective and environmentally appropriate remedy, and proposes an implementation plan and schedule. There are three types of CWMPs: Comprehensive Wastewater Management Plans that evaluate a community's wastewater infrastructure/management needs, Comprehensive Water Supply Management Plans that focus on the community's water supply infrastructure and management issues, and Comprehensive Stormwater Management Plans that focus on the community's stormwater management needs.

Cost. As applied to any water pollution abatement project, any or all costs, whenever incurred, approved by the Department in accordance with M.G.L. c. 21, § 27A, of carrying out a project including, without limiting the generality of the foregoing: costs for planning, preparation of studies and surveys, design, construction, expansion, facilities, improvement and rehabilitation, acquisition of real property, personal property, materials, machinery or equipment, start-up costs, demolitions and relocations, reasonable reserves and working capital, interest on loans, local governmental obligations and notes in anticipation thereof prior to and during construction of such project or prior to the date of such loan, if later, administrative, legal and financing expenses, and other expenses necessary or incidental to the aforesaid.

Department. The Massachusetts Department of Environmental Protection.

District. Any county, regional or local district, commission, board or other political subdivision or instrumentality of the Commonwealth, howsoever named, which is authorized to provide itself or through an officer, board, department or division thereof local water pollution abatement, sewer or stormwater services, or public water supply services, whether established under general law or special act.

EPA. The U.S. Environmental Protection Agency.

Federal Cross-cutters. Federal laws and authorities that apply by their own terms to projects receiving federal financial assistance such as the federal SRF. Such federal cross-cutters include, but are not limited to, environmental laws and authorities such as the Clean Air Act, Safe Drinking Water Act, Endangered Species Act, Coastal Zone Management Act, Wild and Scenic Rivers Act and the National Historic Preservation Act of 1966, and economic and miscellaneous authorities such as the procurement and contractor requirements associated with financial assistance programs under the CWA and Clean Air Act.
44.03: continued

**Fiscal Sustainability Plan.** A plan prepared in compliance with § 603(d)(1)(E) of the CWA, 33 U.S.C. § 1383, for treatment works proposed for repair, replacement, or expansion, that includes at a minimum the following four items:

(a) inventory of critical assets that are part of the treatment works;
(b) evaluation of the condition and performance of inventoried assets or asset groupings;
(c) certification that the applicant has evaluated and will be implementing water and energy conservation efforts as part of the plan; and
(d) a plan for maintaining, repairing, funding, and as necessary, replacing the treatment works.

**Green Infrastructure Projects.** Products, technologies, and practices that use natural systems or processes, or engineered systems that use natural systems or processes, to enhance overall environmental quality. Such projects include, but are not limited to, decentralized wastewater systems that infiltrate treated water; water reuse for beneficial purposes; low impact development projects; the conservation, enhancement and restoration of natural upland, wetland and submerged landscape features that naturally filter and remove silt, nutrients and pollution from surface waters, maintain or restore natural hydrologic cycles, minimize imperviousness in a watershed through preservation and restoration of natural landscape buffers such as forests, floodplains, wetlands and other natural systems and restoration of natural stream channels and submerged habitat; land acquisition and restoration projects that protect and filter drinking water supplies and buffer reservoirs or support ecological restoration in fresh or marine waters; and the mitigation of risks of flooding and erosion using the restoration of saltmarsh, oyster reefs and eelgrass beds from sea-level rise, storm surges and extreme weather events, including the protection and restoration of natural coastal landscapes; provided, that Green Infrastructure Projects may be stand-alone and may also be used to complement built water management infrastructure technologies such as pipes, dikes and treatment facilities; and provided, further, that Green Infrastructure Projects may include innovative technologies that further achievement of the mandates under the CWA.

**Indirect Discharge.** Means the introduction of pollutants into a POTW from any non-domestic source regulated under § 307(b), (c) or (d) of the CWA.

**Infiltration.** Water other than wastewater that enters a sewer system (including sewer service connections and foundation drains) from the ground through means which include, but are not limited to, defective pipes, pipe joints connections, or manholes. Infiltration does not include, and is distinguished from, inflow.

**Infiltration/Inflow Projects.** Projects which remove infiltration and inflow (i.e. water other than wastewater) from a sewer system, including construction associated with infiltration/inflow rehabilitation.

**Infiltration/Inflow Rehabilitation.** Construction associated with the rehabilitation of a sewer system to remove or reduce infiltration/inflow.

**Inflow.** Water other than wastewater that enters a sewer system (including sewer service connections) from sources which include but are not limited to, roof leaders, cellar drains, yard drains, area drains, drains from springs and swampy areas, manhole covers, cross connections between storm sewers and sanitary sewers catch basins, cooling towers, storm waters, surface runoff, street wash waters or drainage. Inflow does not include, and is distinguished from infiltration.

**Innovative Technologies.** New products and processes, and significant technological changes of products and processes, which have not been commercially deployed or are in limited deployment.
Integrated Water Resources Management Plan. In accordance with the Department's Guide to Water Resource Management Planning, an Integrated Water Resource Management Plan is a plan that identifies all of a community's/ies') water resource infrastructure and management needs/problems including wastewater, water supply and stormwater, evaluates alternative means of meeting those needs, selects the most environmentally appropriate and cost-effective remedy, and proposes an implementation plan and schedule.

Intended Use Plan. An annual plan submitted by the Trust to EPA pursuant to § 606(c) of the CWA which identifies the intended use of the amounts available to the Fund as determined by the Trust and derived from the federal capitalization grant, state match amounts, loan repayments, investment earnings and any other moneys deposited by the Trust available to fund projects eligible for funding under Title VI of the CWA. The Intended Use Plan includes a project listing, a description of short and long term goals for the use of the funds, information on the activities to be supported, assurances for meeting certain Title VI requirements, and the criteria and method for the distribution of funds.

Intended Use Plan Project Listing. Those projects identified by the Department for inclusion on the fundable portion of the calendar year priority list pursuant to 310 CMR 44.05(2).

Land Use Controls. Local and regional government zoning ordinances and by-laws and health and sewer use regulations for wastewater.

Loan. Any form of financial assistance subject to repayment, in whole or in part, which is provided by the Trust to a Local Governmental Unit for all or any part of the cost of a water pollution abatement project.

Loan Agreement. Any agreement entered into between the Trust and a Local Governmental Unit pertaining to a loan or local governmental obligations.

Loan Commitment. A written commitment by the Trust to make a loan to a Local Governmental Unit to finance a project approved by the Department on terms consistent with the Department's Project Approval Certificate.

Local Government Unit or Local Governmental Unit. Any town, city, district, commission, agency, authority, board or other instrumentality of the commonwealth or of any of its political subdivisions, including any regional local governmental unit defined in M.G.L. c. 29C, which is responsible for the ownership or operation of a water pollution abatement project and is authorized by a bond act to finance all or any part of the cost thereof through the issue of bonds.

MEPA. The Massachusetts Environmental Policy Act, M.G.L. c. 30, §§ 61 through 62H.

NEPA. The National Environmental Policy Act, 42 U.S.C. 4321 et seq.

Nonpoint Source Project. Projects which implement or are consistent with the Nonpoint Source Management Plan, developed and updated by the Department pursuant to § 319 of the CWA, which may include, but are not limited to, the repair, replacement and/or upgrading of subsurface sewage disposal systems regulated under 310 CMR 15.000: The State Environmental Code, Title 5: Standard Requirements for the Siting, Construction, Inspection, Upgrade and Expansion of On-site Sewage Treatment and Disposal Systems and for the Transport and Disposal of Septage, landfill capping and closure, remediation of leaking underground storage tanks, erosion control, the control of stormwater runoff, brownfields remediation projects, and other water pollution prevention projects.

Nutrient Removal Project. A water pollution abatement project that is being undertaken by a Local Governmental Unit primarily to remediate or prevent nutrient enrichment of a surface water body or a source of water supply to comply with effluent limitations established under a NPDES permit or an EPA-approved TMDL or to otherwise implement a nutrient management plan approved by the Department. Nutrient Removal Projects include those portions of such projects approved by the Department as reasonably necessary for cost-effective nutrient removal or recovery, and as evidenced by the Local Governmental Unit's CWMP or a corresponding engineering report or a 208 Plan or watershed restoration plan that is consistent therewith, as determined by the designated areawide planning agency that prepared the 208 Plan.
Nutrient Sensitive Watershed. Any watershed or sub-watershed containing a water body impaired by nutrients that has been listed, accordingly, on Massachusetts' list of impaired waterbodies under § 303(d) of the CWA or that has been designated as nutrient sensitive by the Department.

Policy on Eligible Project Costs. The Department's document entitled Policy on Eligible Project Costs, which identifies the specific types of project costs determined by the Department to be generally within the eligible project categories identified in 310 CMR 44.08(1) and (2).

POTW Treatment Plant. That portion of a POTW which is designed to provide treatment (including recycling and reclamation) of municipal sewage and industrial waste.

Project Approval Certificate. A certificate issued by the Department to the Trust certifying that a project is approved for financing by the Trust and that the costs of the project are eligible for financial assistance pursuant to M.G.L. c. 29C, § 6.

Project Regulatory Agreement. An agreement between the Department and a Local Governmental Unit, executed and delivered to the Trust on or prior to the date of a loan from the Trust to the Local Governmental Unit to finance a project approved by the Department, which includes a disbursement schedule, procedures for approval and payment of requisitions, conditions related to the borrower's compliance with the Department's regulations and other federal and state statutes and regulations applicable to the construction and operation of the project, and provision for the Department's supervision of the project in accordance with 310 CMR 44.00.

Publicly Owned Treatment Works (POTW). A treatment works as defined by § 212 of the CWA, 33 U.S.C. § 1292, which is owned by a State or municipality (as defined by § 502(4) of the CWA, 33 U.S.C. § 1362(4)). Publicly Owned Treatment Works (POTW) includes any devices and systems used in the storage, treatment, recycling and reclamation of municipal sewage or industrial wastes of a liquid nature. Publicly Owned Treatment Works (POTW) also includes sewers, pipes and other conveyances only if they convey wastewater to a POTW Treatment Plant. Publicly Owned Treatment Works (POTW) also means the municipality as defined in § 502(4) of the CWA, 33 U.S.C. § 1362(4), which has jurisdiction over the Indirect Discharges to and the discharges from such a treatment works.

Regional Land Use Planning Agency. Any one of the public bodies corporate established as a regional planning district commission pursuant to M.G.L. c. 40B, § 3.

Regional Local Government Unit. Any Local Government Unit which is responsible for the ownership or operation of a Regional System.

Regional System. Any District serving two or more municipalities, any private water system serving two or more municipalities, and any other entity established by mutual agreement of two or more municipalities, or by a county in which all municipalities of the county have an agreement to provide public water supply or wastewater services, or both, through shared facilities, sources or distribution networks, and which has authority to set rates and charges for the consumers of such services.

State Revolving Fund (SRF) Program. The financial assistance program for water pollution abatement projects authorized under M.G.L. c. 21, § 27A, and the CWA, including the Clean Water State Revolving Fund Program established pursuant to M.G.L. c. 29C, the Department's related authority and responsibilities set forth in M.G.L. c. 21, § 27A, and elsewhere in M.G.L. c. 21, and the Water Pollution Abatement Revolving Fund established pursuant to M.G.L. c. 29, § 2L.

Title 5. 310 CMR 15.000: The State Environmental Code, Title 5: Standard Requirements for the Siting, Construction, Inspection, Upgrade and Expansion of On-site Sewage Treatment and Disposal Systems and for the Transport and Disposal of Septage.
44.03: continued

**Trust.** The Massachusetts Clean Water Trust established by M.G.L. c. 29C. The Trust administers the Commonwealth's SRF programs, which are authorized by federal legislation - the Water Quality Act of 1987 for the clean water SRF and the Safe Drinking Water Act of 1996 for the drinking water SRF - to provide financial assistance to borrowers for wastewater projects and drinking water projects.

**Wastewater.** Sewage, industrial waste, other wastes or any combination of the three, as defined in 314 CMR 3.00: *Surface Water Discharge Permit Program* and 5.00: *Ground Water Discharge Permit Program*.

**Wastewater Treatment Project.** Abatement facilities eligible for SRF assistance under the CWA providing, or being upgraded or rehabilitated to provide, secondary or more stringent wastewater treatment (or any cost effective alternatives), including conveyance components (such as interceptors) and appurtenances related to such facilities as well as the correction of combined sewer overflows. Wastewater treatment project does not, however, include activities and/or facilities within the definitions of an Infiltration and Inflow Project or a Collection System Project under 310 CMR 44.03.

**Water Pollution Abatement Project.** Any abatement facilities, including without limitation rehabilitation of abatement facilities to remove, curtail or otherwise mitigate infiltration and inflow, collection system, treatment works and treatment facilities as defined in M.G.L. c. 21, § 26A, and any eligible facilities for implementation of a nonpoint source pollution control management program or estuary conservation and management plan pursuant to the CWA.

**Watershed Benchmark Flow.** The existing wastewater facility total flow amount in a planning area, including flow amounts from on-site subsurface disposal systems, collection systems, and wastewater treatment plants, as set forth in a Local Governmental Unit's Department-approved CWMP.

**Watershed Management Plans.** Plans developed, updated and/or approved by the Department to assess and manage the water resources of any watershed or subwatershed, including plans which implement or are consistent with the Department's Nonpoint Source Management Plan. Watershed Management Plans may include watershed related plans developed and updated by other parties which, as approved by the Department, implement or are consistent with the Department's Nonpoint Source Management Plan.

