

105 CMR: DEPARTMENT OF PUBLIC HEALTH

105 CMR 100.000: DETERMINATION OF NEED

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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.

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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 to 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.

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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.

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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.

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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.

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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, the Expenditure 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.

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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.

100.210: continued

- (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: a 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.

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.

100.310: continued

(D) 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.

(E) 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.

(F) (1) 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.

(2) 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:

(a) the initiation of revocation procedures pursuant to 105 CMR 100.640; or

(b) 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.

(3) 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.

(4) 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

(G) 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.

(H) 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 to 105 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 Health 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

100.405: continued

(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(h), 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.

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(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;

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- (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

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(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.

100.620: Preliminary Action by the Department

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.

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).

100.635: continued

(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.

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 other than a Long-term 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.

100.735: continued

- (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;
 - (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.

100.740: continued

(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).

105 CMR: DEPARTMENT OF PUBLIC HEALTH

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

(PAGES 135 THROUGH 168 ARE RESERVED FOR FUTURE USE.)