44.04: Eligible Projects

1) Any water pollution abatement project, as defined in 310 CMR 44.03, is eligible to receive financial assistance from the Trust pursuant to 310 CMR 44.00. More specifically, eligible projects fall into the following categories:

   (a) Wastewater Treatment Projects, as defined in 310 CMR 44.03;
   (b) Infiltration Inflow (I/I) Projects, as defined in 310 CMR 44.03;
   (c) Collection System Projects, as defined in 310 CMR 44.03, provided, however, that at least 85% of the expected wastewater flow into the proposed collection system will be for wastewater flows in existence as of July 1, 1995, except, subject to the approval of the Department, in areas designated as city or town centers, rural village districts, or brownfields redevelopment areas, areas designated under M.G.L. c. 40R as "smart growth districts" or projects in Growth Districts designated by the Executive Office of Housing and Economic Development with the concurrence of the Executive Office of Energy and Environmental Affairs;
   (d) Nonpoint Source Projects, as defined in 310 CMR 44.03, including but not limited to projects financed under the Community Septic Management Program within the Fund to assist eligible homeowners to upgrade failed septic systems in compliance with 310 CMR 15.000: *The State Environmental Code, Title 5: Standard Requirements for the Siting, Construction, Inspection, Upgrade and Expansion of On-site Sewage Treatment and Disposal Systems and for the Transport and Disposal of Septage* through underlying betterment agreements between a Local Governmental Unit and such homeowners;
44.04: continued

(e) The planning and/or design for any one of the project categories identified in 310 CMR 44.04(1)(a) through (d), including but not limited to comprehensive wastewater management planning under 310 CMR 44.09(2) and (3) and planning projects which implement the Nonpoint Source Management Plan, as developed and updated by the Department pursuant to § 319 of the CWA, provided that the total funding allocated for planning and/or design projects shall not exceed 10% of the total financial assistance authorized on the calendar year Intended Use Plan Project Listing portion of the priority list. The Department may modify the allocation of funds consistent with its identification of planning and/or design projects as a funding priority in a particular calendar year pursuant to 310 CMR 44.06(3);
(f) Any project in the categories identified in 310 CMR 44.04(1)(a) through (d) which utilizes a single contractor to design, build and/or operate the project facilities, provided the procurement and use of such contractor is authorized by law, the project conforms with the state constitutional requirements governing the use of Commonwealth funds for public purposes, and the project otherwise meets the requirements of 310 CMR 44.00. The operational costs of such projects shall be ineligible for SRF assistance;
(g) Projects for the development and implementation of a conservation and management plan under § 320 of the CWA, 33 U.S.C. § 1330;
(h) The construction, repair, or replacement of publicly- or privately-owned decentralized wastewater treatment systems that treat municipal wastewater or domestic sewage;
(i) Publicly and privately owned, permitted and unpermitted projects that manage, reduce, treat, or recapture stormwater or subsurface drainage water;
(j) Projects that reduce the demand for POTW capacity through water conservation, efficiency, or reuse, regardless of whether the activity takes place at publicly or privately owned properties;
(k) Projects that develop and implement a watershed pilot project related to at least one of the six areas identified in § 122 of the CWA, 33 U.S.C. § 1274: watershed management of wet weather discharges, stormwater best management practices, watershed partnerships, integrated water resource planning, municipality-wide stormwater management planning, or increased resilience of treatment works;
(l) Projects that reduce energy consumption needs for POTWs and related planning activities, such as energy audits and optimization studies;
(m) Projects that include the equipment and piping required to reuse or recycle wastewater, stormwater, or subsurface drainage water;
(n) Projects that provide financial assistance to any qualified nonprofit entity to provide assistance to small- and medium-sized POTWs for training activities, planning, design, and associated preconstruction activities and to assist POTWs in achieving compliance with the CWA. Ongoing operation and maintenance activities are not eligible;
(o) Acquisition of land that is an integral part of the treatment system (e.g., land for spray irrigation or subsurface disposal) and that is necessary for construction of POTWs, including surface and subsurface easements, a place to store equipment and material during construction, land needed to locate eligible projects (e.g., pumping stations), and land integral to the treatment process;
(p) Projects that increase the security of POTWs; and
(q) Projects that use regional water resources to offset, by at least 100%, the impact of water withdrawals on local water resources in the watershed basin of the receiving community.

44.05: Priority System

(1) Establishment of Calendar Year Priority List.
(a) Prior to the beginning of each calendar year, the Department shall establish a single, annual list of projects prioritized to receive financial assistance pursuant to 310 CMR 44.00. The Department will prioritize projects in the order of their numerical rating, as determined by the Department based on the proponent's responses to questions in the Project Evaluation Form. For the purpose of prioritizing projects financed under the Community Septic Management Program, which has its own legislatively dedicated funding allotment, the Department may distinguish the priority and the funding status of Community Septic Management Program projects from other projects on the priority list.
(b) In establishing the priority list, the Department may require Local Governmental Units to submit a Project Evaluation Form containing information deemed necessary by the Department for project evaluation, including but not limited to, information which addresses the proposed project's compliance with the Intended Use Plan Project Listing criteria in 310 CMR 44.03(2) and the Project Selection Criteria in 310 CMR 44.06. The Department may establish a reasonable deadline for its receipt of such information, and may decline to evaluate and prioritize a project if the Department determines that the Local Governmental Unit has failed to provide sufficient information.

(c) Prior to adopting the priority list, the Department shall conduct a public hearing to receive and consider public comment on the proposed list. The Department will ensure that notice of the public hearing will be published in one or more newspapers of general circulation 30 days prior to the date of the hearing.

(2) Intended Use Plan Project Listing

(a) Eligible projects which the Department finds are ready to proceed and for which funds are available in the calendar year in which the priority list is established shall be placed on the Intended Use Plan Project Listing portion of the priority list. The Department reserves the right to expand the Intended Use Plan Project Listing during the course of the relevant calendar year based on an additional allocation of available funding.

(b) The Local Governmental Unit proposing the project must show that its project meets each of the following criteria in order for the Department to place the project on the Intended Use Plan Project Listing:

1. As determined by the Department, the project's environmental, and/or public health benefits, as evidenced by its ranking on the priority list, are sufficiently high to warrant its funding as a priority in the relevant calendar year;

2. As determined by the Department, based on a review of reliable and relevant information, the project's environmental and/or public health benefits outweigh any expected negative impacts to water quality or water quantity or to the public health which are directly attributable to the project;

3. The Local Governmental Unit has already obtained its local funding authorization for the project, or has committed to a specific schedule to obtain such funding authorization by June 30th of the relevant calendar year; and

4. The Local Governmental Unit demonstrates to the Department's satisfaction that its project is sufficiently advanced in its implementation such that the Local Governmental Unit will file a complete loan application with the Department for the project by October 15th of the relevant calendar year.

A complete application includes, as applicable, approvable plans and specifications for the project and evidence that the Local Governmental Unit has, at a minimum, filed applications for any permits or environmental reviews applicable to the project. As provided in 310 CMR 44.12(1)(b), the Department may deny any application which it determines to be incomplete.

(c) In the event that a project placed on Intended Use Plan Project Listing fails during the course of the calendar year to meet one or more of the criteria in 310 CMR 44.05(2)(b), the project may be removed from the Intended Use Plan Project Listing. In such event, the Department reserves the right to raise one or more project(s) which are determined by the Department to be of the highest priority and which meet the criteria in 310 CMR 44.05(2)(b), consistent with available funding, to the Intended Use Plan Project Listing. Subject to the availability of funding and the project's priority, the Department further reserves the right to restore any project removed from the Intended Use Plan Project Listing for failure to meet the criteria in 310 CMR 44.05(2)(b) if the project thereafter meets those criteria prior to the end of the relevant calendar year.

(d) The implementation of some projects on the Intended Use Plan Project Listing will take place over two years or more. For such multi-year projects, the Department will limit the amount of actual funding reserved for the project on each annual Intended Use Plan Project Listing to the amount needed to fund the project for two years. In the event that a multi-year project receives a project approval certificate from the Department by the end of the relevant calendar year, the Department will reserve another annual increment(s) of funding for the project on subsequent calendar year Intended Use Plan Project Listings, subject to the
availability of funding, and provided the project is implemented in accordance with the schedule in the project approval certificate, as determined by the Department. The limitation on financial assistance in 310 CMR 44.05(3) shall apply to any amounts reserved as annual increments of funding for a multi-year project on subsequent calendar year Intended Use Plan Project Listings.

(3) **Limitation on Financial Assistance.**

(a) No Local Governmental Unit shall receive Department approval for financial assistance from the Trust for a project or projects in a calendar year in any amount in excess of 33% of the total financial assistance authorized on the Intended Use Plan Project Listing portion of the priority list in that calendar year, including any amounts reserved as annual increments of funding for a multi-year project on subsequent calendar year Intended Use Plan Project Listings.

(b) The Department reserves the right to waive the borrower limitation on financial assistance set forth in 310 CMR 44.05(3)(a) if the Department determines that one or more projects on the Intended Use Plan Project Listing portion of the applicable priority list has failed or will fail to meet the criteria in 310 CMR 44.05(2)(b) by October 15th in the relevant calendar year, or if the Department allocates additional available funding to the Intended Use Plan Project Listing during the course of the relevant calendar year.

(c) The Trust reserves the right to call due the unpaid loan balance of any loan and/or other form of financial assistance at the financial equivalent of a loan made at an interest rate at zero per cent if the Local Governmental Unit awarded such loan amends, or suffers the amendment of, any Land Use Control upon which approval of such loan and/or other form of financial assistance was based, unless the Local Governmental Unit demonstrates to the Department's satisfaction that such amended Land Use Controls will ensure that overall wastewater flow in the community will not increase as a result of sewerage beyond the flow authorized under the Land Use Controls that were in effect on the date the Secretary issued a MEPA certificate for the CWMP or the date of a 208 Plan.

44.06: **Project Selection Criteria**

(1) Except as provided for in 310 CMR 44.06(2) through (4), the Department will use the evaluation criteria in 310 CMR 44.06(1)(a) and (b) to determine a project's priority and ranking on the calendar year priority list. The Department, through written guidance, will assign a numerical point range to each of the evaluation criteria in 310 CMR 44.06(1) which will be used to further determine a project's ranking on the priority list.

(a) **Environmental Criteria.**

1. The extent to which the project will eliminate or mitigate a risk to public health.

   Relevant factors to consider may include but are not limited to:

   a. The extent to which the project is needed to improve, restore or protect a public or private drinking water supply.

   b. The size and character of the population threatened or negatively impacted by the identified risk to public health (e.g., users of a community public water system, owners of private wells, the number of children, the elderly, persons with pre-existing health risks), and the extent to which the project will eliminate or mitigate the public health risk to the identified population.

   c. The extent to which the project will eliminate or mitigate a public health hazard or public nuisance, as determined by the local health authority and/or the Department (e.g., sewerage surcharging; failed 310 CMR 15.000: *The State Environmental Code, Title 5: Standard Requirements for the Siting, Construction, Inspection, Upgrade and Expansion of On-site Sewage Treatment and Disposal Systems and for the Transport and Disposal of Septage systems*).

2. The severity of the environmental problem which the project is intended to address.

   Relevant factors to consider may include but are not limited to:

   a. The severity of the specific water quality or sediment parameter problems in the relevant water body (e.g., biochemical oxygen demand, suspended solids, pH, temperature, nitrogen, phosphorus, metals).

   b. Whether the relevant water body has been identified on the Commonwealth's § 303(d) list as failing to meet water quality standards for specific parameters.
c. Whether the relevant water body currently meets water quality standards and its designated water quality uses under 314 CMR 4.00: *Massachusetts Surface Water Quality Standards*, including any Total Maximum Daily Load (TMDL) established by the Department for the relevant water body.
d. Whether the relevant water body is a significant public recreation resource, a state Area of Critical Environmental Concern, an outstanding resource water as determined by the Commonwealth, a federally designated river, etc.
e. Whether there are adverse impacts to living resources such as commercial or recreational fisheries, or endangered or wildlife species and their habitats.
f. The extent to which there are other sensitive environmental resources (such as wetlands, Zones I and II of public water supplies, shellfish or cold water fisheries) or water dependent recreational uses which are threatened or negatively impacted by the identified environmental problem.

3. The extent to which the project will have demonstrable water quality benefits which will effectively address the identified environmental problems. Relevant factors to consider may include, but are not limited to, the extent to which the Local Governmental Unit's jurisdiction and the project's objectives, scope and proposed implementation demonstrate the project's capability to eliminate or significantly mitigate the identified environmental problems.

4. The extent to which the project is needed to come into or maintain compliance with applicable federal and/or state discharge permit(s) or other federal and/or state water pollution control requirements, and the effect of compliance on water quality and/or public health. Relevant factors to consider may include but are not limited to:
   a. The extent to which the project is needed to ensure compliance with an existing federal or state court or administrative order.
   b. The extent to which the project is needed to ensure compliance with a federal or state discharge permit (e.g., NPDES permit limits) or federal or state water pollution control regulations and requirements (e.g., 310 CMR 15.000: *The State Environmental Code, Title 5: Standard Requirements for the Siting, Construction, Inspection, Upgrade and Expansion of On-site Sewage Treatment and Disposal Systems and for the Transport and Disposal of Septage* control of stormwater discharges, compliance with Total Maximum Daily Load Limitations).
   c. The extent to which the project's maintenance of compliance with an order, discharge permit or regulation demonstrably benefits or protects the water quality and/or public health (e.g., projects which rehabilitate or upgrade existing facilities and are designed to keep a facility in compliance and/or to prevent water resource degradations).

(b) Program and Implementation Criteria.
1. The extent to which the project implements or is consistent with one or more current watershed management plans (e.g., DEP basin plans) and/or watershed protection plans (e.g., local Zone II land use controls, comprehensive conservation management plans), or otherwise effectively addresses a watershed priority, as determined by the Department.
2. The extent to which the capacity provided by the project is needed, including, more specifically, whether the project will duplicate existing treatment or disposal capacity available at an economic cost within the relevant region.
3. The extent to which, as determined by the Department based on a review of reliable and relevant information, the project's environmental and/or public health benefits outweigh any expected negative impacts to water quality, water quantity or to the public health which are directly attributable to the project.
4. The extent to which the project is consistent with local and regional growth and/or infrastructure plans, and promotes the rehabilitation and revitalization of infrastructure, structures, sites, and areas previously developed and still suitable for economic (re)use.
5. Whether the project constitutes or is a component of a multi-community or regional approach to addressing the identified environmental problem.
6. The extent to which the project utilizes Department-approved innovative/alternative technology to effectively address the identified environmental problem.
7. Whether the Local Governmental Unit has implemented a pricing system for sewer services in accordance with the provisions of M.G.L. c. 40, § 39J and St. 1985, c. 275.
44.06: continued

8. The extent to which the Local Governmental Unit has implemented the guidelines for best management practices in water management established by the board of the Trust.

(2) Certain of the project selection criteria in 310 CMR 44.06(1) do not apply to planning projects (e.g., the extent to which the project will have demonstrable water quality benefits which will effectively address the identified problem). The Department will limit its evaluation of planning projects to the relevant criteria.

(3) In establishing the calendar year priority list pursuant to 310 CMR 44.05(1), the Department may:
(a) identify project categories and/or watersheds as funding priorities warranting a high priority status in a particular calendar year, consistent with the Project Selection Criteria in 310 CMR 44.06(1); and
(b) modify and/or further specify the factors or point system to be used to evaluate the extent to which a project meets the Project Selection Criteria in 310 CMR 44.06(1), including any project or program priorities identified by the Department as a funding priority in a particular calendar year pursuant to 310 CMR 44.06(3) and (4).

(4) Before finally adopting substantial modifications to the Project Selection Criteria and/or the related point system, the Department will notice such modifications in the Environmental Monitor and provide an opportunity for public comment for a period of not less than 30 days, including conducting a minimum of one public hearing.

44.07: Financing Criteria

(1) In general, the Trust is authorized to structure the debt service costs on loans and other forms of financial assistance for Eligible Projects that provide the financial equivalent of a loan made at an interest rate equal to 2%. Notwithstanding the foregoing, subject to the limits on contract assistance provided in M.G.L. c. 29C, § 6, the Trust may provide additional financial assistance that is the financial equivalent of a loan made at an interest rate equal to 0%, as provided in 310 CMR 44.07(1)(a) for Nutrient Removal Projects in communities that have established Flow Neutral Land Use Controls, as provided in 310 CMR 44.07(2). Notwithstanding the foregoing, subject to the limits on contract assistance provided in M.G.L. c. 29C, § 6, the Trust may provide additional financial assistance that is the financial equivalent of a loan made at an interest rate less than two per cent, as determined by the Trust, for Qualifying Designated Projects, as provided in 310 CMR 44.07(4).

(2) Nutrient Removal Projects. Subject to the limits on contract assistance provided in M.G.L. c. 29C, § 6, a Local Governmental Unit applying for financial assistance for a Nutrient Removal Project, as defined in 310 CMR 44.03, on the Intended Use Plan for calendar year 2009 to calendar year 2069, is eligible for loans and other forms of financial assistance at the financial equivalent of a loan made at an interest rate at 0% if the Local Governmental Unit demonstrates to the Department's satisfaction that it meets all of the following criteria:
(a) the Local Governmental Unit is not currently subject, due to a violation of a nutrient-related total maximum daily load standard or other nutrient based standard, to a Department enforcement order, administrative consent order or unilateral administrative order, enforcement action by the EPA or subject to a state or federal court order relative to the proposed project, excluding any such order or action establishing a schedule for coming into compliance with more stringent effluent limitations contained in a NPDES renewal permit or permit modification;
(b) the Local Governmental Unit has a CWMP that has been approved by the Department or the Department determines that the project is consistent with a 208 Plan;
(c) the project is consistent with the regional water resources management plan, including but not limited to a 208 Plan, if such a plan exists, as evidenced by written notice of such by the Regional Land Use Planning Agency for the region where the Local Governmental Unit is located; and
(d) the Local Governmental Unit demonstrates in accordance with 310 CMR 44.07(3) to the Department's satisfaction, in consultation with the Massachusetts Department of Housing and Community Development and, where applicable, the Regional Land Use Planning Agency for the region where the Local Governmental Unit is located, that it has adopted Land Use Controls that ensure the overall wastewater flow amount in the community will not increase as a result of sewering beyond the flow amount authorized under the Land Use Controls that were in effect on the date the Secretary issued a MEPA certificate for the CWMP or, if none exists, the date of a 208 Plan, if such a plan exists.

(3) Flow Neutral Land Use Controls. To demonstrate that it has adopted adequate Land Use Controls to ensure that the overall wastewater flow in the community will be "flow neutral", as required by M.G.L. c. 29C, § 6, and 310 CMR 44.07(2)(d), a Local Governmental Unit must estimate wastewater flow volume to demonstrate that overall wastewater flow in the sewered watershed will not increase as a result of the project for which a zero rate of interest is sought. A Local Governmental Unit will be deemed to have established such "flow neutral" Land Use Controls if the Local Governmental Unit has a Department-approved CWMP or 208 Plan that includes a watershed benchmark flow, and the Local Governmental Unit has established Land Use Controls that limit future wastewater flow volume to the watershed benchmark flow contained in the Department-approved CWMP or 208 Plan. Such Land Use Controls must be in effect prior to closing to receive zero rate of interest loans. In demonstrating that it has established such "flow neutral" Land Use Controls, a Local Governmental Unit may use either one of the two methods in 310 CMR 44.07(3)(a) or (b). In doing so, the Local Governmental Unit should express all flow volumes as an annual average in gallons per day per acre.

(a) Method 1: Presumptive Determination of Flow Neutrality. To demonstrate that the Local Governmental Unit has established Land Use Controls that limit future wastewater flow volume to the watershed benchmark flow, the Local Governmental Unit shall establish as the watershed benchmark flow the total flow volume for all parcels of land within the nutrient sensitive watershed subject to the Local Governmental Unit's jurisdiction, as identified in the CWMP or 208 Plan, excluding only those parcels whose owners have been allowed to opt out in accordance with M.G.L. c. 83, § 1B, calculated as follows:

1. Flow Volume for the Developed Residential Parcels. The Local Governmental Unit shall utilize actual water meter flow data to establish the annual average flow volume for the developed residential parcels. If no actual water meter flow data exists to establish an annual average residential flow, then the Local Governmental Unit shall utilize actual water meter flow data for comparable developed residential parcels in the same or similarly-sized city or town or watershed to estimate the annual average flow volume for the developed residential parcels.

2. Flow Volume for the Undeveloped Residential Parcels. The Local Governmental Unit shall utilize actual water meter flow data for comparable developed residential properties in the same city or town or watershed to estimate the annual average flow volume for the undeveloped residential properties under the local Land Use Controls in effect as of the date the Secretary issued a MEPA certificate for the CWMP or the date of a 208 Plan.

3. Flow Volume for the Developed Non-residential Parcels. The Local Governmental Unit shall utilize actual water meter flow data to establish the annual average flow volume for the developed non-residential parcels. If no actual water meter flow data exists to establish such annual average flow volumes, then the Local Governmental Unit shall utilize actual water meter flow data for comparable developed non-residential parcels in the same city or town or watershed to estimate the annual average flow volume for the developed non-residential parcels under the local Land Use Controls in effect as of the date the Secretary issued a MEPA certificate for the CWMP or the date of a 208 Plan.

4. Flow Volume for the Undeveloped Non-residential Parcels. The Local Governmental Unit shall utilize actual water meter flow data for comparable developed non-residential parcels in the same city or town or watershed to estimate an annual average flow volume for the undeveloped non-residential properties under the local Land Use Controls in effect as of the date the Secretary issued a MEPA certificate for the CWMP or the date of a 208 Plan.
(b) Method 2: Non-presumptive Determination of Flow Neutrality. As an alternative to Method 1, a Local Governmental Unit may elect to establish flow neutrality by demonstrating that future total wastewater flow volume under full build-out conditions will not exceed the total wastewater flow volume under full build-out conditions in effect as of the date the Secretary issued a MEPA certificate for the CWMP or the date of a 208 Plan. Under this alternative, the watershed benchmark flow is considered the total wastewater flow volume under full build-out conditions in effect as of the date the Secretary issued the MEPA certificate for the CWMP or the date of a 208 Plan. To demonstrate that the Local Governmental Unit has established Land Use Controls that limit future wastewater flow volume to the watershed benchmark flow, the Local Governmental Unit shall prepare two separate build-out analyses for all parcels of land within the nutrient sensitive watershed subject to the Local Governmental Unit’s jurisdiction, as identified in the CWMP or the 208 Plan, excluding only those parcels whose owners have been allowed to opt out in accordance with M.G.L. c. 83, § 1B, as follows:

1. The first build-out analysis shall establish wastewater flows based on a full build-out under the local Land Use Controls in effect as of the date the Secretary issued a MEPA certificate for the CWMP or the date of a 208 Plan (i.e., the "pre-sewer build-out").
2. The second build-out analysis shall establish wastewater flows based on a full build-out under the local Land Use Controls in effect at the time construction of the project for which a zero rate of interest is sought is expected to be completed (i.e., the "post-sewer build-out").
3. For both the pre-sewer and post-sewer build-out analyses, the residential and non-residential flows must be calculated utilizing actual water meter flow data to establish the annual average flow volume. For the pre-sewer build-out analyses, if no actual water meter flow data exists, then the Local Governmental Unit shall utilize actual water meter flow data for comparable parcels in the same city or town or watershed to estimate the annual average flow volume or the flow volume allowable under local Land Use Controls in effect as of the date the Secretary issued a MEPA certificate for the CWMP or the date of the 208 Plan, whichever is less. For the post-sewer build-out analysis, if no actual water use data exists, then the Local Governmental Unit shall utilize actual water meter flow data for comparable parcels in the same city or town or watershed or the flow volume allowable under local Land Use Controls at the time construction of the project for which a zero rate of interest is sought is expected to be completed, whichever is less.
4. Each build-out analysis shall include an analysis of all built and buildable parcels, including redevelopment potential, and a rigorous analysis of typical exceptions to Land Use Controls, such as use/dimensional variances, special permits, waivers, expansion and change of use in pre-existing non-conforming uses, M.G.L. c. 40A, § 3, exempt uses, municipal uses and vested rights (e.g., grandfathered uses).
5. All assumptions made in the build-out analyses shall be clearly identified and explained. Future infrastructure needs, such as parking, wastewater infrastructure, landscape, and driveways, shall be factored into the build-out analyses and include the source and rationale for any ratios, multipliers or variables used in calculating such needs.

(4) Qualifying Designated Projects.
(a) Subject to the limits on contract assistance provided in M.G.L. c. 29C, § 6, a Local Governmental Unit applying for financial assistance for a Qualifying Designated Project, as set forth in 310 CMR 44.07(4), on the Intended Use Plan for calendar year 2017 or later, unless otherwise authorized by the Legislature, is eligible for additional subsidies that may include loans and other forms of financial assistance at the financial equivalent of a loan made at an interest rate less than 2% or other additional subsidies such as principal forgiveness, as determined by the Trust, if the Local Governmental Unit demonstrates to the Department’s satisfaction that it meets all of the following criteria:

1. the project is consistent with the current priorities established by the Trust, as set forth in the Department’s annual project solicitation;
2. the project implements Best Management Practices; and
3. the Local Governmental Unit meets the Trust’s affordability criteria established pursuant to § 603(i) of the CWA, 33 U.S.C. § 1383(I).
44.07: continued

(b) The following projects may be considered for the additional subsidies described in 310 CMR 44.07(4)(a):

1. projects developed pursuant to a regional water resources management plan, including but not limited to a 208 Plan, if such a plan exists, as evidenced by written notice of such by the Regional Land Use Planning Agency for the region where the Local Governmental Unit is located;
2. projects that are necessary to connect a local or Regional Local Governmental Unit to a facility of the Massachusetts Water Resources Authority, if the local or regional Local Governmental Unit has paid or committed to pay the entry fee of that authority;
3. Green Infrastructure Projects;
4. projects that are a direct result of a disaster affecting the service area that is the subject of a declaration of emergency by the governor; or
5. innovative water projects that utilize new technology and which improve environmental or treatment quality, reduce costs, increase access and availability of water, conserve water or energy or improve management in the areas of wastewater, stormwater, groundwater or coastal resources; provided, that the technology has not been commercially deployed, other than as a pilot project, previously in the Commonwealth.

44.08: Eligible Project Costs

(1) Costs which the Department determines are necessary for the completion of the project are eligible for financing in the loan and to receive a subsidy under the loan.

(2) Costs which the Department determines are not necessary for completion of the project are ineligible for financing in the loan.

(3) The Department will base its eligible project cost determinations on its "Policy on Eligible Project Costs", which identifies the specific types of costs that are within the two categories under 310 CMR 44.08(1) and (2).

(4) Project costs incurred by an applicant prior to the date of issuance of the Department's project approval certificate are not eligible for a subsidy under the loan, except as follows:

(a) Preliminary engineering, comprehensive wastewater management planning, design or related professional services and construction work, may be approved by the Department prior to the issuance of a project approval certificate as project costs eligible for subsidy if:
   1. the applicant has submitted a written and adequately substantiated request for approval;
   2. written approval by the Department is obtained before initiation of the project and award of any loan for the project; and
   3. the project is included and maintains its status on the current calendar year priority list.

(b) The Department's prior approval of costs in accordance with 310 CMR 44.08(4)(a) does not constitute a commitment to approve financial assistance for any project. Instead, such costs will be considered eligible project costs only if a loan is made by the Trust for the project. Accordingly, an applicant receiving the Department's prior approval of costs in accordance with 310 CMR 44.08(4)(a) proceeds at its own risk.

(5) Costs incurred in excess of the approved project costs are not eligible for financing by the loan unless the project approval certificate and the loan are both amended to include the cost increase.

(6) A loan recipient shall exercise its best efforts to accomplish the work program set forth in the loan within the loan amount. Whenever a loan recipient reasonably believes that its project costs will exceed or be substantially less than the approved loan amount, it must promptly notify the Department in writing. The loan recipient must submit revised cost estimates for the project to the Department as soon thereafter as practicable. Neither the Department, nor the Trust, is under any obligation to approve costs in excess of the amount previously approved in the project approval certificate and loan.
44.08: continued

(7) The final eligible project costs shall be the eligible costs approved by the Department upon completion of the project, unless audited. If such project costs are audited, the final eligible costs shall be the eligible costs approved by the Department at the completion of the audit.

44.09: Planning Requirements

(1) Introduction. 310 CMR 44.09 addresses requirements related to planning. 310 CMR 44.09 requires a Local Governmental Unit to demonstrate that its proposed SRF project is consistent with existing state, regional and local water resource and wastewater planning requirements. The Department's Guide to Water Resource Management Planning identifies three levels of planning (Project Evaluation or Engineering Reports, CWMPs and Integrated Water Resource Management Plans) which may be used to evaluate different types of SRF projects. Unless determined otherwise by the Department, Comprehensive Wastewater Management Plans or Integrated Water Resource Management Plans are required only for controversial or complex wastewater projects. Unless otherwise determined by the Department, a less comprehensive report, the Project Evaluation Report or Engineering Report, is required for all other wastewater projects eligible for financial assistance from the SRF.

(2) Consistency of SRF Projects with Water Resource and Wastewater Planning Requirements.

(a) As provided in M.G.L. c. 21, § 27A(d), a Local Governmental Unit applying for assistance from the Trust must demonstrate that its project is consistent with existing state, regional and local water resource and wastewater planning requirements, including but not limited to:
   1. river basin water quality plans pursuant to § 303(e) of the CWA, 33 U.S.C. § 1313;
   2. nonpoint source management plans pursuant to § 319 of the CWA, 33 U.S.C. § 1329;
   3. estuaries management plans pursuant to § 320 of the CWA, 33 U.S.C. § 1330;
   4. local water resource management plans pursuant to policies of the Water Resources Commission;
   5. water emergency planning pursuant to M.G.L. c. 21G; and
   6. areawide waste treatment management plans approved by EPA pursuant to § 208 of the CWA, 33 U.S.C. § 1288.

(b) Applicants shall also certify that land use and other controls (e.g., zoning bylaws) are consistent with the wastewater system service populations projected in any CWMP of the applicant. An applicant's certification shall include a description of all such land use and other controls in place as supporting documentation for its certification.

(3) Planning Required for SRF Projects.

(a) Comprehensive Wastewater and Integrated Water Resource Management Planning. Unless otherwise determined by the Department, major, complicated or controversial wastewater projects shall be the result of a CWMP or an Integrated Water Resource Management Plan that systematically:
   1. assesses the need for the project;
   2. examines alternatives to the project;
   3. proposes a plan and schedule for the project;
   4. evaluates all the environmental impacts of the project including without limitation secondary growth impacts and impacts of the overall water balance in the watershed or subwatershed;
   5. identifies means of mitigating those impacts;
   6. demonstrates that the project is not only environmentally appropriate and cost-effective, but also implementable from a legal, institutional, financial and management standpoint. The Department will determine the scope of work for any CWMP or Integrated Water Resource Management Plan used to fulfill the requirements in accordance with the Department's Guide to Water Resource Management Planning. The Scope of Work for all CWMPs and Integrated Water Resource Management Plans must provide for a public participation program that includes at a minimum one public meeting to discuss the alternatives to the project and their environmental impacts and a public hearing on the environmental impacts, plan, and schedule of the project.
44.09: continued

(b) Project Evaluation or Engineering Report. Unless otherwise determined by the Department, planning for projects other than the project categories identified in 310 CMR 44.09(3)(a) shall be limited to the development of a Project Evaluation or Engineering Report. Based on the nature and duration of the proposed project, the Department will determine the required scope of the Project Evaluation or Engineering Report in accordance with the Guide to Water Resource Management Planning. Unless otherwise determined by the Department, a complete Project Evaluation or Engineering Report for a wastewater project shall include:

1. A description of the proposed project;
2. An analysis of the cost-effectiveness of the project and the alternatives considered;
3. For the selected alternative, a concise description at an appropriate level of detail, of at least the following:
   a. the relevant design parameters for the project;
   b. the estimated capital construction and operation and maintenance costs of the project;
   c. the cost impacts on system users and non-users, or where the project is not user-based, cost impacts on the Local Governmental Unit budget; and
   d. the institutional, financial, legal and management arrangements necessary for successful implementation of the project.
4. A public participation program that includes, at a minimum, one public meeting on the proposed project.

(c) Targeted Watershed Management Plans. Notwithstanding 310 CMR 44.09(3)(a), an applicant may submit to the Department for approval a targeted watershed management plan that is consistent with a 208 Plan, as determined by the designated areawide planning agency under § 208 of the CWA, in lieu of a CWMP or an Integrated Water Resource Management Plan for projects that will be carried out under a watershed-based permit issued by the Department.

(d) Fiscal Sustainability Plan. Starting October 1, 2015 the Department will require all applicants to submit a FSP for projects that involve the repair, replacement, or expansion of a treatment works. 310 CMR 44.09(3)(d) does not apply to a loan if, prior to this date, the project was listed on a CWSRF Intended Use Plan or the loan recipient has submitted an application for CWSRF funding assistance.

(e) Cost Effectiveness Study. Starting October 1, 2015, the Department will require all applicants to certify that they have studied and evaluated the cost and effectiveness of the processes, materials, techniques, and technologies for the funded project and that they have selected, to the maximum extent practicable, a project that maximizes the potential for efficient water and energy conservation, taking into consideration capital cost, operation and maintenance, and replacement cost. 310 CMR 44.09(3)(e) does not apply to a loan if, prior to October 1, 2015, the project was listed on a CWSRF Intended Use Plan or the loan recipient submitted an application for CWSRF funding assistance. Prior to October 1, 2015, the Department will be finalizing the cost and effectiveness analysis requirements and guidance and will post them on the Department's CWSRF website at www.mass.gov/eea/agencies/massdep/water/grants/clean-water-state-revolving-fund.html.

44.10: Environmental Review and Federal Cross-cutter Requirements

(1) Environmental Review Requirements.

(a) All projects approved by the Department to receive a loan from the Trust shall, at a minimum, comply with the requirements of MEPA and 301 CMR 11.00: MEPA Regulations. In addition, a public hearing shall be held on the project if the Department determines that the project is controversial, or if the Department otherwise determines that a hearing is in the public interest. The Department may also require the Local Governmental Unit to consider project alternatives and to provide the public an opportunity to comment on such alternatives.

(b) Projects required to be the result of comprehensive wastewater management planning, as provided in 310 CMR 44.09(2)(a) and (3), shall also comply with the environmental review and process requirements in the Department's Guide to Water Resource Management Planning.
44.10: continued

(2) Federal Cross-cutter Requirements. All projects to be funded by funds directly made available by federal capitalization grants shall comply with all federal cross-cutters applicable to the project, as determined by the Department. The Department may require any other project to comply with one or more of the federal cross-cutters deemed applicable to the project by the Department.

44.11: Affirmative Action and Disadvantaged Business Enterprise Requirements

(1) Local Governmental Units receiving financial assistance from the Trust shall comply with applicable federal and state anti-discrimination laws and requirements, including the Department's requirements in the areas of Affirmative Action in employment and Disadvantaged Business Enterprise (DBE) utilization in contracting.
   
   (a) In the area of Affirmative Action, such Local Governmental Units shall adopt, for use in all contracts for $50,000 or more, an adapted version of the Commonwealth of Massachusetts' "Supplemental Equal Employment Opportunity Anti-discrimination and Affirmative Action Program." The contracts may include minority workforce percentages greater than those required for the geographical locations of the construction project as set forth in the Supplemental Program.

   (b) In the area of DBE utilization, such Local Governmental Units shall make positive efforts to use DBEs for use in all construction, service and supply subagreements for the project financed by the loan. Such efforts should achieve the applicable federal and/or state goals established for DBE participation, but, at a minimum, should allow DBEs the maximum feasible opportunity to compete for project subagreements.

(2) A Local Governmental Unit receiving a loan from the Trust shall promptly notify the Department in writing when it has good reason to believe that its positive efforts to use DBEs in the subagreements for the project will not achieve one or both of the applicable DBE utilization goals.

44.12: Project Approval and Regulation

(1) Application.

   (a) A Local Governmental Unit whose project is on the Intended Use Plan Project Listing portion of the calendar year priority list must first apply to the Department to receive a loan from the Trust to finance costs of the project. The Local Governmental Unit must file a complete application with the Department containing the following information and documentation:

   1. General Information which must include evidence of a funding authorization by the Local Governmental Unit sufficient to cover the project cost, and certification of the authority of the Local Governmental Unit to file the application.

   2. Financial Information pertinent to the Trust's evaluation of the applicant's ability to repay the loan.

   3. Project Information which demonstrates to the Department's satisfaction that the project is sufficiently advanced in its implementation, including, as applicable:
      a. approvable plans and specifications for the project;
      b. evidence that the Local Governmental Unit has, at a minimum, filed applications for any permits or environmental reviews applicable to the project;
      c. the project scope of work, project evaluation report or the comprehensive wastewater management planning for the project; and
      d. the project schedule that demonstrates to the Department's satisfaction that the project will commence no later than six months from the expected date of issuance of a project approval certificate, assuming the Department determines that the project is approvable.

   4. Supplemental Information such as title to project site or evidence of some other appropriate property interest in the project site, any necessary inter-municipal agreements, documentation related to the user charge system, etc.

   5. Applicant Certification as to the completeness of the application in accordance with the Department's application form and requirements, and as to the accuracy and completeness of the information provided by the applicant in its application.
310 CMR: DEPARTMENT OF ENVIRONMENTAL PROTECTION

44.12: continued

(b) The Department may deny any application which it determines to be incomplete. Prior to taking final action on an application, the Department may request the applicant to clarify and/or supplement information contained in its application, or to attend an informal conference(s) with the Department to discuss the application.

(2) Project Approval Certificate.

(a) The Department's approval of an applicant's project shall be contained in a Project Approval Certificate issued to the Trust. As provided in the Act, the Department's issuance of a Project Approval Certificate is a prior necessary condition to the award of a loan by the Trust to finance the costs of a project.

(b) The Department shall not approve a project for a loan from the Trust unless the Local Governmental Unit:

1. demonstrates that its project is consistent with existing state, regional and local water resource and wastewater planning requirements as described in 310 CMR 44.09(2) ("Consistency of SRF Projects with Water Resource and Wastewater Planning Requirements"); and

2. adopts a user charge system in accordance with the Department guidance which is designed to provide adequate revenues required for operation and maintenance, including replacement, of the project.

The Department reserves the discretion to determine that the user charge system requirement does not apply to certain Nonpoint Source Projects (e.g., a stormwater control project that is not providing ongoing service to an identified set of users).

(c) In addition to approving the project, the Project Approval Certificate shall certify those costs of the project determined by the Department to be eligible for assistance from a loan, and those costs determined to be eligible for a subsidy or interest rate under the loan. The Project Approval Certificate shall also identify the level of subsidy applicable to the project in accordance with M.G.L. c. 29C and, as applicable, any additional subsidy applicable to the project authorized by special law. Subsidy is expressed as an interest rate in the Project Approval Certificate.

(d) The Project Approval Certificate may also contain such other conditions and limitations as the Department deems necessary to ensure compliance by a Local Governmental Unit with 310 CMR 44.00 and with all other federal and state statutes and regulations applicable to the construction and operation of the project. Such conditions shall include, but are not limited to, a project completion schedule which shall require the Local Governmental Unit to initiate the project, as determined by the Department, no later than six months from the date of the Department's issuance of the Project Approval Certificate. The Department, at its sole discretion, may extend this six-month deadline based on evidence demonstrating to the Department's satisfaction that the delay is beyond the reasonable control of and without the fault of the Local Governmental Unit or its contractors or other agents.

(e) The Department shall issue the Project Approval Certificate to the Trust for its action and forward a copy of such certificate to the Local Governmental Unit concurrently. The Trust shall thereafter enter into a loan commitment with a Local Governmental Unit consistent with the terms of the Project Approval Certificate. Following entry into a binding loan commitment, the Trust shall prepare and deliver a loan agreement for execution by the Local Governmental Unit, consistent with the terms of the Project Approval Certificate as incorporated into the Department's Project Regulatory Agreement.

(3) Project Regulatory Agreement.

(a) On or prior to the date of a loan from the Trust for a project approved by the Department, the Local Governmental Unit and the Department shall execute and deliver to the Trust a Project Regulatory Agreement relating to the Department's regulation and supervision of the project in accordance with 310 CMR 44.00. The Project Regulatory Agreement shall be in form and substance satisfactory to the Department. The Project Regulatory Agreement shall be incorporated by reference in the Trust loan agreement and failure by the Local Governmental Unit to comply with the Project Regulatory Agreement shall constitute an event of default under the loan agreement.
(b) The Project Regulatory Agreement shall contain provisions consistent with the Project Approval Certificate. In addition to incorporating pertinent conditions in the Project Approval Certificate, the Project Regulatory Agreement may also contain such other conditions and limitations as the Department deems necessary for its regulation and supervision of the project in accordance with 310 CMR 44.00, including but not limited to:

1. the schedule for disbursement of loan proceeds;
2. the payment requisition requirements and procedures;
3. the requirements and procedures for the Department's audit of payment requisitions;
4. covenants by the Local Governmental Unit related to the project, including a covenant to comply with all federal and state statutes and regulations applicable to the Local Governmental Unit's construction and operation of the project;
5. the measures available to the Department to remedy a default by the Local Governmental Unit under the Project Regulatory Agreement;
6. any requirements regarding certification of a project's performance in accordance with the Department's approval;
7. compliance with the Department's guidance on the use of and requirements for professional subagreements.

REGULATORY AUTHORITY

310 CMR 44.00: M.G.L. c. 21, § 27A.
# Regulation Filing

To be completed by filing agency

<table>
<thead>
<tr>
<th>CHAPTER NUMBER:</th>
<th>310 CMR 45.00</th>
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<table>
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<tr>
<th>CHAPTER TITLE:</th>
<th>DEP selection, approval and regulation of drinking water projects receiving financial assistance from the State Revolving Fund</th>
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<tr>
<th>AGENCY:</th>
<th>Department of Environmental Protection</th>
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<tr>
<th>SUMMARY OF REGULATION:</th>
<th>State the general requirements and purposes of this regulation.</th>
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<tbody>
<tr>
<td>These regulations govern how MassDEP selects and oversees local governments' drinking water infrastructure projects which voluntarily receive state-subsidized financing under the State Revolving Fund program. These changes are an update required by state statute and conform to federal law. Specifically, the Massachusetts General Court enacted &quot;An Act improving drinking water and waste water infrastructure&quot; (2014), authorizing the appropriation of enhanced SRF loan subsidies. This regulation revision is required to codify the eligibility criteria for the enhanced subsidies outlined in the statute.</td>
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<tr>
<th>REGULATORY AUTHORITY:</th>
<th>M.G.L. c.29C</th>
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<tr>
<th>AGENCY CONTACT:</th>
<th>Steve McCurdy</th>
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<th>ADDRESS:</th>
<th>1 Winter Street 5th floor, Boston, MA 02108</th>
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## Compliance with M.G.L. c. 30A

### EMERGENCY ADOPTION -

If this regulation is adopted as an emergency, state the nature of the emergency.

### PRIOR NOTIFICATION AND/OR APPROVAL -

If prior notification to and/or approval of the Governor, Legislature or others was required, list each notification, and/or approval and date, including notice to the Local Government Advisory Commission.

- **Mass Municipal Association** 2-12-2016
- **Local Government Advisory Commission** 2-12-2016
- **Mass Dept. of Housing and Community Development** 2-16-2016

### PUBLIC REVIEW -

M.G.L. c. 30A sections 2 and/or 3 requires notice of the hearing or comment period, including a small business impact statement, be filed with the Secretary of the Commonwealth, published in appropriate newspapers, and sent to persons to whom specific notice must be given at least 21 days prior to such hearing or comment period.

<table>
<thead>
<tr>
<th>Date of public hearing or comment period:</th>
<th>April 14, 2016</th>
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</table>

The text of the regulations published in the electronic version of the Massachusetts Register is unofficial and for informational purposes only. The official version is the printed copy which is available from the State Bookstore at [http://www.sec.state.ma.us/spr/sprcat/catidx.htm](http://www.sec.state.ma.us/spr/sprcat/catidx.htm).
FISCAL EFFECT - Estimate the fiscal effect of the public and private sectors.

For the first and second year: 

For the first five years: 

No fiscal effect: no fiscal effect

SMALL BUSINESS IMPACT - M.G.L. c. 30A section 5 requires each agency to file an amended small business impact statement with the Secretary of the Commonwealth prior to the adoption of a proposed regulation. If the purpose of this regulation is to set rates for the state, this section does not apply.

Date amended small business impact statement was filed: 1/4/2017

CODE OF MASSACHUSETTS REGULATIONS INDEX - List key subjects that are relevant to this regulation:

PROMULGATION - State the action taken by this regulation and its effect on existing provisions of the Code of Massachusetts Regulations (CMR) or repeal, replace or amend. List by CMR number:

Amend 310 CMR 45

ATTESTATION - The regulation described herein and attached hereto is a true copy of the regulation adopted by this agency. ATTEST:

SIGNATURE: SIGNATURE ON FILE DATE: Jan 6 2017

Publication - To be completed by the Regulations Division

MASSACHUSETTS REGISTER NUMBER: S1331 DATE: 01/27/2017

EFFECTIVE DATE: 01/27/2017

CODE OF MASSACHUSETTS REGULATIONS

Remove these pages: 2181 - 2190

Insert these pages: 2189 - 2190.10

The text of the regulations published in the electronic version of the Massachusetts Register is unofficial and for informational purposes only. The official version is the printed copy which is available from the State Bookstore at http://www.sec.state.ma.us/spr/sprcat/catidx.htm.
310 CMR 45.00: DEP SELECTION, APPROVAL AND REGULATION OF DRINKING WATER PROJECTS RECEIVING FINANCIAL ASSISTANCE FROM THE STATE REVOLVING FUND

Section

45.01: Introduction
45.02: Purpose and Applicability
45.03: Definitions
45.04: Eligible Projects
45.05: Priority System
45.06: Project Selection Criteria
45.07: Financing Criteria
45.08: Eligible Project Costs
45.09: Project Evaluation Report
45.10: Environmental Review and Federal Cross-cutter Requirements
45.11: Affirmative Action and Disadvantaged Business Enterprise Requirements
45.12: Project Approval and Regulation

45.01: Introduction

The federal Safe Drinking Water Act amendments of 1996 authorized a Drinking Water State Revolving Fund program to assist eligible public water systems to finance the cost of the infrastructure needed to achieve or maintain compliance with the SDWA requirements and protect public health. The Massachusetts Drinking Water State Revolving Fund (DWSRF) Program is a federal-state partnership that provides low-cost financing to help community public water suppliers. The DWSRF Program is jointly administered through the Clean Water Trust by the Commissioner of the Department of Environmental Protection (Department), the State Treasurer, and the Secretary of Energy and Environmental Affairs pursuant to M.G.L. c. 29C, § 2. Financial assistance is available for engineering, design, and construction of drinking water projects. Every summer, the Department solicits projects from Massachusetts municipalities and community water systems (with at least 15 residential connections) to be considered for subsidized loans for infrastructure projects. After evaluating the project requests submitted in response to the annual solicitation, the Department develops a list of projects eligible to receive financial assistance. From this annual list, and on the basis of projects' readiness to proceed and priority rating, the Department assigns projects to a fundable list called the Intended Use Plan Project Listing (IUP). Projects placed on the IUP are eligible to apply for financing in the coming year, with the total cost of all projects on the IUP not to exceed the amount of funding available for that year. To qualify for placement on the IUP, a project must have a high enough ranking, have received a local funding appropriation or be scheduled for funding appropriation by June 30th of the coming year, and the applicant must be able to file a complete loan application no later than October 15th of the coming year.

45.02: Purpose and Applicability

310 CMR 45.00 implements the DWSRF Program. Under federal and state law, the DWSRF Program's goals are to protect public health and strengthen compliance with drinking water requirements, while addressing the Commonwealth's drinking water needs. The DWSRF Program incorporates affordability and watershed management priorities. 310 CMR 45.00 sets forth the Department's authority and responsibilities to select, approve and regulate drinking water projects receiving financial assistance from the DWSRF.

310 CMR 45.00 does not apply to the use of set-asides by the Department and the Trust, which is addressed in the pertinent portion of the IUP submitted by the Department and the Trust to EPA on an annual basis after public review and comment. In the event that the set-aside portion of the IUP allocates funding for loans to systems to acquire land or conservation easements or to implement source water protection measures or to implement recommendations in source water quality protection partnership petitions submitted to the Department, the project selection criteria for such loans will also be subject to public review and comment as a component of the IUP. The Department reserves the right to use relevant requirements and procedures contained in 310 CMR 45.00 in its selection, approval and administration of projects receiving loans pursuant to the set-aside portion of the IUP.

The Department may issue supplemental policies, guidelines, guidance documents and/or administrative procedures to assist in its implementation and administration of 310 CMR 45.00 and its use of set-asides.
45.03: Definitions

For the purposes of 310 CMR 45.00, the following terms shall have the meaning set forth in 310 CMR 45.00 unless the context clearly requires otherwise.

310 CMR 22.00: Drinking Water. The Department’s regulations governing the approval, use and operation of drinking water sources and public water systems.

Best Management Practices (BMPs). A method, measure or practice in water management, or a combination thereof, established and published by the Trust pursuant to St. 2014, c. 259, § 55. The Trust’s BMPs can be found on the Official Website of the Treasurer and Receiver General of Massachusetts.

Community Water System. A community water system is a Public Water System as defined in 310 CMR 22.02: Definitions, which serves at least 15 service connections used by year-round residents or regularly serves at least 25 year-round residents.

Cost. Any or all costs, whenever incurred, approved by the Department in accordance with M.G.L. c. 21, § 27A, of carrying out a drinking water project, including, without limiting the generality of the foregoing: the costs for planning, preparation of studies and surveys, design, construction, facilities, improvement and rehabilitation, acquisition of real property, personal property, materials, machinery or equipment, start-up costs, demolitions and relocations, reasonable reserves and working capital, interest on loans, local governmental obligations and notes in anticipation of thereof prior to and during construction of such project or prior to the date of such loan, if later, administrative, legal and financing expenses, and other expenses necessary or incidental to the aforesaid.

Department. The Massachusetts Department of Environmental Protection.

Drinking Water Project. Any project of a type or category which the Department has determined, consistent with guidance issued by EPA in accordance with the SDWA, will facilitate compliance with national primary drinking water regulations under § 1412 of the SDWA, 42 U.S.C. § 300g-1 or otherwise significantly further the health protection objectives of the SDWA or 310 CMR 22.00: Drinking Water.

Eligible Borrower. Any LGU or other community water system which is authorized to own, operate, finance or otherwise implement a drinking water project.

EPA. The U.S. Environmental Protection Agency.

Federal Cross-cutters. Federal laws and authorities that apply by their own terms to projects receiving federal financial assistance such as the federal SRF. Such federal cross-cutters include, but are not limited to, environmental laws and authorities such as the Clean Air Act, Safe Drinking Water Act, Clean Water Act, Endangered Species Act, Coastal Zone Management Act, Wild and Scenic Rivers Act and the National Historic Preservation Act of 1966, and economic and miscellaneous authorities such as the procurement and contractor requirements associated with financial assistance programs under the Safe Drinking Water Act, Clean Water Act and Clean Air Act.

Grant Equivalency or Financial Equivalent of a Grant. The standard measure used by the Department and the Trust to determine the amount of subsidy applicable to the eligible costs of a project under the loan in accordance with St. 1998, c. 78.

Intended Use Plan or IUP. An annual plan submitted by the Trust to EPA pursuant to § 1452(b) of the SDWA, 42 U.S.C. § 300j-12(b), which identifies the intended use of the amounts available to the Fund as determined from time to time by the Trust and derived from the federal capitalization grant, state match amounts, loan repayments, investment earnings and any other moneys deposited by the Trust available to fund projects eligible for funding under St. 1998, c. 78. The IUP includes a listing of projects to receive financial assistance from the Fund, the distribution and use of the funds for set-aside activities, and a description of the short and long term goals for the use of project and set-aside funds.
45.03: continued

**Intended Use Plan Project Listing.** Those projects identified by the Department for inclusion on the fundable portion of the calendar year priority list pursuant to 310 CMR 45.05(2).

**Loan.** Any form of financial assistance subject to repayment, in whole or in part, which is provided by the Trust to an eligible borrower for all or any part of the cost of a drinking water project. A loan may provide for planning, construction, bridge or permanent financing.

**Loan Agreement.** Any agreement entered into between the Trust and an eligible borrower pertaining to a loan or the purchase and delivery of local governmental obligations or other instruments evidencing or securing a loan.

**Loan Commitment.** A written commitment by the Trust to make a loan to a LGU or public water system to finance a project approved by the Department on terms consistent with the Department's Project Approval Certificate.

**Local Government Unit (LGU).** Any town, city, district, commission, agency, authority, board or other instrumentality of the Commonwealth or of any of its political subdivisions, including any regional local governmental unit as defined in M.G.L. c. 29C, § 1, which is responsible for the ownership or operation of a drinking water project and is authorized by a bond act to finance all or any part of the cost thereof through the issue of bonds.

**Maximum Contaminant Level (MCL).** The maximum permissible level of a contaminant in water which is delivered to any user of a public water system, as published in 310 CMR 22.00: *Drinking Water*.

**MEPA.** The Massachusetts Environmental Policy Act, M.G.L. c. 30, §§ 61 through 62H.

**Project Approval Certificate.** A certificate issued by the Department to the Trust certifying that a project is approved for financing by the Trust and that the costs of the project are eligible for financial assistance pursuant to M.G.L. c. 29C, § 6.

**Project Regulatory Agreement.** An agreement between the Department and an eligible borrower, executed and delivered to the Trust on or prior to the date of a loan from the Trust to the eligible borrower to finance a drinking water project approved by the Department, which includes a disbursement schedule, procedures for approval and payment of requisitions, conditions related to the borrower's compliance with the Department's regulations and other federal and state statutes and regulations applicable to the construction and operation of the project, and provision for the Department's supervision of the project in accordance with 310 CMR 45.00.

**Public Water System.** A system for the provision to the public of water for human consumption, through pipes or other constructed conveyances, if such system has at least 15 service connections or regularly serves an average of at least 25 individuals daily at least 60 days of the year, as further defined in 310 CMR 22.02: *Definitions*.

**Safe Drinking Water Act or SDWA.** Title XIV of the Federal Public Health Service Act, commonly known as the Safe Drinking Water Act, 42 U.S.C. 300f et seq.

**Set-asides.** The use of DWSRF federal capitalization grant funds and matching state funds, as applicable, for a range of specific activities identified in § 1452 of the SDWA to encourage source water protection and other Department drinking water program activities.

**Small System.** A public water system which regularly serves fewer than 10,000 persons.

**Trust.** The Massachusetts Clean Water Trust established by M.G.L. c. 29C. The Trust administers the Commonwealth's SRF programs, which are authorized by federal legislation, the Water Quality Act of 1987 for the clean water SRF and the Safe Drinking Water Act of 1996 for the drinking water SRF, to provide financial assistance to borrowers for wastewater projects and drinking water projects.
45.04: Eligible Projects

(1) Any drinking water project of an eligible borrower is eligible to receive financial assistance from the Trust pursuant to M.G.L. c. 29C, § 18 and 310 CMR 45.00. The Department has determined that such eligible projects include, but are not limited to:

(a) Projects to address or prevent violations of the public health standards in 310 CMR 22.00: Drinking Water and the SDWA, including projects to come into or maintain compliance with MCLs and other requirements for contaminants with acute health effects (e.g., the Surface Water Treatment Rule, the Total Coliform Rule, and nitrate standards) and for contaminants with chronic health effects (e.g., the Lead and Copper Rule and the Disinfection Byproducts Rule), including the costs of system activities determined by the Department to constitute an effective alternative to providing treatment to come into or maintain compliance with 310 CMR 22.00: Drinking Water and the SDWA;

(b) Projects to replace aging infrastructure, if such projects are needed to maintain compliance or further the public health goals and requirements in 310 CMR 22.00: Drinking Water and the SDWA, including projects to rehabilitate or develop sources to replace contaminated sources, install or upgrade treatment or storage facilities, and install or replace transmission and distribution pipes to prevent contamination or improve water pressure to safe levels;

(c) Projects to consolidate and/or restructure a public water system (e.g., to address a system with contaminated water supply or when a system is in noncompliance or lacks adequate technical, managerial and financial capability to maintain compliance);

(d) Land acquisition, but only if the Department determines that such land is integral to a project and necessary to meet or maintain compliance and further the protection of public health (e.g., land needed to locate eligible treatment or distribution projects);

(e) The planning and/or design for any eligible project;

(f) Any eligible project which uses a single contractor to design, build and/or operate the project facilities, provided the procurement and use of such contractor is authorized by law, the project conforms with the state constitutional requirements governing the use of Commonwealth funds for public purposes, and the project otherwise meets the requirements of 310 CMR 45.00. The operation and maintenance costs of such projects shall be ineligible for DWSRF assistance;

(g) Projects that use regional water resources to offset, by at least 100%, the impact of water withdrawals on local water resources in the watershed basin of the receiving community;

(h) Projects that are intended to provide public water supply to consumers whose groundwater or public or private wells are impacted by contamination that poses an unacceptable health risk, as determined by the Department;

(i) Innovative water projects that utilize new technology and which improve environmental or treatment quality, reduce costs, increase access and availability of water, conserve water or energy or improve management of drinking water; provided, that the technology has not been commercially deployed, other than as a pilot project, previously in the Commonwealth;

(j) Projects that are necessary to connect an LGU to a facility of the Massachusetts Water Resources Authority, if the LGU has paid or committed to pay the entry fee; and

(k) Projects that are a direct result of a disaster affecting the service area that is the subject of a declaration of emergency by the Governor.

(2) Unless otherwise determined by the Department consistent with 310 CMR 45.03: Drinking Water Project, the following projects and activities are not eligible to receive financial assistance pursuant to 310 CMR 45.00:

(a) The construction, rehabilitation or maintenance of dams;

(b) The purchase of water rights, unless the water rights are owned by a public water system that is being purchased by an eligible borrower through consolidation as part of the eligible borrower's capacity development strategy;

(c) Reservoirs, except for finished water reservoirs and those reservoirs that are part of the treatment process and are located on the treatment facility property;

(d) Laboratory fees for monitoring;

(e) Operation and maintenance costs;

(f) Projects needed primarily for fire protection;

(g) Projects for systems which the Department determines lack adequate technical, managerial and financial capability, unless the Department determines that financial assistance from the DWSRF will ensure compliance over the long term;
45.04: continued

(h) Projects for systems in significant noncompliance, as determined by the Department, unless the Department determines that the project will enable the system to return to compliance and that the system will maintain an adequate level of technical, managerial and financial capability to maintain compliance; and

(i) Projects primarily intended solely to serve future growth.

45.05: Priority System

(1) Establishment of Calendar Year Priority List.

(a) Prior to the beginning of each calendar year, the Department shall establish a single, annual list of projects prioritized to receive financial assistance pursuant to 310 CMR 45.00.

(b) In establishing the priority list, the Department may require eligible borrowers to submit any information deemed necessary by the Department for project evaluation, including but not limited to, information which addresses the proposed project's compliance with the IUP Project Listing criteria in 310 CMR 45.05(2) and the Project Selection Criteria in 310 CMR 45.06. The Department may establish a reasonable deadline for its receipt of such information, and may decline to evaluate and prioritize a project if the Department determines that the eligible borrower has failed to provide sufficient information.

(c) Prior to adopting the priority list, the Department shall conduct a public hearing to receive and consider public comment on the proposed list. The Department will ensure that notice of the public hearing will be published in one or more newspapers of general circulation 30 days prior to the date of the hearing.

(2) Intended Use Plan Project Listing.

(a) Eligible projects which the Department finds are ready to proceed and for which funds are available in the calendar year in which the priority list is established shall be placed on the IUP Project Listing portion of the priority list. The Department reserves the right to establish an IUP Project Listing that contains fewer projects than would use the total amount of funding available in the relevant calendar year, or, alternatively, to expand the IUP Project Listing during the course of the relevant calendar year based on an additional allocation of available funding.

(b) The eligible borrower proposing the project must show in its application that its project meets each of the following criteria in order for the Department to place the project on the IUP Project Listing:

   1. As determined by the Department, the project's benefits to public health and/or drinking water quality, as evidenced by its ranking on the priority list, are sufficiently high to warrant its funding as a priority in the relevant calendar year;
   2. The eligible borrower has already obtained its local funding authorization or otherwise committed funding for the project, or has provided a specific schedule to obtain such funding authorization or funding commitment by June 30th of the relevant calendar year; and
   3. The eligible borrower demonstrates to the Department's satisfaction that its project is sufficiently advanced in its implementation such that the LGU or public water system will file a complete loan application with the Department for the project by October 15th of the relevant calendar year.

A complete application includes, as applicable, approvable plans and specifications for the project and evidence that the eligible borrower has, at a minimum, filed applications for any permits or environmental reviews applicable to the project. As provided in 310 CMR 45.12(1)(b), the Department may deny any application which it determines to be incomplete.

(c) In the event that a project placed on an IUP Project Listing fails during the course of the calendar year to meet one or more of the criteria in 310 CMR 45.05(2)(b), the project may be removed from the IUP Project Listing and returned to the applicable priority level on the priority list. In such event, the Department reserves the right to raise one or more project(s) which are determined by the Department to be of the highest priority and which meet the criteria in 310 CMR 45.05(2)(b), consistent with available funding, to the IUP Project Listing, provided the Department shall raise a small system project which meets the criteria in 310 CMR 45.05(2)(b) before an otherwise higher ranked project if the funding of such
small system project is needed to meet the 15% allocation of funds for small systems, as
provided in the SDWA. Subject to the availability of funding and the project's priority, the
Department further reserves the right to restore any project removed from the IUP Project
Listing for failure to meet the criteria in 310 CMR 45.05(2)(b) if the project thereafter meets
those criteria prior to the end of the relevant calendar year.

(d) The implementation of some projects on the IUP Project Listing will take place over two
years or more. For such multi-year projects, the Department will limit the amount of actual
funding reserved for the project on each annual IUP Project Listing to the amount needed to
fund the project for one year. In the event that a multi-year project receives a project
approval certificate from the Department by the end of the relevant calendar year, the
Department will reserve another annual increment(s) of funding for the project on subsequent
calendar year IUP Project Listings, subject to the availability of funding, and provided the
project is implemented in accordance with the schedule in the project approval certificate,
as determined by the Department. The limitation on financial assistance in 310 CMR
45.05(3) shall apply to any amounts reserved as annual increments of funding for a
multi-year project on subsequent calendar year IUP Project Listings.

(3) Limitation on Financial Assistance.

(a) No eligible borrower shall receive Department approval for financial assistance from the
Trust for a project or projects in a calendar year in any amount in excess of 25% of the total
financial assistance authorized on the IUP Project Listing portion of the priority list in that
calendar year, including any amounts reserved as annual increments of funding for a
multi-year project on subsequent calendar year IUP Project Listings.

(b) The Department reserves the right to waive the limitation on financial assistance set
forth in 310 CMR 45.05(3)(a), in whole or in part, if the Department determines that one or
more projects on the IUP Project Listing portion of the applicable priority list has failed or
will fail to meet the criteria in 310 CMR 45.05(2)(b) by October 15th in the relevant calendar
year, or if the Department allocates additional available funding to the IUP Project Listing
during the course of the relevant calendar year.

45.06: Project Selection Criteria

(1) Except as provided in 310 CMR 45.06(2) through (4), the Department will use the
evaluation criteria set forth in 310 CMR 45.06(1)(a) through (d) to determine a project's
placement on the calendar year priority list. The Department, through written guidance, will
assign a numerical point range to each of the evaluation criteria in 310 CMR 45.06(a) which will
be used to further determine a project’s placement on the priority list. Such Department guidance
may also address tie breakers for projects with the same point score rating.

(a) Public Health Criteria.

1. The extent to which the project will eliminate or mitigate a serious risk to public
health. Relevant factors to consider may include but are not limited to:
   a. The severity of the public health problem the project is intended to address (e.g.,
      the nature and frequency of MCL violations).
   b. The size and character of the population threatened or negatively impacted by the
      identified risk to public health (e.g., the number of children, the elderly or persons
      with pre-existing health risks served by the system), and the extent to which the
      project will eliminate or mitigate the public health risk to the identified population.
   c. The extent to which the project demonstrably eliminates or mitigates the
      identified serious risk to public health in an effective and timely manner.

(b) Compliance Criteria.

1. The extent to which the project is needed to come into or maintain compliance with
310 CMR 22.00: Drinking Water, the SDWA or other required or related federal and/or
state permit(s), approvals, regulations and requirements, and the effect of compliance on
public health and drinking water quality. Relevant factors to consider may include but
are not limited to:
   a. The extent to which the project is needed to ensure compliance with an existing
      federal or state court or administrative order.
   b. The extent to which the project is needed to come into or maintain compliance
      with 310 CMR 22.00: Drinking Water, the SWDA, or other required or related
      federal or state permit or approval, including the Department's approval of a new
drinking water source.
c. The extent to which the project's maintenance of compliance with 310 CMR 22.00: Drinking Water, the SDWA, or other required or related federal or state order, permit, approval demonstrably benefits or protects drinking water quality and/or public health (e.g., projects which upgrade or rehabilitate water treatment or distribution facilities and are designed to keep a system in compliance on an ongoing basis).

(c) Affordability Criteria.
   1. The extent to which DWSRF financial assistance for the project will assist systems whose service area consists of users with median household income (MHI) of 80% or less of the state median household income for non-metropolitan areas or as otherwise established by the Trust.
   2. The extent to which the cost of the project will result in increased water rates to users of the system of an eligible borrower. Relevant factors to consider may include, but are not limited to, whether the annual user charges will fall within a range of 1% to 1.75% of such users' MHI.

(d) Other Program and Implementation Criteria.
   1. Whether the project is to consolidate and/or restructure a public water system (e.g., to address a system with a contaminated water supply or when a system is in noncompliance or lacks adequate technical, managerial and financial capability to maintain compliance).
   2. The extent to which the project implements or is consistent with one or more current watershed management plans (e.g., DEP basin plans) and/or watershed protection plans (e.g., local Zone II land use controls, comprehensive conservation management plans), or otherwise effectively addresses a watershed priority, as determined by the Department.
   3. The extent to which the project is consistent with local and regional growth and/or infrastructure plans, and promotes the rehabilitation and revitalization of infrastructure, structures, sites, and areas previously developed and still suitable for economic (re)use, as provided in Executive Order 385: Growth Planning.
   4. Whether the project constitutes or is a component of a multi-community or regional approach to addressing the identified public health or drinking water quality problem.

(2) Because certain of the Project Selection Criteria in 310 CMR 45.06(1) do not apply to eligible planning and/or design projects, the Department will limit its evaluation of such projects to the relevant criteria.

(3) In establishing the calendar year priority list pursuant to 310 CMR 45.04(1), the Department may:
   (a) identify project categories and/or watersheds as funding priorities in a particular calendar year, consistent with the Project Selection Criteria in 310 CMR 45.06(1); and
   (b) modify and/or further specify the factors or point system to be used to evaluate the extent to which a project meets the Project Selection Criteria in 310 CMR 45.06(1), including any project or program priorities identified by the Department as a funding priority in a particular calendar year pursuant to 310 CMR 45.06(3) and (4).

(4) Before finally adopting any substantial modification to the Project Selection Criteria and/or the related point system, the Department will notice such modifications in the Environmental Monitor and to the regulated community and provide an opportunity for public comment for a period of not less than 30 days, including conducting a minimum of one public hearing.

45.07: Financing Criteria

(1) In General. The Trust is authorized to structure the debt service costs on loans and other forms of financial assistance for Eligible Projects that provide the financial equivalent of a loan made at an interest rate equal to 2%. Notwithstanding the foregoing, subject to the limits on contract assistance provided in M.G.L. c. 29C, § 6, the Trust may provide additional financial assistance that is the financial equivalent of a loan made at an interest rate less than 2%, as determined by the Trust, for Qualifying Designated Projects, as provided in 310 CMR 45.07(2).
(2) Qualifying Designated Projects. Subject to the limits on contract assistance provided in M.G.L. c. 29C, § 6, a LGU applying for financial assistance for a Qualifying Designated Project on the IUP for calendar year 2017 or later, unless otherwise authorized by the Legislature, is eligible for additional financial assistance in accordance with 310 CMR 45.07(2) that may include loans and other forms of financial assistance at the financial equivalent of a loan made at an interest rate less than 2% or other additional subsidies such as principal forgiveness, as determined by the Trust, if the LGU demonstrates to the Department's satisfaction that it meets all of the following criteria:

(a) the project is an eligible project described in 310 CMR 45.04(1)(g) through (k);
(b) the project is consistent with the current priorities established by the Trust, as set forth in the Department's annual project solicitation;
(c) the project implements Best Management Practices; and
(d) the LGU meets the Trust's affordability criteria and is consistent with the Trust's guidelines for best management practices in water management, including, without limitation, the practice of full cost pricing, sound financial management, the use and protection of enterprise funds, the coordination of intra-municipal and inter-municipal projects involving inter-related infrastructure, the adoption of an asset management plan and a plan for leak detection.

45.08: Eligible Project Costs

(1) Costs which the Department determines are necessary for the completion of the project are eligible for financing in the loan and to receive a subsidy under the loan.

(2) Costs which the Department determines are not necessary for completion of the project are ineligible for financing in the loan.

(3) Project costs incurred by an eligible borrower prior to the date of issuance of the Department's project approval certificate are not eligible for a subsidy under the loan, except as follows:

(a) project design, including preliminary engineering and a project evaluation report, project construction or related professional services may be approved by the Department prior to the issuance of a project approval certificate as project costs eligible for subsidy if:
   1. The eligible borrower has submitted a written and adequately substantiated request for approval;
   2. The Department's written approval is obtained before initiation of the project and award of any loan for the project; and
   3. The project is included and maintains its status on the current calendar year Intended Use Plan Project Listing.
(b) The Department's prior approval of costs in accordance with 310 CMR 45.08(3)(a) does not constitute a commitment to approve financial assistance for any project. Instead, such costs will be considered eligible project costs only if a loan is made by the Trust for the project. Accordingly, an eligible borrower receiving the Department's prior approval of costs in accordance with 310 CMR 45.08(3)(a) proceeds at its own risk.

(4) Costs incurred in excess of the approved project costs are not eligible for financing by the loan unless the project approval certificate and the loan are both amended to include the cost increase.

(5) As a loan recipient, an eligible borrower shall exercise its best efforts to accomplish the work program set forth in the loan within the loan amount. Whenever a loan recipient reasonably believes that its project costs will exceed or be substantially less than the approved loan amount, it must promptly notify the Department in writing. The loan recipient must submit revised cost estimates for the project to the Department as soon thereafter as practicable. Neither the Department nor the Trust is under any obligation to approve costs in excess of the amount previously approved in the project approval certificate and loan.

(6) The final eligible project costs shall be the eligible costs approved by the Department upon completion of the project, unless audited. If such project costs are audited, the final eligible costs shall be the eligible costs approved by the Department at the completion of the audit.
45.09: Project Evaluation Report

(1) Unless otherwise determined by the Department, the planning information required for projects receiving financial assistance pursuant to 310 CMR 45.00 shall be contained in a Project Evaluation Report.

(2) The Department will determine the required scope of a Project Evaluation Report based on the nature and duration of the proposed project. Unless otherwise determined by the Department, a complete Project Evaluation Report generally must include:
   (a) A description of the proposed project;
   (b) An analysis of the cost-effectiveness of the project and the alternatives considered;
   (c) For the selected alternative, a concise description which addresses, at a minimum, the following areas:
      1. the relevant design parameters for the project;
      2. the estimated capital construction and operation and maintenance costs of the project (identifying possible federal, state, local, and other shares), and a description of the manner in which costs will be financed;
      3. the cost impacts on users of the system; and
      4. the institutional, financial, legal and management arrangements necessary for successful implementation of the project.
   (d) A public participation program that includes, at a minimum:
      1. a public informational meeting to discuss the project alternatives and their environmental impact; and
      2. a subsequent public hearing on the selected proposed project, including its environmental impact.

45.10: Environmental Review and Federal Cross-cutter Requirements

(1) Environmental Review Requirements. All projects approved by the Department to receive a loan from the Trust shall, at a minimum, comply with the requirements of MEPA and 301 CMR 11.00: MEPA Regulations. In addition, a public hearing shall be held on the project if the Department determines that the project is controversial, or if the Department otherwise determines that a hearing is in the public interest. The Department may also require the eligible borrower to consider project alternatives and to provide the public an opportunity to comment on such alternatives.

(2) Federal Cross-cutter Requirements. All projects to be funded by funds directly made available by federal capitalization grants shall comply with all federal cross-cutters applicable to the project, as determined by the Department. The Department may require any other project to comply with one or more of the federal cross-cutters deemed applicable to the project by the Department.

45.11: Affirmative Action and Disadvantaged Business Enterprise Requirements

(1) Eligible borrowers receiving financial assistance from the Trust shall comply with applicable federal and state anti-discrimination laws and requirements, including the Department's requirements in the areas of Affirmative Action in employment and Disadvantaged Business Enterprise (DBE) use in contracting.
   (a) In the area of Affirmative Action, such eligible borrowers shall adopt, for use in all contracts for $50,000 or more, an adapted version of the Commonwealth of Massachusetts' Supplemental Equal Employment Opportunity Anti-discrimination and Affirmative Action Program. The contracts may include minority workforce percentages greater than those required for the geographical locations of the construction project as set forth in the Supplemental Program.
   (b) In the area of DBE utilization, eligible borrowers shall make positive efforts to use DBEs for use in all construction, service and supply subagreements for the project financed by the loan.
   Such efforts should achieve the applicable federal and/or state goals established for DBE participation, but, at a minimum, should allow DBEs the maximum feasible opportunity to compete for project subagreements.
45.11: continued

(2) An eligible borrower receiving a loan from the Trust shall promptly notify the Department in writing when it has good reason to believe that its positive efforts to use DBEs in the subagreements for the project will not achieve one or both of the applicable DBE utilization goals.

45.12: Project Approval and Regulation

(1) Application.

(a) An eligible borrower whose project is on the IUP Project Listing portion of the calendar year priority list must first apply to the Department to receive a loan from the Trust to finance costs of the project. The eligible borrower must file a complete application with the Department containing the following information and documentation:

1. General Information which must include evidence of a funding authorization or commitment by the eligible borrower sufficient to cover the project cost, and, as applicable, certification of the authority of the eligible borrower to file the application.
2. Financial Information pertinent to the Trust's evaluation of the eligible borrower's ability to repay the loan.
3. Project Information which demonstrates to the Department's satisfaction that the project is sufficiently advanced in its implementation, including, as applicable:
   a. approvable plans and specifications for the project;
   b. evidence that the eligible borrower has, at a minimum, filed applications for any permits or environmental reviews applicable to the project; and
   c. a project schedule that demonstrates to the Department's satisfaction that the project will commence no later than six months from the expected date of issuance of a project approval certificate, assuming the Department determines that the project is approvable.
4. Supplemental Information such as title to the project site or evidence of some other appropriate property interest in the project site, any necessary intermunicipal agreements, documentation related to the user charge system, etc.
5. Applicant Certification as to the completeness of the application in accordance with the Department's application form and requirements, and as to the accuracy and completeness of the information provided by the eligible borrower in its application.

(b) The Department may deny any application which it determines to be incomplete. Prior to taking final action on an application, the Department may request the eligible borrower to clarify and/or supplement information contained in its application, or to attend an informal conference(s) with the Department to discuss the application.

(2) Project Approval Certificate.

(a) The Department's approval of an applicant's project shall be contained in a Project Approval Certificate issued to the Trust. The Department's issuance of a Project Approval Certificate is a necessary prior condition to the award of a loan by the Trust to finance the costs of a project.

(b) The Department shall not approve a project for a loan from the Trust unless the eligible borrower adopts a user charge system which is designed to provide adequate revenues required for operation and maintenance, including replacement, of the project, and is based on a flat or on an ascending unit rate per volume. This requirement does not apply to any project for which a user charge system is inapplicable, as determined by the Department.

(c) In addition to approving the project, the Project Approval Certificate shall certify those costs of the project determined by the Department to be eligible for assistance from a loan, and those costs determined to be eligible for a subsidy under the loan. The Project Approval Certificate shall also identify the level of subsidy applicable to the project in accordance with M.G.L. c. 29C and, as applicable, any additional subsidy applicable to the project authorized by special law. Subsidy is expressed as a grant equivalency percentage in the Project Approval Certificate.

(d) The Project Approval Certificate may also contain such other conditions and limitations as the Department deems necessary to ensure compliance by an eligible borrower with 310 CMR 45.00 and with all other federal and state statutes and regulations applicable to the construction and operation of the project. Such conditions shall include, but are not limited to, a project completion schedule which shall require the eligible borrower to initiate the project, as determined by the Department, no later than six months from the date of the Department's issuance of the Project Approval Certificate.
45.12: continued

(e) The Department shall issue the Project Approval Certificate to the Trust for its action and concurrently forward a copy of such certificate to the eligible borrower. The Trust shall thereafter enter into a loan commitment with an eligible borrower consistent with the terms of the Project Approval Certificate. Following entry into a binding loan commitment, the Trust shall prepare and deliver a loan agreement for execution by the eligible borrower, consistent with the terms of the Project Approval Certificate as incorporated into the Department's Project Regulatory Agreement.

(3) Project Regulatory Agreement.

(a) On or prior to the date of a loan from the Trust for a project approved by the Department, the eligible borrower and the Department shall execute and deliver to the Trust a Project Regulatory Agreement relating to the Department's regulation and supervision of the project in accordance with 310 CMR 45.00. The Project Regulatory Agreement shall be in form and substance satisfactory to the Department. The Project Regulatory Agreement shall be incorporated by reference in the Trust loan agreement and failure by the LGU or public water system to comply with the Project Regulatory Agreement shall constitute an event of default under the loan agreement.

(b) The Project Regulatory Agreement shall contain provisions consistent with the Project Approval Certificate. In addition to incorporating pertinent conditions in the Project Approval Certificate, the Project Regulatory Agreement may also contain such other conditions and limitations as the Department deems necessary for its regulation and supervision of the project in accordance with 310 CMR 45.00, including but not limited to:

1. the schedule for disbursement of loan proceeds;
2. the payment requisition requirements and procedures;
3. the requirements and procedures for the Department's audit of payment requisitions;
4. covenants by the eligible borrower related to the project, including a covenant to comply with all federal and state statutes and regulations applicable to the eligible borrower's construction and operation of the project;
5. the measures available to the Department to remedy a default by the eligible borrower under the Project Regulatory Agreement;
6. any requirements regarding certification of a project's performance in accordance with the Department's approval; and
7. compliance with the Department's guidance on the use of and requirements for professional subagreements.

REGULATORY AUTHORITY

310 CMR 45.00: M.G.L. c. 29C, § 18.
Notice of Correction

Regulation Filing  To be completed by filing agency

CHAPTER NUMBER:  520 CMR 16.00

CHAPTER TITLE:  Enforcement of Civil Fines for Expired Elevator Certificates

AGENCY:  Department of Public Safety

ORIGINAL PUBLICATION REFERENCE:   1325  Date:   11/04/2016

SUMMARY OF CORRECTION:
520 CMR 16.02(8) was printed to read, in part, “Unless the violator files an appeal requests an administrative review for administrative review pursuant to 520 CMR 16.03(2)” and should read instead, “Unless the violator requests an administrative review pursuant to 520 CMR 16.03(2)”.  520 CMR 16.03(6)(h) was printed to read, in part, “other than those in 520 CMR 16.03(6)(a) through (h)” and should read instead “other than those in 520 CMR 16.03(6)(a) through (g)”.  520 CMR 16.03(8) was printed to read, in part, “If a fine is upheld in whole or in part. the Commissioner or the Commissioner’ s designee may, in his or her discretion” and should read instead “If a fine is upheld in whole or in part, the Commissioner or the Commissioner’s designee may, in his or her discretion”.

AGENCY CONTACT:  Stephen Carley  PHONE:  617-826-5216

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ATTESTATION -  The regulation described herein and attached hereto is a true copy of the regulation adopted by this agency.

SIGNATURE:  SIGNATURE ON FILE  DATE:  Jan 4 2017

Publication  To be completed by the Regulations Division

MASSACHUSETTS REGISTER NUMBER:  S1331  DATE:  01/27/2017

EFFECTIVE DATE:  11/04/2016

CODE OF MASSACHUSETTS REGULATIONS

Remove these pages:  127 - 130

Insert these pages:  127 - 130
520 CMR 16.00: ENFORCEMENT OF CIVIL FINES FOR EXPIRED ELEVATOR CERTIFICATES

Section

16.01: Purpose, Scope, and Definitions
16.02: Assessment of Fines for Operation of Elevator Beyond Certificate Expiration Date
16.03: Appeals

16.01: Purpose, Scope, and Definitions

(1) Purpose and Scope. The purpose of 520 CMR 16.00 is to establish reasonable standards for the issuance and appeal of civil fines pursuant to M.G.L. c. 143, § 65 by authorized personnel of the Department for the operation of an elevator beyond its certificate expiration date.

(2) Definitions.

Board. The Board of Elevator Regulations.
Commissioner. The Commissioner of the Department of Public Safety.
Department. The Department of Public Safety.

16.02: Assessment of Fines for Operation of Elevator Beyond Certificate Expiration Date

(1) 520 CMR 16.02 establishes the standards for the assessment of fines for operating an elevator after the expiration of its certificate in violation of M.G.L. c. 143, § 65.

(2) No elevator shall be operated without a valid inspection certificate issued by the Department. An elevator shall be deemed to be operating for the purposes of 520 CMR 16.00 unless it has been placed out of service or decommissioned in accordance with a procedure approved by the Board.

(3) The Department shall fine an owner or operator of an elevator for $100 per day that an elevator is in operation without a valid certificate.

(4) Fines shall stop accruing on the date on which the Department receives a written request from the owner or operator for an inspection of the elevator by the Department, or on which the elevator has been placed out of service or decommissioned in accordance with a procedure approved by the Board, whichever comes first.

(5) Upon application for an annual inspection, the owner or operator shall provide to the Department a current mailing address for the location of the elevator and a current mailing address for the owner of the elevator.

(6) Maximum Fines. The maximum fines for all elevators shall be in accordance with M.G.L. c. 143, § 65.

(7) Notice. The Commissioner or the Commissioner's designee, or another person as the Commissioner may specifically authorize, may issue a written notice of violation under M.G.L. c. 22, § 22 for a violation of 520 CMR 16.02. The notice shall specify:
   (a) The provision(s) of the law or regulation with which there has been non-compliance;
   (b) The amount that is being assessed as a penalty for each alleged violation;
   (c) The procedure for requesting an administrative review as set forth in 520 CMR 16.03.

(8) Unless the violator requests an administrative review pursuant to 520 CMR 16.03(2), fines shall be due within 30 days of receipt of the notice of violation.
(9) **Failure to Pay Fines.** If a violator fails to pay a fine issued pursuant to 520 CMR 16.02 or file an appeal requesting administrative review under 520 CMR 16.03(2) within 30 days of receipt of the notice of violation, the Department may shut down the elevator(s) pursuant to and as provided in the applicable provisions of 524 CMR pertaining to noncompliance with Department directives and violations of M.G.L. c. 143, §§ 62 through 71G, c. 22, § 22, 524 CMR: *Board of Elevator Regulations* and 520 CMR 16.00.

**16.03: Appeals**

(1) **Purpose and Scope.** 520 CMR 16.03 establishes procedures and standards for the appeal of all fines assessed pursuant to 520 CMR 16.00, including administrative review and requests for hearings.

(2) **Initial Request for Administrative Review.** A person aggrieved by the issuance of a fine may make written demand upon the Commissioner for an administrative review by the Commissioner or his or her designee on forms approved by the Department. The request for review must fully state and support the reasons why a waiver or reduction of a fine is warranted, including specific reference to all relevant factors under 520 CMR 16.03(6) and any and all supporting documentation. The Commissioner or his or her designee shall conduct an administrative review, based solely on the evidence presented within the written request and Department records, and shall issue a written decision.

(3) **Request for Hearing.** An appellant may request a hearing within 30 days upon receipt of the decision after administrative review if the requested relief was denied in whole or in part. Upon receipt of a valid request, the Department shall schedule and conduct a hearing and shall issue a written decision thereon.

(4) **Fees.** The Commissioner may assess a fee for an appeal filed under 520 CMR 16.03, to be determined by the secretary of administration and finance under M.G.L. c. 7, § 3B.

(5) **Waiver of Appeal.** The failure to file an appeal requesting administrative review within 30 days of receipt of the notice of violation constitutes a waiver of the right to appeal, and all fines set forth in the notice shall be imposed. The payment of a fine constitutes a waiver of the right to appeal.

(6) **Waiver or Reduction of Fines.** The Commissioner or the Commissioner's designee may waive all or a portion of the $100 per day fine assessed for operating an elevator after the expiration of its certificate in violation of M.G.L. c. 143, § 65. In determining whether to waive all or a portion of the fine, the Department may consider the following factors:

(a) **Willfulness or lack thereof;**

(b) **Previous violations of 520 CMR 16.02;**

(c) **Clerical Errors.** Substantial evidence of a clerical error shall include, but not be limited to, inadvertent errors on the application for annual inspection;

(d) **Inaccurate Assessment.** Substantial evidence of an inaccurate assessment shall be limited to evidence that a fine was issued in excess of or contrary to statutory authority or regulation, or based on incorrect information;

(e) **Lack of Prior Use.** Substantial evidence of lack of prior use shall include proof that the unit was not capable of being operated during the period for which the fine was assessed;

(f) **De minimis Risk of Injury to Public.** Substantial evidence of a *de minimis* risk of injury shall include proof that members of the public were incapable of accessing the elevator for the entire period of operation without a valid certificate. Per 520 CMR 16.02(2), an elevator is deemed operational unless it has been placed out of service or decommissioned in accordance with a procedure approved by the Board;

(g) **Financial Hardship.** For all elevator owners, including individuals and corporate entities, organizations, municipalities, religious institutions, or other entities, demonstrated financial hardship shall mean financial difficulty paying the fine as determined by the Commissioner or his or her designee based on substantial evidence provided by the owner or his or her representative. Upon a finding of severe financial hardship, the Commissioner or the Commissioner's designee shall waive the fine; and
16.03: continued

(h) Other Factors. Any reason for appeal or relief from the imposed fine other than those in 520 CMR 16.03(6)(a) through (g), supported by substantial evidence.

(7) Payment of Fines Upheld on Appeal. Unless the violator requests a hearing, fines shall be due within 30 days of receipt of the written decision provided for in 520 CMR 16.03(2). If a hearing is requested, and the fine is upheld in whole or in part, payment is due within 30 days of receipt of the hearing decision. If a violator fails to pay the fine within the applicable timeframe, the Department may shut down the elevator(s) pursuant to and as provided in the applicable provisions of 524 CMR pertaining to noncompliance with Department directives and violations of M.G.L. c. 143. §§ 62 through 71G, c. 22, § 22, 524 CMR: Board of Elevator Regulations and 520 CMR 16.00.

(8) Extensions of Time. If a fine is upheld in whole or in part, the Commissioner or the Commissioner's designee may, in his or her discretion, allow an extended period of time in which to pay upon the violator's submission of substantial evidence of an inability to pay within the applicable timeframe. Such extension shall not exceed three months from the date of the decision except upon a showing of extraordinary circumstances.

(9) Judicial Review. Any person aggrieved by a determination of the Department following a hearing may appeal to the Superior Court in accordance with M.G.L. c. 30A, § 14.

REGULATORY AUTHORITY

520 CMR 16.00: M.G.L. c. 22, § 22 and c. 143, § 65.
Notice of Correction

Regulation Filing  To be completed by filing agency

CHAPTER NUMBER: 527 CMR 12.00
CHAPTER TITLE: Massachusetts Electrical Code
AGENCY: Board of Fire Prevention Regulations

SUMMARY OF CORRECTION:
Correct Section 400.5: The number of conductors stated in the first line of Table 400.5(A)(3) should read "4 through 6" as submitted by the Board, rather then 4 through 680.

AGENCY CONTACT: Peter A. Senopoulos, Legal Counsel, Dept. Fire Services
ADDRESS: Board of Fire Prevention Regulations, P.O. Box 1025-State Road, Stow, MA 01775
PHONE: 978-567-3181

ATTESTATION - The regulation described herein and attached hereto is a true copy of the regulation adopted by this agency.
SIGNATURE: ______________________ DATE: Jan 13 2017
SIGNATURE ON FILE

MASSACHUSETTS REGISTER NUMBER: S1331 DATE: 01/27/2017
EFFECTIVE DATE: 12/30/2016

CODE OF MASSACHUSETTS REGULATIONS

Remove these pages: 143 & 144 Insert these pages: 143 & 144
12.00: continued

Exception to (B)(2): By special permission in industrial establishments only, where the conditions of maintenance and supervision ensure that only qualified persons will service the installation, flexible cord suitable for hard usage or extra hard usage or bus drop cable shall be permitted to extend horizontally greater lengths than 2.5 m (8 ft) where the longer length is essential for periodic repositioning of equipment. The flexible cord or bus drop cable shall be supported at intervals not to exceed 2.5 m (8 ft), and suitable tension take-up device(s) shall be installed at the end of the horizontal run to relieve strain in both the horizontal and vertical directions.

372.23. Revise this section to read as follows:

372.23 Ampacity of Conductors. The ampacity adjustment factors in 310.15(B)(3)(a) shall not apply where 30 or fewer current-carrying conductors occupy no more than 20% of the interior cross-sectional area of cellular concrete floor raceways.

374.23. Revise this section to read as follows:

374.23 Ampacity of Conductors. The ampacity adjustment factors in 310.15(B)(3)(a) shall not apply where 30 or fewer current-carrying conductors occupy no more than 20% of the interior cross-sectional area of cellular metal floor raceways.

390.17. Revise this section to read as follows:

390.17 Ampacity of Conductors. The ampacity adjustment factors in 310.15(B)(3)(a) shall not apply where 30 or fewer current-carrying conductors occupy no more than 20% of the interior cross-sectional area of underfloor raceways.

400.5. Revise Table 400.5(A)(3) to read as follows:

<table>
<thead>
<tr>
<th>Number of Conductors</th>
<th>Percent of Values in Tables 400-5(A) and 400-5(B)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 through 6</td>
<td>80</td>
</tr>
<tr>
<td>7 through 24</td>
<td>70</td>
</tr>
<tr>
<td>25 through 42</td>
<td>60</td>
</tr>
<tr>
<td>43 and above</td>
<td>50</td>
</tr>
</tbody>
</table>

Informational Note: Overheating may occur where continuous, fully loaded conductor diversity is less than 50% and the number of current-carrying conductors exceeds nine. See 310.15(A)(3).

400.12(4). Revise the existing exception as follows:

Exception to (4): Flexible cord and cable shall be permitted to be installed in accordance with 368.56(B). For other applications, where the length of the cord from the supply termination to a suitable tension take-up device is limited to 2.5 m (8 ft), flexible cord shall be permitted to have one connection to the building surface.

400.17. Revise the second paragraph to read as follows:

Flexible cords and cables shall be permitted to be installed in raceways not longer than 15 m (50 ft) in length where required to protect the flexible cord or cable from physical damage. The ampacity of the conductors within a raceway shall be adjusted in accordance with Table 400.5(A)(3) based on the total number of current-carrying conductors within the raceway, and then further derated by a factor of 0.8, or the ampacity shall be calculated in accordance with 310.15(C). The raceway shall be exposed over its entire length.
12.00: continued

406.4(D)(3). Delete the exception.

410.36(B). Add a second paragraph as follows:

In addition to, or in lieu of, the mechanical fastening means, electric luminaires containing ballasts, other than simple fluorescent reactance ballasts, shall be supported directly to the building structure by wire, chain, or threaded rod of sufficient strength to carry the luminaire. Fluorescent luminaires shall be supported at each end of a diagonal axis of the luminaire.

440.14. Insert a third informational note as follows:

Informational Note No. 3: See 440.3(B) for general provisions regarding the inapplicability of Article 440 to equipment that does not incorporate hermetic refrigerant motor-compressors. See also 430.109(B) for specific provisions governing the disconnecting requirements for such equipment, wherever located, that uses a motor that is ½ hp or less.

517.13(B)(1). Delete Exception No. 3.

550.2 Manufactured Home, Informational Note No. 2. Add the following sentence:

Manufactured housing that is not designed to be transportable on running gear, and that is not produced under regulations that expressly cover such housing, is classified under Article 545.

620.51(D)(2). Delete this requirement.

680.7. Insert an informational note ahead of 680.7(A) as follows:

Informational Note: Unlisted swimming pool pump motors have been observed in the field as having been supplied by their manufacturer with undersized cords, cords of excessive length, cord connectors on outdoor applications that are unsuitable for wet locations, and other violations of this Code. The fact that a manufacturer may supply them in this form does not excuse compliance with the rules of this Code.

Listed storable swimming pool pump motors with long factory-supplied cords are prominently marked as such and are not covered in Part II of Article 680. They are not manufactured for use with permanently installed pools and they need not be bonded where used as intended. See 680.31.

680.21(A)(1). Revise the second paragraph to read as follows:

Where installed in dry, noncorrosive environments, branch circuits shall comply with the general requirements in Chapter 3. Any wiring method employed shall contain an insulated or covered equipment grounding conductor of a wire type, sized in accordance with 250.122 but not smaller than 12 AWG

Article 691. Delete this article.

700.10. Make the following two revisions:

I. Revise (D) to read as follows: Emergency systems shall meet the additional requirements in (D)(1) through (D)(4).

II. Revise (D)(1) by deleting (1) and renumbering the remaining numbered items accordingly.

700.12. Add an exception after the first paragraph as follows:

Exception: A fire pump shall be permitted to use a connection ahead of the service disconnecting means in accordance with 695.3(A)(1).
Regulation Filing  

<table>
<thead>
<tr>
<th>CHAPTER NUMBER:</th>
<th>958 CMR 3.000</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHAPTER TITLE:</td>
<td>Health Insurance Consumer Protection</td>
</tr>
<tr>
<td>AGENCY:</td>
<td>Health Policy Commission</td>
</tr>
</tbody>
</table>

**SUMMARY OF REGULATION:**  
State the general requirements and purposes of this regulation.  

958 CMR 3.000 establishes requirements for carriers in administering their internal grievance procedures and establishes the requirements for the conduct of external reviews of carriers’ medical necessity adverse determinations. 958 CMR 3.000 also sets out requirements for continuity of care and referral to specialty care. The regulation incorporates additional reporting requirements for carriers to the Office of Patient Protection.

**REGULATORY AUTHORITY:**  
M.G.L. c. 6D, sec. 16 and M.G.L. c. 176O

**AGENCY CONTACT:**  
Lois Johnson  
PHONE: 617-979-1405

**ADDRESS:**  
50 Milk Street, 8th Floor, Boston, MA 02109

**Compliance with M.G.L. c. 30A**

**EMERGENCY ADOPTION -**  
if this regulation is adopted as an emergency, state the nature of the emergency.

**PRIOR NOTIFICATION AND/OR APPROVAL -**  
If prior notification to and/or approval of the Governor, Legislature or others was required, list each notification, and/or approval and date, including notice to the Local Government Advisory Commission.

Notice to Local Government Advisory Committee on 10/24/16

**PUBLIC REVIEW -**  
M.G.L. c. 30A sections 2 and/or 3 requires notice of the hearing or comment period, including a small business impact statement, be filed with the Secretary of the Commonwealth, published in appropriate newspapers, and sent to persons to whom specific notice must be given at least 21 days prior to such hearing or comment period.

Date of public hearing or comment period: 11/30/2016

The text of the regulations published in the electronic version of the Massachusetts Register is unofficial and for informational purposes only. The official version is the printed copy which is available from the State Bookstore at http://www.sec.state.ma.us/spr/sprcat/catidx.htm.
FISCAL EFFECT - Estimate the fiscal effect of the public and private sectors.

For the first and second year: Minimal or no effect

For the first five years: Minimal or no effect

No fiscal effect:

SMALL BUSINESS IMPACT - M.G.L. c. 30A section 5 requires each agency to file an amended small business impact statement with the Secretary of the Commonwealth prior to the adoption of a proposed regulation. If the purpose of this regulation is to set rates for the state, this section does not apply.

Date amended small business impact statement was filed: 01/12/2017

CODE OF MASSACHUSETTS REGULATIONS INDEX - List key subjects that are relevant to this regulation:
Health Insurance
Consumer Protection
External Review of Carrier Adverse Determinations
Carrier Reporting

PROMULGATION - State the action taken by this regulation and its effect on existing provisions of the Code of Massachusetts Regulations (CMR) or repeal, replace or amend. List by CMR number:
Amends 958 CMR 3.000

ATTESTATION - The regulation described herein and attached hereto is a true copy of the regulation adopted by this agency. ATTEST:

SIGNATURE: SIGNATURE ON FILE DATE: Jan 13 2017

Publication - To be completed by the Regulations Division

MASSACHUSETTS REGISTER NUMBER: S1331 DATE: 01/27/2017

EFFECTIVE DATE: 01/27/2017

CODE OF MASSACHUSETTS REGULATIONS
Remove these pages: 28.1 - 28.4
Insert these pages: 28.1 - 28.4

The text of the regulations published in the electronic version of the Massachusetts Register is unofficial and for informational purposes only. The official version is the printed copy which is available from the State Bookstore at http://www.sec.state.ma.us/spr/sprcat/catidx.htm.
3.503: continued

(3) With respect to an insured with a terminal illness, coverage pursuant to 958 CMR 3.503(1) shall apply to services rendered until the insured's death.

3.504: Carrier's Coverage Conditions

(1) A carrier may condition coverage of continued treatment by a provider under 958 CMR 3.500 through 3.502, upon the provider's agreeing:

(a) to accept reimbursement from the carrier at the rates applicable prior to the notice of disenrollment as payment in full;
(b) to not impose cost sharing with respect to the insured in an amount that would exceed the cost sharing that could have been imposed if the provider had not been disenrolled;
(c) to adhere to the quality assurance standards of the carrier and to provide the carrier with necessary medical information related to the care provided; and,
(d) to adhere to such carrier's policies and procedures, including procedures regarding referrals, obtaining prior authorization and providing treatment pursuant to a treatment plan, if any, approved by the carrier.

(2) A carrier may condition coverage of treatment by a provider under 958 CMR 3.503 upon the provider's agreeing:

(a) to accept reimbursement from the carrier at the rates applicable to participating providers as payment in full;
(b) to not impose cost sharing with respect to the insured in an amount that would exceed the cost sharing that could have been imposed if the provider participated in the carrier's network;
(c) to adhere to the quality assurance standards of the carrier and to provide the carrier with necessary medical information related to the care provided; and,
(d) to adhere to the carrier's policies and procedures, including procedures regarding referrals, obtaining prior authorization and providing treatment pursuant to a treatment plan, if any, approved by the carrier.

(3) Nothing in 958 CMR 3.500 through 3.502 or 3.504 shall be construed to require the coverage of benefits that would not have been covered if the provider involved had remained a participating provider. Nothing in 958 CMR 3.503 shall be construed to require coverage of benefits that would not have been covered if the provider involved was a participating provider.

3.505: Standing Referrals

(1) A carrier that requires an insured to designate a primary care provider shall allow such a primary care provider to authorize a standing referral for specialty health care, including mental health care, provided by a health care provider participating in such carrier's network when:

(a) the primary care provider determines that such referrals are appropriate;
(b) the provider of specialty health care agrees to a treatment plan for the insured and provides the primary care provider with all necessary clinical and administrative information on a regular basis; and
(c) the health care services to be provided are consistent with the terms of the carrier's evidence of coverage.

(2) Nothing in 958 CMR 3.505 shall be construed to permit a provider of specialty health care who is the subject of a referral to authorize any further referral of an insured to any other provider without the approval of the insured's carrier.

(3) For the purposes of 958 CMR 3.505, "specialty health care" means health care services rendered by a provider other than a primary care provider.

3.506: Specialty Care Not Requiring Prior Authorization

(1) No carrier that requires an insured to obtain referrals or prior authorizations from a primary care provider for specialty care shall require an insured to obtain a referral or prior authorization from a primary care provider for the following specialty care provided by an obstetrician, gynecologist, certified nurse-midwife or family practitioner participating in such carrier's health care provider network:
3.506: continued

(a) annual preventive gynecologic health examinations, including any subsequent obstetric or gynecological services determined by such obstetrician, gynecologist, certified nurse-midwife or family practitioner to be medically necessary as a result of such examination;
(b) maternity care; and
(c) medically necessary evaluations and resultant health care services for acute or emergency gynecological conditions.

(2) No carrier shall require higher copayments, coinsurance, deductibles or additional cost sharing arrangements for such services provided to such insureds in the absence of a referral from a primary care provider.

(3) Carriers may establish reasonable requirements for participating obstetricians, gynecologists, certified nurse-midwives or family practitioners to communicate with an insured's primary care provider regarding the insured's condition, treatment and need for follow-up care.

(4) Nothing in 958 CMR 3.506 shall be construed to permit an obstetrician, gynecologist, certified nurse-midwife or family practitioner to authorize any further referral of an insured to any other provider without the approval of the insured's carrier.

(5) For the purposes of 958 CMR 3.506, the term "specialty care" is limited to those services that are medically necessary and consistent with the terms of the carrier's evidence of coverage.

(6) Nothing in 958 CMR 3.506 shall be construed to prohibit a carrier from applying all other applicable health plan requirements for preauthorization or other prior approval for admission to a facility or specific procedures for specialty care provided by an obstetrician, gynecologist, certified nurse-midwife or family practitioner.

3.507: Coverage of Pediatric Specialty Care

Carriers shall provide coverage of pediatric specialty care, including mental health care, by persons with recognized expertise in providing specialty pediatric care to insureds requiring such services.

3.508: Denial of Provider Application

Carriers shall provide health care providers who are applying to be participating providers and who are denied such status with a written reason or reasons for the denial of such application.

3.509: Provider Termination Without Cause Provisions

(1) Contracts between carriers and health care providers shall state that neither the carrier nor the provider has the right to terminate the contract without cause.

(2) Carriers shall provide a written statement to a provider of the reason or reasons for such provider's involuntary disenrollment.

3.600: Reporting Requirements

(1) Carriers shall provide the following information to the Office of Patient Protection no later than April 1st of each year, with the exception of the materials required under 958 CMR 3.600(1)(e), which shall be submitted concurrent with their submission to the Division of Insurance for parity certification under M.G.L. c. 26, § 8K, and 958 CMR 3.600(1)(f), which shall be submitted concurrent with their submission to the Division of Insurance. Such information shall be submitted in a manner specified by the Office of Patient Protection or using a template or form developed by the Office of Patient Protection. Unless concurrent submission is required, where the carrier is also providing the requested information or materials to the Division of Insurance within the same calendar year, the related element of the reporting requirement to the Office of Patient Protection may be satisfied by providing a written statement.
to the Office of Patient Protection describing which information or materials are being provided to the Division and on what date the carriers will provide the information or materials to the Division.

(a) a list of sources of independently published information assessing insureds' satisfaction and evaluating the quality of health care services offered by the carrier;
(b) the percentage of physicians and nurse practitioners who voluntarily and involuntarily terminated participation contracts with the carrier during the previous calendar year for which such data has been compiled and the three most common reasons for voluntary and involuntary provider disenrollment;
(c) the medical loss ratio, which is percentage of premium revenue expended by the carrier for health care services provided to insureds for the most recent year for which information is available;
(d) a report detailing, for the previous calendar year:

1. the total number of filed grievances, the type of medical or behavioral health treatment at issue where applicable, the number of grievances that were approved internally, the number of grievances that were denied internally, and the number of grievances that were withdrawn before resolution;
2. the number of grievances which resulted from an adverse determination, the type of medical or behavioral health treatment at issue, and the outcomes of those grievances; or if this information is also being reported to the Commissioner of Insurance on or prior to July 1st, a statement to that effect;
3. the percentage of insureds who filed internal grievances with the carrier;
4. the total number of internal grievances that were reconsidered pursuant to 958 CMR 3.308, the number of reconsidered grievances that were approved internally, the number of reconsidered grievances that were denied internally, and the number of reconsidered grievances that were withdrawn before resolution;
5. the total number of external reviews pursued after exhausting the internal grievance process, and the resolution of all such external reviews.

The report shall identify, for each such category, to the extent such information is available, the demographics of such insureds, which shall include, but need not be limited to, race, gender and age. 958 CMR 3.600(1)(d)2. through 4. shall take effect for reports due to the Office of Patient Protection on and after April 1, 2015.

(e) a report detailing the information required to be reported pursuant to M.G.L. c. 176O, § 7(b)(5), in a manner and form to be specified by the Office of Patient Protection. 958 CMR 3.600(1)(e) shall take effect for reports due to the Office of Patient Protection in 2018.

(f) An electronic copy of the following, which are required to be provided upon enrollment to at least one adult insured in each household residing in Massachusetts pursuant to M.G.L. c.176O, §§ 6 and 7(a):

1. Evidence of coverage and any amendments thereto;
2. A list of health care providers in the carrier's network, organized by specialty and by location and summarizing for each such provider the method used to compensate or reimburse such provider, provided, however, that disclosure of the specific details of any financial arrangements between a carrier and a provider is not required;
3. A statement that physician profiling information, so-called, may be available from the board of registration in medicine;
4. A summary description of the process by which clinical guidelines and utilization review criteria are developed;
5. The voluntary and involuntary disenrollment rate among insureds of the carrier;
6. A statement that insureds have the opportunity to obtain health care services for an emergency medical condition, including the option of calling the local pre-hospital emergency medical service system, whenever the insured is confronted with an emergency medical condition which in the judgment of a prudent layperson would require pre-hospital emergency services; and
7. A statement that the information specified in 958 CMR 3.600(1)(a) through (d) is available to the insured or prospective insured from the Office of Patient Protection.

(2) Carriers shall provide to the Office of Patient Protection, concurrent with the submission to the Center for Health Information and Analysis pursuant to M.G.L. c. 111, § 217, a copy of the health plan data and information set compiled for the National Committee on Quality Assurance or other information collected by the carrier and deemed to be similar or equivalent thereto. At the carrier's option, proprietary financial data may be excluded from this submission.
3.600: continued

(3) Each carrier shall provide to the Office of Patient Protection no later than April 1st of each year, information to assist the Office of Patient Protection in resolving appeals.
   (a) Each carrier shall provide the name, telephone number and e-mail address of the person or persons within its organization who will serve as the general contact for the Office of Patient Protection for appeals and grievances.
   (b) Each carrier shall provide the name, telephone number and e-mail address of the person or persons who have the authority to approve appeals and approve the payment of claims for all products and for all types of services.
   (c) If any of this contact information changes, the carrier shall provide the new information in writing to the Office of Patient Protection within ten business days following the change.

(4) The confidentiality of any information about a carrier or utilization organization which, in the opinion of the Office of Patient Protection in consultation with the Division of Insurance, is proprietary in nature shall be protected, except where disclosure is otherwise required by law.

(5) The Office of Patient Protection shall establish a site on the internet and through other communication media, make managed care information collected by the Office of Patient Protection readily accessible to consumers. The internet site shall, at a minimum, include:
   (a) a chart comparing the information obtained on premium revenue expended for health care services as provided pursuant to 958 CMR 3.600(1)(c) for the most recent year for which information is available; and
   (b) data collected pursuant to 958 CMR 3.600(2).

3.700: Required Oral Interpretation and Written Translation Services

(1) Each carrier shall provide to the insured or the insured's authorized representative, upon request, oral interpretation and written translation services related to all procedures under 958 CMR 3.000, as required by M.G.L. 176O, § 15(k), including but not limited to notices of adverse determinations and final adverse determinations. Oral interpretation services shall include but not be limited to oral interpretations of documents, answering questions and providing information and assistance with filing grievances or external review requests.

(2) A carrier must include in the English version of all notices required by 958 CMR 3.000 and provided to the insured or the insured's authorized representative, a statement describing how the insured or the insured's authorized representative can request oral interpretation and written translation services from the carrier. At a minimum the statement must be prominently displayed within the notice in English, Arabic, Khmer (Cambodian), Chinese, French, Greek, Haitian-Creole, Italian, Lao, Portuguese, Russian and Spanish, and in any non-English language in which 10% or more of the population residing in any Massachusetts county served by the carrier is only literate in the same non-English language, as determined by the Office of Patient Protection, or as otherwise specified by the Office of Patient Protection in consultation with the Division of Insurance.

(3) Effective July 1, 2014, once an insured or insured's authorized representative has requested written translation of documents into Spanish, the carrier must provide all subsequent written notices required by 958 CMR 3.000 to the insured or the insured's authorized representative in Spanish along with the English version.

REGULATORY AUTHORITY

958 CMR 3.000: M.G.L. c. 6D, § 16 and c.176O.